Risk Factors Comparison 2024-04-16 to 2023-02-28 Form: 10-K

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Careful consideration should be given to the following ~~Investing in our securities involves a high degree of~~ risk **factors** ~~. Before deciding whether to invest in our securities~~ , **together with all** ~~you should consider carefully the~~ **other information set forth** ~~risks and uncertainties described~~ in ~~this section of~~ this Annual Report on Form 10- K **(" Annual Report "), including our consolidated financial statements and related notes, and " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " and in other documents that we file with the Securities and Exchange Commission (the " SEC "), in evaluating Ocugen, Inc. and our subsidiaries (collectively, the " Company ", " we ", or " our ") and our business, before investing in our common stock. Investing in our common stock involves a high degree of risk. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The market price of our common stock could decline if one or more of these risks or uncertainties were to occur, which may cause you to lose all or part of the money you paid to buy our common stock. The risk factors described below disclose both material and other risks, and are not intended to be exhaustive and are not the only risks facing the Company. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition and results of operations. Certain statements below are forward- looking statements. See " Special Note Regarding Forward- Looking Statements " in this Annual Report. Risk Factors Summary Investing in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks and uncertainties described in this section of this Annual Report on Form 10- K** . These risks and uncertainties include, but are not limited to, the following: • We have incurred significant losses and negative cash flows from operations since our inception. We may incur losses over the next several years and may never achieve or maintain profitability. These factors raise substantial doubt about our ability to continue as a going concern absent obtaining significant additional funding. • We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts. • We will need additional capital in order to enable us to successfully develop our product candidates, and such funding may not be available on acceptable terms, or at all. Raising additional capital may cause dilution to stockholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates. • We are substantially dependent on the success of our product candidates. We cannot guarantee that our product candidates will successfully complete development, receive regulatory approval, or be successfully commercialized. • Our product candidates generated from our modifier gene therapy platform are based on a novel technology and face an uncertain regulatory environment, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval ~~. • COVAXIN has been evaluated by Bharat Biotech in a Phase 3 clinical trial in India in adults, who were healthy or had stable chronic medical conditions ages 18 and older, and approved for EUL by the WHO. We have conducted a Phase 2 / 3 immuno- bridging and broadening clinical trial and will need to conduct a safety clinical trial to support a BLA submission for COVAXIN for adult use in the United States. We may be unable to successfully produce and commercialize a vaccine that effectively and safely treats the virus in a timely manner, if at all, and ultimately may be unable to obtain regulatory approval for adult use in the United States. • We have obtained the rights to develop, manufacture, and commercialize COVAXIN in Canada and Mexico. We have no experience in obtaining marketing approvals for, or commercializing products in Canada or Mexico. Our results of operations may be negatively impacted if we are unable to successfully commercialize COVAXIN in Canada or Mexico~~ . • If we experience delays or difficulties in the enrollment of patients in clinical trials, our completion of clinical trials and receipt of necessary regulatory approvals could be delayed or prevented. • We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. • We have no prior experience in the marketing, sale, and distribution of biotechnology products and there can be no assurance that our product candidates, if approved, will be successfully commercialized. • We face significant competition from other pharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations. Our operating results will suffer if we fail to compete effectively. • If third- party payors do not reimburse patients for our products candidates, if approved, or if reimbursement levels are set too low for us to sell our product candidates at a profit, our ability to successfully commercialize our product candidates, if approved, and our results of operations will be harmed. • We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials we may initiate, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements. • If we encounter difficulties in negotiating commercial manufacturing and supply agreements with third- party manufacturers and suppliers of our product candidates or any product components, our ability to commercialize our product candidates, if approved, would be impaired. • If the manufacturers upon whom we rely fail to produce our product candidates or product components pursuant to the terms of contractual arrangements with us or fail to comply with stringent regulations applicable to biotechnology manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our product candidates, if approved, and may lose potential revenues. • We may seek to collaborate with third parties for the development or commercialization of our product candidates. We may not be successful in establishing or maintaining collaborative relationships, any of which could adversely affect our ability to develop and commercialize our product candidates. • We may be unable to obtain and maintain patent

protection for our technology and product candidates, or the scope of the patent protection obtained may not be sufficiently broad or enforceable, such that our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired. • We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time- consuming, and unsuccessful. • Certain aspects of our product candidates are protected by patents exclusively licensed from other companies or institutions. If these third parties terminate their agreements with us or fail to maintain or enforce the underlying patents or licenses thereto, or we otherwise lose our rights to these patents, our competitive position and our market share in the markets for any of our approved products will be harmed. • Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management. • The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses. • Our future success depends on our ability to retain key executives and to attract, retain, and motivate qualified personnel. • If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting, and the trading price of our common stock may decline ~~.~~ Risks Related to Our Financial Position and Capital Requirements Since inception, we have incurred significant net losses and may continue to incur net losses in the future. Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern for the next 12 months from the date of the consolidated financial statements included in this Annual Report on Form 10- K are issued. As a result, our independent public accounting firm included an explanatory paragraph regarding the same in its report on this Annual Report on Form 10- K. Substantial doubt about our ability to continue as a going concern may create negative reactions to the price of our common stock and we may have a more difficult time obtaining financing in the future as a result. We have not generated significant revenue to date and have funded our operations to date through the sale of common stock, warrants to purchase common stock, the issuance of convertible notes and debt, and grant proceeds. We incurred net losses of approximately $ ~~81~~ **63** . ~~4~~ **1** million and $ ~~58~~ **86** . ~~4~~ **8** million for the years ended December 31, **2023 and** 2022 ~~and 2021~~ , respectively. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~213~~ **286** . ~~0~~ **2** million and a cash ~~,~~ **and** cash equivalents ~~, and investments~~ balance of $ ~~90~~ **39** . ~~9~~ **5** million. This amount will not meet our capital requirements over the next 12 months. We estimate that our cash ~~,~~ **and** cash equivalents ~~, and investments~~ will enable us to fund our operations into the ~~first~~ **fourth** quarter of 2024. Based on this estimate, we will need to raise significant additional capital in order to fund our future operations. We have based this estimate on assumptions that may prove to be wrong, and our operating and capital requirements may change as a result of many factors currently unknown to us. There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms or at all. If such additional financing is not available on satisfactory terms, is not available in sufficient amounts, or we do not have sufficient authorized shares, we may be required to delay, limit, or eliminate the development of business opportunities and our ability to achieve our business objectives, our competitiveness, and our business, financial condition, and results of operations will be materially adversely affected. In addition, economic circumstances outside of our control such as a recession or depression and inflation may reduce our ability to access capital, which could negatively affect our liquidity and ability to continue as a going concern. Further, the perception that we may not be able to continue as a going concern may cause others to choose not to do business with us due to concerns about our ability to meet our contractual obligations. To date, we have not generated any revenues from the sale of products, and absent the realization of sufficient revenues from product sales, if any, of our current or future product candidates, we may never attain profitability in the future. To date, we have devoted substantially all of our financial resources and efforts to research and development, including preclinical and clinical studies. We may continue to incur losses from operations in the next several years as we increase our expenditures in research and development in connection with our ongoing and planned clinical trials and other development and pre- commercialization activities. Even if we obtain a regulatory approval to market a product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received such approval, and our ability to achieve sufficient market acceptance, reimbursement from third- party payors, and adequate market share for our products in those markets. We anticipate that our expenses will ~~increase~~ **decrease** in **fiscal year 2024 as compared to** fiscal year 2023 **due** ~~as compared~~ to **a reduced headcount** ~~fiscal year 2022 as we continue to conduct preclinical and clinical activities with respect to our product candidates~~ , **lower legal expenses** ~~including the continuation and planned initiation of several clinical trials for our product candidates~~ , as well as **internal cost savings initiatives** ~~increased headcount, including management personnel to support our research and development, clinical, and business activities, expanded infrastructure, and increased insurance premiums, among other factors~~ . Due to the inherently unpredictable nature of preclinical and clinical development and the numerous risks and uncertainties associated with such activities, we are unable to predict with any certainty the nature or amounts of the costs we will incur, the timelines we will require in our continued development efforts or the timing, or if, we will be able to achieve profitability. Additionally, our expenses will also increase if, and, as we: • initiate preclinical studies and clinical trials for any additional product candidates that we may pursue in the future, particularly if there are any delays in enrollment of patients in or completing our clinical trials or the development of our product candidates; • seek marketing approvals for product candidates that successfully complete clinical development; • establish sales, marketing, and distribution capabilities for our product candidates for which we obtain a regulatory approval; • scale up our manufacturing processes and capabilities to support our clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain a regulatory approval; • expand our operational, financial, and management systems and increase personnel, including personnel to support our clinical development, manufacturing, and commercialization efforts, and our operations as a public company; • acquire other companies, products, product candidates, or technologies, or in- license the rights to other products, product candidates, or technologies; and • develop, maintain, expand, and protect our intellectual property portfolio. Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate revenue that is sufficient to achieve

profitability unless and until we obtain marketing approval for and commercialize one of our product candidates **and even if we obtain marketing approval for and commercialize one of our product candidates, we may never become profitable** . Our product candidates are in various stages of preclinical and clinical development or pre- commercialization, and it is unknown whether our near- term efforts to obtain regulatory approval or commercial sales may be successful or whether additional preclinical, clinical, or manufacturing data may be needed before we obtain regulatory approval for any candidate. 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 profitable or inability to 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, continue or undertake commercialization efforts, diversify our product offerings, or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment. We have no history of commercializing pharmaceutical products, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability. We are a biotechnology company and investment in biotechnological product development is a highly speculative endeavor. Biotechnology product development entails substantial upfront capital expenditures and there is significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, to gain any required regulatory approvals or to become commercially viable. To date, our operations have been limited to organizing and staffing our company, acquiring rights to intellectual property, business planning, raising capital, and developing our product candidates. We have not yet demonstrated an ability to obtain marketing approvals (only EUA), manufacture a commercial- scale product, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. We have encountered, and will continue to encounter, risks and difficulties frequently experienced by growing companies in a rapidly developing and changing industry, such as the biotechnological industry, including challenges in forecasting accuracy, determining appropriate investments of our limited resources, gaining market acceptance of our products, if approved, managing a complex regulatory landscape, and developing new product candidates. Our current operating model may require changes in order for us to scale our operations efficiently. We will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. You should consider our business and prospects in light of the risks and difficulties we face as a company focused on developing products in the fields of biopharmaceuticals and biotechnology. We expect our financial condition and operating results to fluctuate significantly from quarter- to- quarter and year- to- year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance. We expect to devote substantial financial resources to our ongoing and planned product development activities, particularly as we continue the development of and seek EUA or marketing approval for our product candidates and any potential future product candidates, as applicable. As of December 31, ~~2022~~ **2023** , we had cash ~~,~~ **and** cash equivalents ~~, and investments~~ of approximately $ ~~90~~ **39** . ~~9~~ **5** million. This amount will not meet our capital requirements over the next 12 months. We estimate that our cash ~~,~~ **and** cash equivalents ~~, and investments~~ will enable us to fund our operations into the ~~first~~ **fourth** quarter of 2024. Based on this estimate, we will need to raise significant additional capital in order to fund our future operations. We have based this estimate on assumptions **that may prove to be wrong, and our operating and capital requirements may change as a result of many factors currently unknown to us.** Conducting preclinical testing and clinical trials is a time- consuming, expensive, and uncertain process that takes years to complete. We cannot predict when we will be able to generate the necessary data or results required to obtain regulatory approval of products with the market potential sufficient to enable us to achieve profitability, if ever. Accordingly, we may need to obtain substantial additional funding in connection with our continuing operations. Our future capital requirements will depend on many factors, including: • the initiation, progress, timing, costs, and results of clinical trials for our product candidates; • the outcome, timing, and cost of the regulatory approval process for our product candidates; • the costs of manufacturing and commercialization; • the costs related to doing business internationally with respect to the development and commercialization of our product candidates; • the cost of filing, prosecuting, defending, and enforcing our patent claims and other intellectual property rights; • the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us; • the costs of expanding infrastructure to support our development, commercialization, and business efforts, including the costs related to the development of a laboratory and manufacturing facility; • the costs involved in recruiting and retaining skilled personnel; • the extent to which we in- license or acquire other products, product candidates, or technologies; • the extent to which we out- license our product candidates; and • the impact of geopolitical turmoil, macroeconomic conditions, social unrest, political instability, terrorism, or other acts of war. Any additional fundraising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our product candidates. Moreover, adequate additional financing may not be available to us on acceptable terms, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce, or terminate preclinical studies, clinical trials, or other development activities for one or more of our product candidates or delay, limit, reduce, or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates. **Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain product candidates over other potential product candidates. These decisions may prove to have been wrong and may adversely affect our ability to develop our own programs, our attractiveness as a commercial partner and may ultimately have an impact on our commercial success. Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management, and financial resources toward particular proprietary molecules in our library, product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities.**

Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the biopharmaceutical industry, in particular for our lead product candidates, our business, financial condition and results of operations could be materially adversely affected. We will need additional capital in order to enable us to successfully develop and obtain authorization or approval for our product candidates. Such funding may not be available on acceptable terms, or at all. We expect to raise additional capital through public and private placements of equity and / or debt, payments from potential strategic research and development arrangements, sales of assets, government grants, licensing and / or collaboration arrangements with pharmaceutical companies or other institutions, funding from the government, or funding from other third parties. ~~For example, we anticipate that the continued development of our vaccine candidates will require government funding to support the regulatory pathway of such candidates, including the safety clinical trial that will be used, together with data from our Phase 2 / 3 immuno- bridging and broadening clinical trial, to support a BLA submission for COVAXIN, subject to discussions with the FDA.~~ We also intend to work closely with government agencies to obtain funding for the development of our novel inhaled mucosal vaccine platform. In ~~January~~ **April** 2023, the **FDA** ~~Biden Administration~~ announced **the cancellation of emergency use authorizations (" EUA") issued to monovalent vaccines and the simplification of the vaccination schedule of bivalent vaccines** that **have EUAs in** ~~it intends to extend~~ the United States **,** ~~' COVID- 19 national emergency~~ and **in May 2023 the** public health emergency ~~declarations until May 11, 2023, at which time such emergency declarations will come to an end~~ **ended** . It is currently unclear what effect, if any, the planned cessation of the emergency declarations will have on our ability to obtain government funding to advance the development of our vaccine product candidates. **We are opportunistically pursuing vaccines development. In October 2023, the NIAID selected OCU500, a mucosal vaccine candidate specifically targeted to fight COVID- 19, for inclusion in a Phase 1 trial comparing the administration of OCU500 via different mucosal routes — inhalation into the lungs or up the nose via a nasal spray.** If we raise additional funds through collaborations, strategic alliances, licensing arrangements, or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. Such arrangements may require us to grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market on our own. Our management **has** ~~will have~~ broad discretion in the use of the net proceeds from our capital raises, including our ~~February~~ **May** ~~2022~~ **2023** public offering ~~and our ongoing at- the- market offering program~~ , and may not use ~~them~~ **these proceeds** effectively. Our management **has** ~~will have~~ broad discretion in the application of the net proceeds from our capital raises (our " Capital Raises "), including our ~~February~~ **May** ~~2022~~ **2023** public offering ~~and our ongoing at- the- market offering program~~ , and our stockholders will not have the opportunity as part of their investment decision to assess whether the net proceeds from our Capital Raises are being used appropriately. Our stockholders may not agree with our decisions, and our use of the proceeds may not yield any return on investment for our stockholders. Because of the number and variability of factors that will determine our use of the net proceeds from our Capital Raises, their ultimate use may vary substantially from their currently intended use. Our failure to apply the net proceeds of our Capital Raises effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of those net proceeds. Our stockholders will not have the opportunity to influence our decisions on how to use our net proceeds from our Capital Raises. We have and may continue to invest the net proceeds from our Capital Raises in investment- grade, interest- bearing instruments and U. S. government agency securities and treasuries. These investments are not likely to yield a significant return. Our **management might not apply our existing cash and cash equivalents in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business. Our** existing and future indebtedness may limit cash flow available to invest in the ongoing needs of our business. As of December 31, ~~2022~~ **2023** , we had $ 2. ~~0~~ **5** million of outstanding principal borrowings under a Loan Agreement (the" EB- 5 Loan Agreement") with EB5 Life Sciences, L. P. (" EB- 5 Life Sciences"), which we are required to repay on the seventh anniversary of the date of the last disbursement under the EB- 5 Loan Agreement (unless terminated earlier pursuant to the terms of the EB- 5 Loan Agreement). Our obligations under the EB- 5 Loan Agreement are secured by substantially all of our assets other than our intellectual property. We could in the future incur additional indebtedness beyond our borrowings under the EB- 5 Loan Agreement. Our existing or future debt could have significant adverse consequences, including: • requiring us to dedicate a substantial portion of cash flow from operations or cash on hand to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts, and other general corporate purposes; • increasing our vulnerability to adverse changes in general economic, industry, and market conditions; • subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing (for instance, the EB- 5 Loan Agreement includes restrictive covenants related to, among other things, the disposition of our property, the incurrence by us of any additional indebtedness, and the creation by us of any liens or other encumbrances); and • limiting our flexibility in planning for, or reacting to, changes in our business and our industry; and placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options. A failure to comply with the covenants under the EB- 5 Loan Agreement, including covenants to take or avoid specific actions as set forth above, could result in an event of default and acceleration of amounts due. If an event of default occurs and EB- 5 Life Sciences accelerates the amounts due under the EB- 5 Loan Agreement, we may not be able to make accelerated payments, and EB- 5 Life Sciences could seek to enforce security interests in the collateral securing such indebtedness. In order to satisfy our current and future debt service obligations, we will be required to raise funds from external sources. We may be unable to arrange for additional financing to pay the amounts due under our existing debt. Funds from external sources may not be available on acceptable terms, if at all. Our failure to satisfy our current and future debt obligations could adversely affect our financial condition and results of operations. Our ability to utilize our tax net operating losses is

uncertain. We have incurred significant net operating losses since our inception. As of December 31, ~~2022~~ **2023**, we had U. S. federal net operating loss carryforwards of approximately $ ~~200~~ **226**. ~~5~~ **2** million. Our ability to utilize these net operating losses to offset future tax liabilities depends on the successful development of our product candidates and future financial performance. Additionally, our net operating losses may be subject to Section 382 of the Internal Revenue Code of 1986, as amended (" Section 382"). Generally, if an ownership change occurs within three years of the closing date of an entity' s most recent change in control transaction, any existing net operating losses and certain built- in losses would be subject to an additional limitation, pursuant to Section 382. Change in control as defined by Section 382 occurs when there is an ownership change among stockholders owning directly or indirectly 5 % or more of our common stock, as well as an aggregate ownership change with respect to such stockholders of more than 50 % of our common stock. We have not yet conducted a comprehensive study to assess whether a change of ownership as defined by Section 382 has occurred since our inception. If it is determined that we are unable to use our net operating losses to reduce future tax liabilities, our financial condition, results of operations, and cash flows may be adversely affected. We may be subject to future changes in tax legislation or exposure to additional tax liabilities that may adversely affect our financial condition, results of operations, and cash flows. We are subject to taxes in the United States as well as the foreign jurisdictions where our subsidiaries are organized. Due to economic and political conditions, tax rates, tax laws, and other non- tax legislation, we may experience significant impacts as a result of prospective changes. Our future effective tax rates may be affected by changes in the valuation of deferred tax assets and liabilities, changes in available tax credits or tax deductions, as well as changes in tax law and other non- tax laws, or their interpretation. Our tax returns and other tax matters are subject to examination by applicable tax authorities and governmental bodies. We regularly assess the likelihood of an adverse outcome resulting from examination, in order to determine any resulting impact to our provision for income taxes or deferred tax balances. There can be no assurance as to the outcome of these examinations. As such, if we were to sustain an adjustment as a result of a tax examination in excess of amounts previously accrued, our financial condition could be adversely affected. Risks Related to Our Business and the Development of Our Product Candidates We have invested a significant portion of our efforts and financial resources in the development of our product candidates. We currently have no products authorized or approved for which we have successfully commercially distributed, and we have not generated revenues from sales of any products. Our business and our ability to generate revenues in the near term depends entirely on the successful development, approval, and commercialization of our product candidates, which may never occur. If the results or timing of regulatory filings, the regulatory process, regulatory developments, clinical trials or preclinical studies, or other activities, actions, or decisions related to our product candidates do not meet our or others' expectations, the market price of our common stock could decline significantly. Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected or unacceptable adverse events or failure to demonstrate efficacy in clinical trials. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials, and our product candidates may not be successfully commercialized even if they receive regulatory approval. Our product candidates are in various stages of development ranging from preclinical development to pre- commercialization. The success of our product candidates and our ability to generate revenues from our product candidates, if approved, will depend on many factors including our ability to: • complete and obtain favorable results from our clinical trials and preclinical studies with respect to our product candidates; • apply for and receive marketing approval from the applicable regulatory authorities; • receive regulatory approval for claims that are necessary or desirable for successful marketing; • receive approval for our manufacturing processes and facilities from the applicable regulatory authorities; • recruit and enroll qualified patients for clinical trials with respect to our product candidates in a timely manner; • expand and maintain a workforce of experienced scientists and others with experience in relevant technologies to continue to develop our product candidates; • hire, train, and deploy marketing and sales representatives or contract with a third- party for marketing and sales representatives to commercialize product candidates in the United States and key foreign markets; • launch and create market demand for our product candidates, if approved, through marketing and sales activities, and any other arrangements to promote these product candidates that we may otherwise establish; • achieve market acceptance of our product candidates by patients, the medical community, and third- party payors; • effectively compete with other therapies and establish a market share; • maintain a continued acceptable safety and efficacy profile of our product candidates, if approved, following commercial launch; • achieve appropriate reimbursement, pricing, and payment coverage for our product candidates, if approved; • manufacture product candidates in sufficient quantities and at acceptable quality and manufacturing cost to meet commercial demand at launch and thereafter; • establish and maintain agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms; • pursue partnerships with, or offer licenses to, qualified third parties to promote and sell product candidates, if approved, in domestic and key foreign markets where we receive marketing approval; • develop our product candidates for additional indications or for use in broader patient populations; • maintain patent and trade secret protection and regulatory exclusivity for our product candidates; and • qualify for, identify, register, maintain, enforce, and defend intellectual property rights and claims covering our products and intellectual property portfolio; and not infringe on others' intellectual property rights. To the extent we are not able to do any of the foregoing, our business may be materially harmed. If we do not receive FDA or other applicable foreign regulatory approval for, and successfully commercialize our product candidates, we will not be able to generate revenue from these product candidates in the United States or other key foreign markets for the foreseeable future or at all. A substantial portion of our product research and development efforts is centered around our modifier gene therapy platform. The regulatory approval and successful commercialization of OCU400, OCU410, and OCU410ST depend on the successful development of this platform. There can be no assurance that any development problems we experience in the future related to our modifier gene therapy platform will not cause significant delays or unanticipated costs, or that such development problems can be solved. The clinical trial requirements of the FDA, the EMA, and other regulatory agencies, and the criteria used by these regulators to determine the safety and efficacy of a product

candidate vary substantially according to the type, complexity, novelty, and intended use and market of such product candidates. The regulatory approval process for novel product candidates such as these can be more expensive and take longer than for other, better known, or extensively studied pharmaceuticals or other product types. Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. For example, the FDA established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research (" CBER") to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Gene therapy clinical trials conducted at institutions that receive funding for recombinant deoxyribonucleic acid (" DNA") research from the NIH are also subject to review by the NIH Novel and Exceptional Technology and Research Advisory Committee (" NExTRAC"), formerly the Recombinant DNA Advisory Committee, which now focuses on emerging areas of research including, but not restricted to, technologies surrounding advances in recombinant or synthetic nucleic acid research. Although the FDA decides whether individual gene therapy protocols may proceed, it is possible the NExTRAC review process, which is still being implemented, could delay the initiation of a clinical trial, even if the FDA has reviewed the trial design and details and approved its initiation. Before a clinical trial can begin at a study site, the institution' s IRB and its IBC have to review the proposed clinical trial to assess the safety of the trial. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates. These regulatory review committees and advisory groups and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates, or lead to significant post- approval limitations or restrictions. As we advance our gene therapy product candidates, we will be required to consult with these regulatory and advisory groups, and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of our gene therapy product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected for orphan ophthalmology product candidates. Delay or failure to obtain, or unexpected costs in obtaining the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business. Existing data on the safety and efficacy of gene therapy is very limited and sometimes include historically poor clinical efficacy of previous non- replicating gene therapy products. In addition, there have been publicized safety issues associated with previous gene therapy products in third- party clinical trials, including patient deaths. The results of preclinical and clinical trials performed for our product candidates will not definitively predict safety or efficacy in humans. OCU400, OCU410, and OCU410ST use an AAV vector. Possible serious side effects of other viral vector- based gene therapies in general include uncontrolled viral infections and the development of cancer, particularly lymphoma or leukemia. The risk of insertional mutagenesis or oncogenesis remains a significant concern for gene therapy, and we cannot provide any assurance that it will not occur in any of our ongoing or planned clinical trials with respect to our product candidates based on our modifier gene therapy platform. There is also the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of products used to carry the genetic material. Potential procedure- related adverse reactions, including inflammation, can also occur. If any such adverse events occur during clinical trials, further advancement of such clinical trials could be halted or delayed, which would have a material adverse effect on our business and operations. Finally, the public' s attitude may be influenced by claims that gene therapy technology is unsafe, unethical, or immoral. If we are unable to convincingly demonstrate the safety and efficacy of our product candidates arising from our gene modifier platform, our product candidates, even if approved by the FDA or foreign regulatory authorities, may not gain the acceptance of the public or the medical community. ~~We cannot predict~~ **For example, in November 2023, the FDA announced it is investigating the risk of T cell malignancies associated with currently approved BCMA- and CD19-directed autologous CAR T cell immunotherapies. The FDA stated the overall benefits of** ~~the~~ **these products continue** ~~speed at which we will be able~~ to ~~obtain~~ **outweigh their potential risks, but the agency is evaluating the need for** regulatory **action** ~~marketing approval for adult use for COVAXIN in the United States, if at all~~ . **It is unclear whether** ~~In February 2021, we entered into the Covaxin Agreement with Bharat Biotech, pursuant to which we obtained an~~ **any regulatory action that** ~~exclusive right and license under certain of Bharat Biotech' s intellectual property rights, with~~ the **FDA may take following** ~~right to grant sublicenses, to develop, manufacture, and commercialize COVAXIN, a whole- virion inactivated COVID- 19 vaccine candidate, in the United States,~~ its **investigation may** ~~territories and possessions. Our development efforts with respect to the U. S. market are still ongoing and remain uncertain. We completed our Phase 2 / 3 immuno- bridging and broadening clinical trial for COVAXIN in the United States for adults ages 18 years and older to support a BLA submission and in January 2023, we announced top- line results from our Phase 2 / 3 immuno- bridging and broadening clinical trial in the United States evaluating COVAXIN for adults ages 18 years and older. The clinical trial was designed to evaluate whether the immune response observed in participants in Bharat Biotech' s completed Phase 3 clinical trial in India is similar to a demographically representative, adult population in the United States. The clinical trial enrolled 419 adult participants that were randomized to receive either two doses of COVAXIN or a placebo, 28 days apart. Immune responses were adjusted for differences between the U. S. and Indian cohorts in baseline neutralizing antibody, body mass index, gender, and age. Both co- primary immunogenicity endpoints were met, with the 95 % CI for the propensity score- adjusted geometric mean titer ratio being well above the non-inferiority limit of 0. 667. The 95 % CI for the propensity score- adjusted difference in seroconversion rates were well above the non- inferiority limit of (10) %. There were no deaths, related potential immune mediated medical conditions, or related adverse** **adversely impact** ~~events of special interest. Additionally, there were no cases of myocarditis, pericarditis, thrombotic events, or Guillain- Barré syndrome. There were no cases of adverse events and SAEs related to the vaccination. 30 medically attended adverse events in 18 subjects and two SAEs in one subject were reported, all of which were considered unrelated to the vaccination. Data from the Phase 2 / 3 immuno- bridging and broadening clinical trial and a safety clinical trial, subject to~~

discussions with the FDA, will be utilized to support a BLA submission. We plan to initiate the adult safety clinical trial, subject to discussions with the FDA, and intend to work with government agencies in the United States to obtain funding to do so. There can be no assurances that the results of any clinical trials we may conduct will resemble the results obtained by Bharat Biotech in their clinical trials in India. Any results from further clinical testing by Bharat Biotech or by us may raise new questions and require us to redesign clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects. In addition, the FDA' s analysis of **approach to regulating** any **product** clinical data may differ from our interpretation and the FDA may require that we conduct additional analysis or trials. Further, ongoing clinical testing by Bharat Biotech and administration of COVAXIN in authorized or approved jurisdictions may demonstrate that the vaccine candidate **candidates we may** is less effective than currently believed, including against new or emerging variants, or has an unacceptable safety profile, which would have a negative impact on our development ---- **develop** efforts in the United States. The clinical trials to be used as the basis for a BLA submission must meet certain criteria related to trial participant demographics and manufacturing standards. BLA approval is a lengthy development process. Moreover, evolving or changing plans or priorities at the FDA, including changes based on new knowledge of COVID- 19, the effectiveness of other available vaccines for COVID- 19, the extent to which the U. S. population has been vaccinated or obtained natural immunity, emerging variants of SARS- CoV- 2, and how the new variants of the disease affect the human body, may significantly affect the regulatory development and timeline for COVAXIN in the United States. In June 2021, we entered into an amendment to the Covaxin Agreement with Bharat Biotech that provided us with the rights to develop and commercialize COVAXIN in Canada. In order to market and sell COVAXIN in Canada, we must obtain marketing approval for COVAXIN from Health Canada and must comply with that agency' s regulatory requirements. Effective September 16, 2020, COVID- 19 vaccine products in Canada were being evaluated for approval under the Interim Order. The Interim Order provided temporary regulatory tools to expedite the approval of drugs and vaccines developed for the treatment of COVID- 19. In July 2021, we completed our rolling submission to Health Canada for COVAXIN. The rolling submission process, which permits companies to submit safety and efficacy data and information as they become available, was recommended and accepted under the Interim Order and transitioned to an NDS for COVID- 19. In August 2022, we withdrew our NDS based on discussions with Health Canada and are evaluating the requirements for resubmitting an updated NDS. In April 2022, we entered into a second amendment to the Covaxin Agreement that provided us with the rights to develop, manufacture, and commercialize COVAXIN in Mexico. COFEPRIS previously authorized emergency use for COVAXIN for adults ages 18 years and older, which remains active. We are also in discussions with CONACYT in Mexico regarding our submission for EUA for COVAXIN for pediatric use in ages five to 18 years. The clinical trials of COVAXIN conducted by Bharat Biotech in India and our Phase 2 / 3 immuno- bridging and broadening clinical trial conducted in the United States may not be sufficient to support an application for marketing approval in Canada or **our** Mexico. Accordingly **modifier gene therapy platform** , seeking regulatory approval in these jurisdictions could result in difficulties and costs for **or** us and require additional preclinical studies or clinical trials which could be costly and time- consuming. We do not have regulatory approvals for product candidates in any jurisdiction and we do not have experience in obtaining regulatory approval in Canada or Mexico. We, or any collaborators, may not obtain approval for COVAXIN from the regulatory agencies in these jurisdictions on a timely basis, if at all. Even if we obtain approval from the FDA for COVAXIN, approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, including in Canada or Mexico, or vice versa. Ultimately, we may not receive the necessary approval to commercialize COVAXIN in Canada or Mexico. Although, COFEPRIS authorized emergency use for COVAXIN for adults ages 18 years and older, such EUA may be revoked at any time and is not a replacement for regulatory approval. We have not sold or administered any doses of COVAXIN under such EUA to date. Newly emerging SARS- CoV- 2 variants could reduce the immunogenicity and effectiveness of COVAXIN as a potential COVID- 19 vaccine. Multiple variants of the virus that causes COVID- 19 have been documented in the United States and globally over the course of the pandemic. New and emerging SARS- CoV- 2 variants could be less affected by the immune responses generated by COVAXIN in the vaccine recipients and therefore could reduce the overall efficacy of our intramuscular vaccine candidate in controlling COVID- 19. The ongoing COVID- 19 pandemic and actions taken in response to it may result in disruptions to our business operations, which would have a materially adverse effect on our business, financial position, operating results, and cash flows. In December 2019, the strain of coronavirus, SARS- CoV- 2, causing the disease known as COVID- 19, was reported to have surfaced in Wuhan, China. In March 2020, the WHO declared the COVID- 19 outbreak a global pandemic. Since being discovered, new variants of SARS- CoV- 2 have emerged. If COVID- 19 continues to spread in the United States and elsewhere, it may impact our business and development activities, including, but not limited to, delay of enrollment and ultimate completion of current clinical trials and delay of enrollment in any clinical trials that we have planned or otherwise may initiate in the future, strain on our suppliers and other third parties, possibly resulting in supply disruptions of our product candidates for preclinical development and clinical trials, and the ability to raise capital when needed on acceptable terms, if at all. The COVID- 19 pandemic continues to impact the global supply chain, causing disruptions to service providers, logistics, and the flow and availability of supplies and products. Disruptions in our operations or supply chain, whether as a result of government intervention, restricted travel, quarantine requirements, or otherwise, could negatively impact **patients', providers',** our **or public perception** ability to proceed with our clinical trials, preclinical development, and other activities and delay our ability to receive product approval and generate revenue. In addition, the continued spread of **such product candidates** COVID- 19 may lead to severe disruption and volatility in the global capital markets, which could increase our cost of capital and adversely affect our ability to access the capital markets. It is possible that the continued spread of COVID- 19 could cause an economic slowdown or recession or cause other unpredictable events, each of which could adversely affect our business, results of operations, or financial condition . The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining required regulatory approvals, we will not be able to commercialize our product candidates as expected, and our

ability to generate revenue will be materially impaired. The research, testing, manufacturing, labeling, approval, selling, marketing, and distribution of pharmaceutical products are subject to extensive regulations by the FDA and other regulatory authorities, which regulations differ from country to country. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials. The outcome of the approval process is inherently uncertain and depends upon numerous factors, including the substantial discretion of the regulatory authorities. This is especially true for rare and / or complicated diseases. Failure can occur at any time during the clinical trial process. We cannot predict if or when we might receive regulatory approvals for any of our product candidates currently under development. Any delay in our obtaining or our failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy for that indication. We may be unable to design and execute a clinical trial to support marketing approval. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by the regulatory authorities. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical, or other studies. The number and types of preclinical studies and clinical trials that will be required for regulatory approval also varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. The FDA or other similar regulatory authorities may determine that our product candidates are not effective or only moderately effective (e. g., studies may not produce the necessary result on all study endpoints), that our studies failed to reach the necessary level of statistical significance, or that our product candidates have undesirable or unintended side effects, toxicities, or other characteristics that preclude us from obtaining marketing approval or prevent or limit commercial use. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including: • regulators, including the FDA and the NIH, or IRBs or IBCs may not authorize us or our investigators to commence or continue a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or regulators, IRBs, or IBCs may require that we modify or amend our clinical trial protocols; • we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and our CDMOs; • the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials, or be lost to follow- up at a higher rate than we anticipate; • our third- party contractors may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring; • us, the regulators, IRBs, or IBCs may require the suspension or termination of clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects, or other unexpected characteristics (alone or in combination with other products) of the product candidate, or due to findings of undesirable effects caused by a chemically or mechanistically similar therapeutic or therapeutic candidate; • changes in marketing approval policies or regulations, or changes in or the enactment of additional statutes or regulations, during the development period rendering our data insufficient to obtain marketing approval and requiring us to conduct additional studies; • the cost of clinical trials of our product candidates may be greater than we anticipate or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of a marketing application; • the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; • we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites; • patients that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the study, increase the needed enrollment size for the study, or extend the study' s duration; • the FDA or comparable foreign regulatory authorities may disagree with our study design, including endpoints, or our interpretation of data from preclinical studies and clinical trials or find that a product candidate' s benefits do not outweigh its safety risks; • the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries; • the FDA or comparable foreign regulatory authorities may disagree with our intended indications; • the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our contract manufacturer' s manufacturing facility for clinical and future commercial supplies; • the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a marketing application, or other comparable submissions in foreign jurisdictions, or to obtain regulatory approval in the United States or elsewhere; • the FDA or comparable foreign regulatory authorities may take longer than we anticipate to make a decision on our product candidates; and • we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development. Significant delays relating to any preclinical or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring products to market before we do. This may prevent us from receiving marketing approvals and impair our ability to successfully commercialize our product candidates, if approved, and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays in clinical trials may ultimately lead to the denial of marketing approval of any of our product candidates. If any of this occurs, our business, financial condition, results of operations, and prospects will be materially harmed. The failure to comply with FDA and comparable foreign regulatory requirements may, either before or after product approval, if any, subject us to administrative or judicially imposed sanctions,

including: • restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials ; • restrictions on our products, manufacturers, or manufacturing process ; • warning letters, Form 483s, or untitled letters alleging violations ; • civil and criminal penalties ; • injunctions ; • suspension or withdrawal of regulatory approvals ; • product seizures, detentions, or import bans ; • voluntary or mandatory product recalls and publicity requirements ; • total or partial suspension of production ; • imposition of restrictions on operations, including costly new manufacturing requirements ; and • refusal to approve pending marketing applications or supplements to approved marketing applications. Even if we were to obtain regulatory approval of a product candidate, the FDA or comparable foreign regulatory authorities may grant approval for fewer or more limited indications, populations, or uses than we request, may require significant safety warnings, including black box warnings, contraindications, and precautions, may grant approval contingent on the performance of costly post- marketing clinical trials, surveillance, restrictions on use or other requirements, including a REMS to monitor the safety or efficacy of the product, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of these scenarios could compromise the commercial prospects for our product candidates. As an organization, we have limited experience in the development, manufacturing, distribution, or commercialization of a vaccine candidate. We have limited experience in the development of vaccine candidates and have never undertaken the manufacturing, distribution, or commercialization of a vaccine candidate, and we may be unable to obtain regulatory authorization or approval. Additionally, development of an effective vaccine candidate depends on the success of our and our partner' s manufacturing capabilities. **In** ~~We have not previously ramped our organization for a commercial launch of any product and doing so in a pandemic environment with an urgent, critical global need creates additional~~ -- **addition** ~~challenges such as clinical trials~~, ~~licensing, distribution channels, intellectual property disputes or challenges, and~~ the **development and manufacture** ~~need to establish teams~~ of **inhaled mucosal** ~~people with the relevant skills. We may also face challenges with sourcing a sufficient amount of raw materials to support the demand for a vaccine~~ **vaccines may prove** ~~, including any potential import issues and the ability of our collaboration partner, Bharat Biotech,~~ to ~~successfully respond to~~ **be more complex than** the **development** ~~deficiencies identified in an~~ **and manufacture of traditional vaccines** ~~inspection conducted by the WHO~~. ~~We~~ **Further, we** may be unable to effectively create a supply chain for our vaccines that will adequately support demand. ~~Furthermore~~ **We may also face challenges with sourcing a sufficient amount of raw materials to support the demand for a vaccine. While we are currently collaborating with NIAID for early clinical studies for the OCU500 program**, there ~~are no assurances that any vaccine candidate would be authorized or approved at all or for inclusion in government stockpile programs or transition to the private market, which may be material to the commercial success of a vaccine product candidate. There~~ can also be no assurance that we will be able to obtain the required funding from government agencies ~~to continue the~~ **for further development of OCU500 or for** development of our vaccine candidates **, OCU510 and OCU520. Due to the end of the COVID- 19 public health emergency and decline in vaccination rates, the demand for any COVID- 19 vaccine product candidate we develop may decrease significantly. As noted elsewhere in this Annual Report, on May 11, 2023, the U. S. Department of Health and Human Services announced the COVID- 19 public health emergency ended. In addition, the demand for COVID- 19 vaccines is becoming more endemic and seasonal. As other companies continue to develop, receive regulatory approval for and commercialize their own COVID- 19 vaccines and as demand for such vaccines declines, demand for our COVID- 19 product candidates OCU500 and OCU520 may be diminished**. The development and manufacture of biologics is a complex process and entails particular risks. OCU200 is our novel biologic designed to treat retinal diseases. The process of developing and manufacturing biologics is complex, highly regulated, and subject to multiple risks, and we have no experience in successfully developing, manufacturing, or commercializing a biologics product. The manufacturing of biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions, and higher costs. The raw materials required in our third- party vendors' manufacturing processes are derived from biological sources. We cannot assure you that our third- party vendors have, or will be able to obtain on commercially reasonable terms, or at all, sufficient rights to these materials derived from biological sources. Such raw materials are difficult to procure and may also be subject to contamination or recall. If microbial, viral, or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of drug product, and adversely harm our business. A material shortage, recall, or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the clinical and commercial manufacturing of our product candidates, which could materially and adversely affect our operating results and development timelines. In addition, the U. S. government may impose restrictions on goods, including biologically derived substances, manufactured in or imported from China. This could have a material adverse effect on our business and operations. In addition, our biologic product candidates may expose us to additional potential product liability claims. The development of biologic products entails a risk of additional product liability claims because of the risk of transmitting disease to human recipients, and substantial product liability claims may be asserted against us as a result. OCU400 **and OCU410ST have received orphan drug designation, or ODDs from the FDA and OCU400** has received ~~ODDs from the FDA and~~ **orphan medicinal product designation, or** OMPD from the **European Commission, or** EC. However, there is no guarantee that we will be able to maintain these designations, receive ~~this~~ **these** ~~designation~~ **designations** for any of our other product candidates, or receive or maintain any corresponding benefits, including periods of exclusivity. We have obtained from the FDA Office of Orphan Products, ODDs for OCU400 for ~~NR2E3- related~~ RP and LCA and had previously received ODDs for the treatment of the following disease genotypes: NR2E3, RHO, CEP290, and PDE6ß mutation- associated inherited retinal degenerations. OCU400 has additionally received OMPD from the EC, based on the recommendation of the EMA, for RP and

LCA. We **have also received ODD for OCU410ST for the treatment of ABCA4- associated retinopathies including Stargardt, RP19 and CORD3 diseases. We** may also seek ODD or OMPD for our other product candidates, as appropriate. While these ODDs and OMPDs provide us with certain advantages, they neither shorten the development time or regulatory review time of a product candidate nor give the product candidate any advantage in the regulatory review or approval process. Generally, if a product candidate with ODD or OMPD ~~subsequently~~ **is the first to** ~~receives~~ **receive** marketing approval ~~before another product considered by the FDA or~~ **for** ~~EMA to be~~ the ~~same, for the same~~ orphan indication, the product is entitled to a period of marketing exclusivity, which precludes the FDA or EMA from approving another marketing application for the same drug or biologic for the same indication for a specified time period. The applicable period is seven years in the United States and 10 years in Europe. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for OMPD or if the product is sufficiently profitable so that market exclusivity is no longer justified. We may not be able to obtain any future ODDs or OMPDs that we apply for ~~,~~**. Receiving** ODDs or OMPDs do not guarantee that we will be able to successfully develop our product candidates, and there is no guarantee that we will be able to maintain any ODDs or OMPDs that we receive. For instance, ODDs may be revoked if the FDA finds that the request for designation contained an untrue statement of a material fact or omitted material information, or if the FDA finds that the product candidate was not eligible for designation at the time of the submission of the request. Moreover, even if we are able to receive and maintain ODDs or OMPDs, we may ultimately not receive any period of regulatory exclusivity if our product candidates are approved. For instance, we may not receive orphan product regulatory exclusivity if the indication for which we receive FDA or EMA regulatory approval is different than the ODD or OMPD. Orphan exclusivity may also be lost for the same reasons that ODD or OMPD may be lost. Orphan exclusivity may further be lost if we are unable to assure a sufficient quantity of the product to meet the needs of patients with the rare disease or condition. Even if we obtain orphan exclusivity for any of our current or future product candidates, that exclusivity may not effectively protect the product candidate, if approved, from competition as different products can be approved for the same condition or products that are the same as ours can be approved for different conditions. Even after an orphan product is approved, the FDA or EMA can also subsequently approve a product containing the same principal molecular features for the same condition if the regulatory authority concludes that the latter product is clinically superior by means of greater effectiveness, greater safety, or providing a major contribution to patient care. If another sponsor receives approval for such product before we do, we would be prevented from launching our product for the orphan indication during the period of marketing exclusivity unless we can demonstrate clinical superiority. We have or may pursue fast track, breakthrough therapy, or RMAT designations from the FDA for one or more of our product candidates. Even if one or more of our product candidates receives fast track, breakthrough therapy, or RMAT designations, we may be unable to obtain and maintain the benefits associated with such designations. These designations may not lead to a faster development or regulatory review or approval process, and will not increase the likelihood that such product candidates will receive marketing approval. In May 2022, the FDA granted RMAT designation to NeoCart for the repair of full- thickness lesions of the knee cartilage in adults **. In December 2023, the FDA granted RMAT designation to OCU400 for the treatment of RP associated with NR2E3 and RHO mutations** . In the future, we may seek additional product designations, such as fast track, breakthrough therapy, or RMAT designation, which are intended to facilitate the development or regulatory review or approval process for product candidates. Receipt of such a designation is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for a designation, the FDA may disagree. In any event, the receipt of such a designation for a product candidate may not result in a faster development process, review, or approval compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate marketing approval by the FDA. In addition, the FDA may later decide that the product candidates no longer meet the designation conditions, in which case any granted designations may be revoked. The FDA may determine that our product candidates have undesirable side effects that could delay or prevent their regulatory approval or commercialization. If such side effects are identified during the development of our product candidates, we may need to abandon our development of such product candidates. Undesirable side effects caused by our product candidates could cause us, IRBs, and other reviewing entities or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. For example, if concerns are raised regarding the safety of one of our product candidates as a result of undesirable side effects identified during preclinical or clinical testing, the FDA may order us to cease further development or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the product candidate. FDA requests for additional data or information can result in substantial delays in the approval of a new product candidate. Undesirable side effects caused by any unexpected characteristics (alone or in combination with other products) for any of our product candidates could also result in denial of regulatory approval by the FDA or other comparable foreign authorities for any or all targeted indications or the inclusion of unfavorable information in our product labeling, such as limitations on the indicated uses or populations for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, may result in requirements for costly post- marketing testing and surveillance, or other requirements, including REMS, to monitor the safety or efficacy of the products. These could prevent us from commercializing and generating revenues from the sale of our product candidates. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause side effects that prevented further development of the compound. In addition, adverse events which had initially been considered unrelated to the study treatment may later be found to be caused by the study treatment. Moreover, incorrect or improper use of our product candidates (including use more frequently than is prescribed), if approved, by patients could cause unexpected side effects or adverse events. There can be no assurance that our product candidates, if approved, will be used correctly, and if used incorrectly, such misuse could prevent our receipt or maintenance of marketing approval, resulting in label changes or regulatory authority safety communications or warnings, or

hamper commercial adoption of our product candidate, if approved, at the rate we currently expect. If any of our product candidates are associated with serious adverse events, undesirable side effects, or have properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk- benefit perspective. The therapeutic- related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. We may also be held liable for harm caused to patients and our reputation may suffer. Any of these occurrences may significantly harm our business, financial condition, results of operations, and prospects. Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates. Our ongoing clinical trials could be discontinued early if they experience slow enrollment, and we may also experience similar difficulties in future clinical trials. If patients are unwilling to participate in our clinical trials because of negative publicity from adverse events related to vaccines, gene therapy, or in the industry more broadly, in the clinical trials for related third party product candidates, or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our product candidates, or termination of the clinical trials altogether. We or our clinical trial sites may not be able to identify, recruit, and enroll a sufficient number of patients, or those with the required or desired characteristics in a clinical trial, to complete our clinical trials in a timely manner. Patient enrollment is affected by other factors including: • the size and nature of the patient population (for instance, we are pursuing clinical trials for certain orphan indications, for which the size of the patient population is limited); • the severity of the disease under investigation; • the existence of current treatments for the indications for which we are conducting clinical trials; • the eligibility criteria for and design of the clinical trial in question, including factors such as frequency of required assessments, length of the study, and ongoing monitoring requirements; • the perceived risks and benefits of the product candidate, including the potential advantages or disadvantages of the product candidate being studied in relation to other available therapies; • competition in recruiting and enrolling patients in clinical trials; • efforts to facilitate timely enrollment in clinical trials; • patient referral practices of physicians; • effectiveness of publicity created by clinical trial sites regarding the trial; • patients' ability to comply with the specific instructions related to the trial protocol, proper documentation, and use of the product candidate; • an inability to obtain or maintain patients' informed consents; • the risk that enrolled patients will drop out before completion or not return for post- treatment follow- up; • the ability to monitor patients adequately during and after treatment; • the ability to compensate patients for their time and effort; and • the proximity and availability of clinical trial sites for prospective patients. We may not be able to initiate or continue conducting clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these **clinical** trials as required by the FDA or similar regulatory authorities outside the United States. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. In particular, there may be low or slow enrollment, and the studies may enroll subjects that do not meet the inclusion criteria, requiring the erroneously enrolled subjects to be excluded and the trial population to be increased. Moreover, patients in our clinical trials, especially patients in our control groups, may be at risk for dropping out of our studies if they are not experiencing relief of their disease. A significant number of withdrawn patients would compromise the quality of a study' s data. Enrollment difficulties or delays in our clinical trials may result in increased development costs for our product candidates, or the inability to complete development of our product candidates, which would cause our value to decline, limit our ability to obtain additional financing, and materially impair our ability to generate revenues. Data from preclinical studies and early- stage clinical trials may not be predictive of success in later clinical trials. The results of preclinical studies, preliminary study results, and early- stage clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials or the ultimately completed clinical trial. Preliminary and final results from such studies may not be representative of study results that are found in larger, controlled, blinded, and more long- term studies. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies have suffered significant setbacks in advanced clinical trials, notwithstanding promising results in earlier **clinical** trials. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols, and the rate of dropout among clinical trial participants. In addition, from time to time, we may publish interim, " top- line, " initial, or preliminary data from our clinical trials ~~. For example, in January 2023 we announced top- line results from our Phase 2 / 3 immuno- bridging and broadening study for COVAXIN, which we intend to use together with data from a safety clinical trial, subject to discussions with the FDA, to support a BLA submission for COVAXIN~~ . Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. Preliminary, initial, or " top- line " data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously published. As a result, interim, " top- line ", initial, and preliminary data should be viewed with caution until the final data are available. Adverse changes between preliminary, initial, " top- line " or interim data and final data could significantly harm our business prospects. Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not

yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. We may, in the future, conduct clinical trials for product candidates at sites outside the United States, and the FDA may not accept data from **clinical** trials conducted in such locations. We may, in the future, choose to conduct one or more of our clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of data is in either case subject to the respective conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and be performed by qualified investigators in accordance with ethical principles, such as IRB or ethics committee approval and informed consent. The trial population must also adequately represent the U. S. population, and the data must be applicable to the U. S. population and U. S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws (and therefore failure to comply with such laws could result in regulatory enforcement action), acceptance of the data by the FDA will be dependent upon its determination that the **clinical** trials were conducted consistent with all applicable U. S. laws and regulations. If the FDA does not accept the data from any **clinical** trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time- consuming and could delay or permanently halt our development of the applicable product candidates. Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad. In order to market and sell our products in jurisdictions outside the United States, we must obtain separate marketing approvals in international jurisdictions and comply with numerous and varying regulatory requirements. The approval procedures vary among countries and the time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. The clinical trials of our product candidates may not be sufficient to support an application for marketing approval outside the United States. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. We, or any current or eventual collaborators, may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not guarantee approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not guarantee approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, the failure to obtain approval in one jurisdiction may compromise our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. We may be subject to fines, penalties, injunctions, or other enforcement actions if we are determined to be promoting the use of our products, if approved, for unapproved or " off- label " uses, resulting in damage to our reputation and business. We must comply with requirements concerning advertising and promotion for any product candidates for which we obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. We may not market or promote them for other indications and uses, referred to as off- label uses. We further must be able to sufficiently substantiate any claims that we make for our products, if approved, including claims comparing our products to other companies' products and must abide by the FDA' s strict requirements regarding the content of promotion and advertising. While physicians may choose to prescribe products for uses that are not described in the product' s labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, we are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA. If we are found to have impermissibly promoted any of our product candidates, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off- label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed. In the United States, engaging in the impermissible promotion of our products, following approval, for off- label uses can also subject us to false claims and other litigation under federal and state statutes, including fraud and abuse and consumer protection laws. Such litigation can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and do business through, for example, corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, suspension and debarment from government contracts, and refusal of orders under existing government contracts. These false claims statutes include the federal civil FCA, which allows any individual to bring a lawsuit against a company on behalf of the federal government (" qui tam" action) alleging submission of false or fraudulent claims, or causing others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. These FCA lawsuits against sponsors of drugs and biologics have increased significantly in volume and breadth **in recent years** , leading to several

substantial civil and criminal settlements, up to $ 3. 0 billion, pertaining to certain sales practices and promoting off- label uses. In addition, FCA lawsuits may expose sponsors to follow- on claims by private payors based on fraudulent marketing practices. This growth in litigation has increased the risk that companies will have to defend a false claim action, and pay settlements fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations, and prospects. In the United States, the distribution of product samples to physicians must further comply with the requirements of the U. S. PDMA, and the promotion of biologic and pharmaceutical products are subject to additional FDA requirements and restrictions on promotional statements. If the FDA determines that our promotional activities violate our regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or subject us to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. These regulatory and enforcement actions could significantly harm our business, financial condition, results of operations, and prospects. Even if our product candidates receive regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities, including requirements related to the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, marketing, and promotional activities for such product. These requirements further include submissions of safety and other post- marketing information, including manufacturing deviations and reports, registration and listing requirements, the payment of annual fees, continued compliance with current GMP requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and GCPs, for any clinical trials that we conduct post- approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses and populations for which the product may be marketed or to the conditions of approval, including significant safety warnings, such as boxed warnings, contraindications, and precautions that are not desirable for successful commercialization. Any approved products may also be subject to a REMS that render the approved product not commercially viable or other post- market requirements, such as Phase 4 studies, or restrictions. If the FDA or comparable foreign regulatory authorities become aware of new safety information after the approval of any of our product candidates, they may, among other actions, withdraw approval, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product' s indicated uses or marketing, or impose ongoing requirements for potentially costly post- approval studies or post- market surveillance. We and any of our collaborators, including our contract manufacturers, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with current GMP and other FDA regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre- approval for product and manufacturing changes. In addition, later discovery of previously unknown adverse events or that the product is less effective than previously thought or other problems with our products, manufacturers, or manufacturing processes, or failure to comply with regulatory requirements both before and after approval, may yield various results, including: • restrictions on manufacturing, distribution, or marketing of such products; • restrictions on the labeling, including restrictions on the indication or approved patient population, and required additional warnings, such as black box warnings, contraindications, and precautions; • modifications to promotional pieces; • issuance of corrective information; • requirements to conduct post- marketing studies or other clinical trials; • clinical holds or termination of clinical trials; • requirements to establish or modify a REMS, or a comparable foreign authority may require that we establish or modify a similar strategy; • liability for harm caused to patients or subjects; • reputational harm; • warning, untitled, Form 483s, or cyber letters; • suspension of marketing or withdrawal or recall of the products from the market; • regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product; • refusal to approve pending applications or supplements to approved applications that we submit; • fines, restitution, or disgorgement of profits or revenues; • suspension or withdrawal of marketing approvals; • refusal to permit the import or export of our products; • product seizure or detention; • FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; or • injunctions or the imposition of civil or criminal penalties, including imprisonment. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, or could substantially increase the costs and expenses of developing and commercializing such product, which in turn could delay or prevent us from generating significant revenues from its sale. Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our stock price and could significantly harm our business, financial condition, results of operations, and prospects. The FDA' s policies may change, and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates, limit the marketability of our product candidates, or impose additional regulatory obligations on us. Changes in medical practice and standard of care may also impact the marketability of our product candidates, if approved. We will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely affect our business. Any name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the

FDA objects to any of our proposed product names, we may be required to adopt alternative names for our product candidates. If we adopt alternative names, we would lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe upon the existing rights of third- parties, and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates, if approved **. Changes in the economic, political, legal and social conditions and policies of the Chinese government or in relations between China and the United States may materially and adversely affect our business, financial condition, results of operations, access to capital, and the market price of our common stock. We have a co- development and commercialization agreement with CanSinoBIO with respect to the development and commercialization of our modifier gene therapy platform including OCU400, OCU410 and OCU410ST as well as manufacturing part of our inhaled mucosal vaccine platform including OCU500, and as a result, have significant operations in China. Due to our operations in China, our business, results of operations, financial condition, access to capital, market price of our common stock and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China or changes in government relations between China and the United States or other governments. Furthermore, we face the risk that our business operations in China will be impacted by government regulations and / or foreign sanctions. Escalation of current geopolitical tensions may implicate China and could increase the risk of government regulations and / or foreign sanctions and imposition of export controls and import restrictions. In addition, our information technology systems may be at risk of being blocked from our world- wide operations. Ongoing human rights concerns in China may result in boycotts of our services or client requests not to use Chinese operations to support their projects** . Risks Related to the Commercialization of Our Product Candidates We have no prior experience in the marketing, sale, and distribution of biotechnology products, and there are significant risks involved in the building and managing of a commercial infrastructure. The establishment and development of commercial capabilities, including compliance plans, to market any products we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We will have to compete with other pharmaceutical or biotechnology companies to recruit, hire, train, manage, and retain marketing and sales personnel. Factors that may inhibit our efforts to commercialize our product candidates include: • the inability to recruit, train, manage, and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our product candidates; • our inability to effectively oversee a geographically dispersed sales and marketing team; • the costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions; • an inability to secure adequate coverage and reimbursement by government and private health plans; • reduced realization on government sales from mandatory discounts, rebates and fees, and from price concessions to private health plans and pharmacy benefit managers necessitated by competition for access to managed formularies; • the clinical indications for which the products are approved and the claims that we may make for the products; • limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling; • any distribution and use restrictions imposed by the FDA or other foreign regulatory agencies, including those that we may agree to as part of a mandatory REMS or voluntary risk management plan; • liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and • unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization. Should any of the foregoing occur, we may not be successful in commercializing any product candidates for which we receive marketing approval. If we obtain approval to commercialize our product candidates outside of the United States, a variety of risks associated with international operations could materially adversely affect our business ~~. COVAXIN has received EUA in Mexico in adults ages 18 years and older~~ . If any of our product candidates are approved for commercialization, we may enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect that we will be subject to additional risks related to conducting marketing and sales activities in international jurisdictions and entering into international business relationships, including: • different regulatory requirements for approval of drugs and biologics in foreign countries ; • the potential for so- called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally ; • challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States ; • the need to seek additional patent approvals, licenses to patents held by third parties, and / or face claims of infringing third- party patent 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 ; • difficulties staffing and managing foreign operations ; • workforce uncertainty in countries where labor unrest is more common than in the United States ; • potential liability under the FCPA, the U. K. Bribery Act 2010 (the" Bribery Act"), or other comparable foreign regulations ; • 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, or natural disasters including pandemics or other outbreaks of infectious disease, earthquakes, typhoons, floods, and fires. These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations. If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may be unable to generate product revenues. We currently do not have a commercial infrastructure for the

marketing, sale, and distribution of biotechnology products. If approved, in order to commercialize our products, we must build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services. If we do not establish sales, marketing, and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidates for which we receive marketing approval. Subject to regulatory approval of any of our product candidates, we may build a commercial team of specialty sales and marketing representatives in support of our product candidates that we develop in the United States or other foreign countries, if approved, as well as distribution capabilities. There are risks involved with us establishing our own sales, marketing, and distribution capabilities. Recruiting and training a sales force is expensive and time- consuming, particularly to the extent that we seek to commercialize any product, if approved, for an indication, such as ~~dry AMD~~ **dAMD** , that has a large patient population. We will be competing with many companies that currently have extensive and well- funded marketing and sales operations to recruit, hire, train, and retain marketing and sales personnel. Further, we may underestimate the size of the sales force required for a successful product launch and may need to expand our sales force earlier and at a higher cost than we anticipate. If the commercial launch of our product candidates, if approved, for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. We may also or alternatively decide to collaborate with a third- party or contract sales organization to commercialize any approved product candidates, in which event, our ability to generate product revenues may be limited. Our product revenues and our profitability, if any, under any third- party collaboration, distribution, or other marketing arrangements are likely to be lower than if we were to market, sell, and distribute the applicable product candidate, if approved, entirely ourselves. We may not be successful in entering into arrangements with third parties to sell, market, and distribute our product candidates, if approved, or may be unable to do so on terms that are favorable to us. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts and any of them may fail to devote the necessary resources and attention to sell and market our product candidates, if approved, effectively. We could also be held liable if such third parties failed to comply with applicable legal or regulatory requirements. In the event we are unable to develop a team of marketing and sales representatives or to establish an effective third- party contractual relationship for such services, we may not be able to commercialize our product candidates, if approved, which would limit our ability to generate product revenues. Even if we are able to effectively hire a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing our product candidates, if approved. The biotechnology industry is characterized by rapidly advancing technologies as well as a strong emphasis on intellectual property leading to a highly competitive environment for the development and commercialization of therapeutic products, regenerative medicines, and vaccines. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future. We face competition from many different sources, including from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization. The development and commercialization of gene therapies is highly competitive. We are aware of several companies focusing on gene therapies for various ophthalmic indications including Applied Genetic Technologies Corporation, as acquired by Syncona Limited, Astellas Pharma Inc., MeiraGTx Holdings plc in partnership with Janssen Pharmaceuticals, Inc., Nanoscope Therapeutics Inc., REGENXBIO Inc., Novartis AG, F. Hoffmann- La Roche AG (" Roche AG"), Kiora Pharmaceuticals, Inc., Genentech, Inc. in partnership with Lineage Cell Therapeutics, Inc., and Luxturna, the product developed by Spark Therapeutics, Inc. and marketed by Roche AG, is currently the only gene therapy approved to treat IRDs in the United States which addresses only mutations in the RPE65 gene. The mutation associated with the RPE65 gene represents just one of more than 125 mutated genes linked to RP and LCA. The regenerative medicine sector is characterized by innovative science, rapidly advancing technologies, and a strong emphasis on proprietary products. The competitive landscape in the field of articular cartilage repair in the U. S. is emerging and has stimulated a substantial amount of interest from companies developing tissue repair solutions. Companies that may compete with our NeoCart product candidate include Vericel Corporation' s MACI, the only FDA- approved ACI product in the United States, and Aesculap Biologics, LLC' s NOVOCART 3D, which is currently enrolling subjects in their Phase 3 clinical trial. We face, and will continue to face, intense competition from companies as well as institutions that are pursuing or have commercialized vaccines that would compete with our ~~vaccine candidates, COVAXIN and our novel~~ inhaled mucosal vaccine platform, if commercialized. The competitive landscape of COVID- 19 vaccines has been rapidly developing since the beginning of the COVID- 19 pandemic and includes competitors such as Pfizer Inc. / BioNTech SE, Moderna, Inc., AstraZeneca PLC, Novavax, Inc., Sinovac Biotech Ltd., Gamaleya Research Institute of Epidemiology and Microbiology, and Center for Genetic Engineering and Biotechnology. Each of the aforementioned vaccines have been authorized or approved in at least one country within the Ocugen ~~COVAXIN Territory or the~~ Mucosal Vaccine Territory and are intramuscular vaccines. CanSinoBIO' s Convidecia Air, an intranasal vaccine targeting COVID- 19, has been approved in China. Other competitors for our novel inhaled mucosal vaccine platform include CyanVac LLC, Meissa Vaccines, Inc., Codagenix, Inc., Intravacc B. V., McMaster University, and Tetherex Pharmaceuticals Corporation. Companies such as Pfizer Inc. / BioNTech SE, Moderna, Inc., CureVac N. V in partnership with GSK plc, Vivaldi Biosciences Inc., and Novavax, Inc. are also in the process of developing a combination vaccine that will protect against COVID- 19 and the seasonal flu. Vivaldi Biosciences Inc. is also currently undergoing clinical trials for their intranasal vaccine for the seasonal flu. The development and commercialization of biologic products is highly competitive as well. Companies that may compete with our OCU200 product candidate include Roche AG, Regeneron Pharmaceuticals, Inc., AsclepiX Therapeutics, Inc., Outlook Therapeutics, Inc., Novartis AG, Oxurion NV, Unity Biotechnology, Inc., Opthea Limited, and 4D Molecular Therapeutics, Inc.

Roche AG, Regeneron Pharmaceuticals, Inc., and Novartis AG have marketed anti- VEGF products. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop and for which we receive approval. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market. They may obtain patent protection or other intellectual property rights that allow them to develop and commercialize their products before us and could limit our ability to develop or commercialize our product candidates. In addition, our ability to compete may be affected in many cases by insurers or other third- party payors' coverage decisions, particularly Medicare, seeking to encourage the use of generic or biosimilar products. Many of the products that will compete with our product candidates, if approved, are available on a generic basis, and our product candidates may not demonstrate sufficient additional clinical benefits to clinicians, patients, or payors to justify a higher price compared to generic products. Additional competing products are expected to become available on a generic basis over the coming years. Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. If our product candidates for which we receive approval do not achieve broad market acceptance, the revenues that we generate from their sales will be limited. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third- party payors, and others in the medical community. Physicians are often reluctant to switch their patients and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market. We have never commercialized a product candidate for any indication, and efforts to educate the medical community and third- party payors on the benefits of our product candidates may require significant resources and may not be successful. With respect to our product candidates being developed based on our modifier gene therapy platform, market acceptance may also be constrained by ethical, social, and legal concerns about gene therapy and genetic research, which could result in additional regulations restricting or prohibiting the products and processes we may use. The novelty of the technology and any negative publicity surrounding adverse events associated with gene therapy may also prevent the medical community, patients, and third- party payors from accepting gene therapy products in general, and our product candidates in particular, as medically useful, cost- effective, and safe. Market acceptance of our product candidates by the medical community, patients, and third- party payors will depend on a number of factors, some of which are beyond our control. If any product candidates for which we obtain regulatory approval does not gain an adequate level of market acceptance, it may not generate significant product revenues or become profitable. The degree of market acceptance of any of our product candidates will depend on a number of factors, including: • the efficacy of our product candidates; • the prevalence and severity of adverse events associated with such product candidates; • the clinical indications for which the product candidates are approved and the approved claims that we may make for the products; • limitations or warnings contained in the product' s FDA- approved labeling, including potential limitations or warnings for such product candidates that may be more restrictive than other competitive products; • changes in the standard of care for the targeted indications for such product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval, if obtained; • the relative convenience and ease of administration of such product candidates; • cost of treatment versus economic and clinical benefit in relation to alternative treatments or therapies; • the availability of third- party formulary coverage and adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicaid and particularly by Medicare in light of the prevalence of retinal diseases in persons over age 55; • the price concessions required by third party payors to obtain coverage; • the extent and strength of our manufacturing, marketing, and distribution of such product candidates; • distribution and use restrictions imposed by the FDA with respect to such product candidates or to which we agree as part of a REMS or voluntary risk management plan; • the extent of availability of generic or biosimilar versions of any products that compete with any of our product candidates and the extent to which they are offered at a substantially lower price than we expect to offer for our product candidates, if approved; • adverse publicity about the product or favorable publicity about competitive products; and • potential product liability claims. If the market opportunities for our product candidates are smaller than we believe, our revenue may be adversely affected and our business may suffer. The potential market opportunities for our product candidates are difficult to precisely estimate. Our estimates of the potential market opportunities are predicated on many assumptions, which may include industry knowledge and publications, third- party research reports, and other surveys, some of which we may have commissioned. Industry publications and third- party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third- party research, surveys, and studies are reliable, we have not independently verified such data. In addition, while we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and the reasonableness of these assumptions has not been assessed by an independent source. If any assumptions prove to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities, and as a result, our product revenue may be limited, and it may be more difficult for us to achieve or maintain profitability. Our ability to successfully commercialize our product

candidates, if approved, will depend in part on the extent to which coverage and adequate reimbursement for our product candidates will be available in a timely manner from third- party payors, including governmental healthcare programs such as Medicare and Medicaid, commercial health insurers, and managed care organizations. This is particularly true with respect to OCU200, our novel biologic product candidate, in the case of ~~wet~~ **Wet** AMD, which is most prevalent in persons over age 55. Government authorities and other third- party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Reimbursement decisions by particular third- party payors depend upon a number of factors, including each third- party payor' s determination that use of a product is: • a covered benefit under its health plan; • appropriate and medically necessary for the specific condition or disease; • cost effective; and • neither experimental nor investigational. Obtaining coverage and reimbursement approval for our product candidates from government authorities or other third- party payors may be a time consuming and costly process that could require us to provide supporting scientific, clinical, and cost- effectiveness data, including expensive pharmacoeconomic studies beyond the data required to obtain marketing approval, for the use of each product candidate to each government authority or other third- party payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. Third- party payors may deny reimbursement for covered products if they determine that a medical product was not used in accordance with cost- effective diagnosis methods, as determined by the third- party payor, or was used for an unapproved indication. Third- party payors also may refuse to reimburse for procedures and devices deemed to be experimental. Third- party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. Increasingly, third- party payors are also requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. These third- party payors could also impose price controls and other conditions that must be met by patients prior to providing coverage for use of our product candidates, if approved. For example, insurers may establish a" step- edit" system that requires a patient to first use a lower price alternative product prior to becoming eligible for reimbursement of a higher price product. Third- party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for medical products and services. The process for determining whether a payor will provide coverage for a product may be separate from the process of setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Levels of reimbursement may also decrease in the future, and legislation, regulation, or reimbursement policies of third- party payors may adversely affect the demand for and reimbursement available for our product candidates, which in turn, could negatively impact pricing. If patients are not adequately reimbursed for our product candidates, if approved, they may reduce or discontinue purchases of it, which would result in a significant shortfall in achieving revenue expectations and negatively impact our business, prospects, and financial condition. ~~The~~ **For example, the** IRA contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U. S. Department of Health and Human Services that would require manufacturers to charge a negotiated" maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the IRA. The IRA could have the effect of reducing the prices we can charge and reimbursement we receive for our products, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations, and growth prospects. The **IRA' s drug price negotiation provisions are subject to ongoing constitutional challenges, and the** effect of IRA on our business and the biotechnology industry in general is not yet known. Risks Related to Our Dependence on Third Parties We rely **, and expect to continue to rely,** on third parties ~~, study sites, and others~~ to conduct, supervise, and monitor our preclinical **studies** and clinical trials **we may initiate, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such preclinical studies** ~~for~~ **or clinical trials** ~~our~~ **or** ~~product candidates~~ **failing to comply with regulatory requirements** . We ~~expect to continue to~~ rely on third parties, **study sites, and others to conduct, supervise, and monitor our preclinical and clinical trials for our product candidates. We expect to continue to rely on third parties,** such as CDMOs, clinical data management organizations, medical and scientific institutions, and clinical and preclinical investigators to conduct our preclinical studies and clinical trials **. We often have to negotiate budgets and contracts with such third parties, and if we are unsuccessful or if the negotiations take longer than anticipated, this could result in delays to our development timelines and increased costs** . While we have, or expect to have, agreements governing the activities of such third parties, we will have limited influence and control over their actual performance and activities. Third- party service providers are not our employees, and except for remedies available to us under agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our preclinical studies or clinical trials. Nevertheless, we will be responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards, and our reliance on third parties will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for the trial. We must also ensure that our preclinical ~~trials~~ **studies** are conducted in accordance with GLP and under current GMP conditions, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCPs for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites, and IRBs **. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws** . If

these third parties upon which we depend do not successfully carry out their contractual duties, meet expected deadlines, conduct our preclinical studies or any clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons: • we, our CDMOs, or other third- party collaborators may be subject to regulatory enforcement or other legal actions; • the data generated in our preclinical studies or clinical trials may be deemed unreliable and our such studies and clinical trials may need to be repeated, extended, delayed, or terminated; • we may **need to identify new CDMOs with which to partner for the supply of our product candidates; • we may** not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates; or • we may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates, if approved. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our preclinical studies or clinical trials will comply with the applicable regulatory requirements. To the extent we are unable to successfully identify and manage the performance of third- party service providers in the future, our business may be materially and adversely affected. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed **. If we need to identify and retain alternative CDMOs for any reason during our product development programs, the technical skills required to manufacture our product candidates may be unique or proprietary to the original CDMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back- up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CDMOs for any reason, we will be required to verify that the new CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CDMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CDMO may possess technology related to the manufacture of our product candidate that such CDMO owns independently. This would increase our reliance on such CDMO or require us to obtain a license from such CDMO in order to have another CDMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials** . Our anticipated reliance on third parties for clinical trials will entail additional risks. Our third- party service providers may have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other therapeutic development activities that could harm our competitive position. In addition, we will be required to report certain financial interests of our third- party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest. Lastly, we are required to register certain clinical trials and post the results of certain completed clinical trials on a government- sponsored database, clinicaltrials. gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity. Agreements with third parties conducting or otherwise assisting with our clinical or preclinical studies might terminate for a variety of reasons, including a failure to perform by the third parties. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, if we need to enter into alternative arrangements, it could delay our product development activities and adversely affect our business. Though we intend to carefully manage our relationships with third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, prospects, and results of operations. We will also rely on other third parties to store and distribute our product candidates for preclinical purposes or clinical trials that we conduct. Any performance failure on the part of our distributors could delay development, marketing approval, or commercialization of our product candidates, if approved, producing additional losses and depriving us of potential product revenue. We have entered into a strategic partnership with CanSinoBIO to manufacture our modifier gene therapy pipeline product candidates. Under this agreement, CanSinoBIO is responsible for the CMC development and manufacture of clinical supplies for OCU400, OCU410 and OCU410ST. The agreement also provides commercialization rights to CanSinoBIO in Greater China. This agreement may be adversely affected if the U. S. government were to impose restrictions related to goods manufactured in or imported from China. We ~~do not currently have the internal capacity to manufacture COVAXIN, if approved. Accordingly, we are dependent upon third parties for the manufacture of COVAXIN for clinical trials and commercial supply, if approved. Bharat Biotech agreed to provide us with preclinical and clinical data, and to transfer to us certain proprietary technology owned or controlled by Bharat Biotech, that is necessary for the successful commercial manufacture and supply of COVAXIN to support its commercial sale in the Ocugen Covaxin Territory, if approved. Until the completion of the technology transfer and until we are capable and primarily responsible for the manufacture and supply of COVAXIN in the Ocugen Covaxin Territory through the third- party manufacturer we have selected, Bharat Biotech has the exclusive right to manufacture COVAXIN and we will be wholly dependent on Bharat Biotech for the manufacture and supply of clinical testing materials required for our development activities and all of our requirements of commercial quantities of COVAXIN, if approved. We and Bharat Biotech have entered into a separate Supply Agreement setting forth the terms of such supply arrangements. Although the Supply Agreement is in effect, there can be no assurance that Bharat Biotech will in fact provide such doses, whether due to shortages in supply, diversion of~~

~~vaccine resources to other uses deemed more immediate, or other factors, including Bharat Biotech's ability to successfully respond to the deficiencies identified in an inspection conducted by the WHO. We have selected Jubilant HollisterStier of Spokane, Washington, as our manufacturing partner for COVAXIN, if approved, to prepare for the potential commercial manufacturing of COVAXIN. There can be no assurance that we will be successful in transitioning the manufacture of COVAXIN from Bharat Biotech to Jubilant HollisterStier or any other third- party manufacturer. A technology transfer of a manufacturing process can be time- consuming and expensive and there can be no assurance that such transfer will be successful or that Jubilant HollisterStier will be able to manufacture our drug products successfully, if approved. Certain manufacturing processes for COVAXIN are novel and complex. Due to the nature of this vaccine candidate, we may encounter difficulties in manufacturing, product release, shelf life, testing, storage and supply chain management, or shipping. These difficulties could be due to any number of reasons including, but not limited to, complexities of producing batches at a larger scale, equipment failure, choice, availability, and quality of raw materials, analytical testing technology, and product instability. Insufficient stability or shelf life of COVAXIN could materially delay our ability to continue any potential commercialization activities due to the need to manufacture additional commercial supply of COVAXIN, if approved. Moreover, notwithstanding our selection of Jubilant HollisterStier as our commercial manufacturing partner, we expect to continue to be dependent on Bharat Biotech as a single- source supplier for the supply of certain raw materials necessary for the manufacture of COVAXIN, including the adjuvant and active pharmaceutical ingredient. If, for any reason, Bharat Biotech is unable to provide an adequate supply of these materials (including Bharat Biotech's ability to successfully respond to the deficiencies identified in an inspection conducted by the WHO), our ability to timely complete the technology transfer to Jubilant HollisterStier and to obtain adequate quantities of commercial supply of COVAXIN, if authorized or approved, could be jeopardized. Engaging Jubilant HollisterStier as our commercial manufacturing partner may also require additional testing, notification, or approval by the FDA or another comparable foreign regulatory authorities. If Jubilant HollisterStier proceeds to scale up its manufacturing of COVAXIN for commercialization, if approved, we may encounter unexpected issues relating to the manufacturing process or the quality, purity, and stability of the product candidate, and we may be required to refine or alter our manufacturing processes to address these issues, which may not be successful. This could jeopardize our ability to commence COVAXIN sales and generate revenue, if approved. If our third- party manufacturing partners cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or another comparable foreign regulatory authorities in other jurisdictions, we may not be able to rely on our third- party manufacturing partners' facilities for the manufacture of COVAXIN, if approved. If the FDA or another comparable regulatory authority finds their facilities inadequate for the manufacture of COVAXIN, or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for, or market COVAXIN. If we are unable to obtain and maintain adequate supply of COVAXIN, our development and commercialization efforts would be impaired. We~~ expect to rely on our qualified suppliers and other third parties to manufacture clinical supplies of our product candidates and commercial supplies of our products, if and when approved for marketing by applicable regulatory authorities, as well as for packaging, serialization, storage, distribution, and other production logistics. We, however, may not succeed in our efforts to establish manufacturing relationships or other alternative arrangements for any of our product candidates, components, and programs, or may be unable to do so on commercially favorable terms. If we are unable to enter into such agreements on commercially favorable terms, our future profit margins would be adversely affected and our ability to commercialize any products that receive marketing approval on a timely and competitive basis would be impaired. As a result, our business, financial condition, and results of operations would be materially adversely affected. ~~If the~~ **We rely on third- party contract** manufacturers ~~upon whom we rely fail~~ to **manufacture some of our preclinical** ~~produce~~ **product** ~~our product candidates~~ **candidate supplies and some of** ~~or~~ **our clinical trial** product **supplies** ~~components pursuant to the terms of contractual arrangements with us or fail to comply with stringent regulations applicable to biotechnology manufacturers, we may face delays in the development~~ and ~~commercialization of, or be unable to meet demand for, our product candidates~~, if approved, **will rely on third- party contract manufacturers to manufacture some of our commercial product supplies, including all of our drug substance, vialing, labeling,** and ~~may lose potential revenues~~ **packaging. We do not own manufacturing facilities for producing any clinical trial or commercial product supplies. There can be no assurance that our preclinical, clinical development, and, if approved, commercial product supplies will not be limited or interrupted, including as a result of impacts of current macroeconomic and geopolitical events, increasing rates of inflation, rising interest rates, or that our product supplies will be of satisfactory quality or continue to be available at acceptable prices** . As with the third parties on which we rely or expect to rely for our preclinical activities and clinical trials, we have agreements governing the activities of our manufacturers but have limited influence and control over their actual performance and activities. Our third- party manufacturers are not our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our manufacturing requirements. If these third- party manufacturers do not successfully carry out their contractual duties, meet expected deadlines or manufacture our product candidates in accordance with regulatory requirements, and if there are disagreements between us and such parties, clinical development or marketing approval of our product candidates could be delayed. The manufacture of biotechnology products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of therapeutics often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, and compliance with strictly enforced federal, state, and foreign regulations. If our manufacturers were to encounter any of these difficulties and were unable to perform as agreed, our ability to provide product candidates to patients in our clinical trials and for commercial use, if approved, would be jeopardized. In addition, all

manufacturers of our product candidates and therapeutic substances must comply with current GMP requirements enforced by the FDA that are applicable to both finished products and their active components used for both, clinical and commercial supply. The FDA enforces these requirements through its facilities inspection program. Our manufacturers must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing applications to the agency. Our manufacturers will also be subject to continuing FDA and other regulatory authority inspections should we receive marketing approval. Further, we, in cooperation with our contract manufacturers, must supply all necessary CMC documentation to the FDA in support of a marketing application on a timely basis. The current GMP requirements include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our product candidates, therapeutic substances, and the active pharmaceutical ingredients necessary to produce our product candidates may be unable to comply with our specifications, current GMP requirements, and with other FDA, state, and foreign regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of a product candidate that may not be detectable in final product testing. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. Any such deviations may also require remedial measures that may be costly and / or time- consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any resulting delays in obtaining products, if approved, or product candidates that comply with the applicable regulatory requirements may result in delays to clinical trials, product approvals, and commercialization. It may also require that we conduct additional studies. While we are ultimately responsible for the manufacture of our product candidates, other than through our contractual arrangements, we have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with the applicable regulatory requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, including imprisonment, suspension or restrictions of production, injunctions, delays, withdrawal or denial of product approval or supplements to approved products, clinical holds or termination of clinical studies, warning or untitled letters, Form 483s, regulatory authority communications warning the public about safety issues with the product, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil FCA, corporate integrity agreements, or consent decrees. Depending on the severity of any potential regulatory action, our clinical or commercial supply could be interrupted or limited, which could have a material adverse effect on our business. Any problems or delays we experience in preparing for commercial- scale manufacturing of a product candidate or component, including manufacturing validation, may result in a delay in FDA approval or commercial launch, if approved, of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of commercialization of our product candidates and could adversely affect our business. The risks associated with any problems or delays may be greater should the U. S. government impose restrictions relating to goods manufactured in or imported from China. We or our third- party manufacturers may also encounter shortages in the materials necessary to produce our product candidates in the quantities needed for our clinical trials or, if our product candidates are approved, in sufficient quantities for commercialization. We or our third- party manufacturers may also encounter shortages in the raw materials, therapeutic substances, or active pharmaceutical ingredients necessary to produce our product candidates in the quantities needed for our clinical trials or, if our product candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand. Such shortages may occur for a variety of reasons, including capacity constraints, delays or disruptions in the market, and shortages caused by the purchase of such materials by our competitors or others. We or our third- party manufacturers' failure to obtain the raw materials, therapeutic substances, or active pharmaceutical ingredients necessary to manufacture sufficient quantities of our product candidates may cause the manufacturers to fail to deliver the required commercial quantities of our product candidates on a timely basis and at commercially reasonable prices. If such failure occurs, we would likely be unable to meet the demand for our products, if approved, and we would lose potential revenues. The number of available, qualified third- party manufactures is limited, and if we are compelled to locate an alternative manufacturing partner, our product development activities and commercialization could be delayed and additional expense would be incurred. There are a limited number of manufacturers that operate under current GMP regulations, that are both capable of manufacturing for us and willing to do so, and therefore our product candidates may compete with other products and product candidates for access to manufacturing facilities. Moreover, because our product candidates must be manufactured under sterile conditions, the number of manufacturers who can meet this requirement are even more limited. If our existing third- party manufacturers, or the third parties that we engage in the future to manufacture a product, if approved, or component for commercial sale or for any clinical trials we expect to initiate in the future should cease to continue to do so for any reason (including the termination of our agreements with such manufacturers, which can occur for a variety of reasons, or the bankruptcy of such manufacturers), it would be difficult to obtain a suitable alternative manufacturer. We would likely experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant. If the FDA or a comparable foreign regulatory authority inspects the facilities for the manufacture of our product candidates and finds that they are not in compliance with current GMP regulations now or in the future, we may need to find alternative manufacturing facilities. Any new manufacturers would need to either obtain or develop the necessary manufacturing know- how, and obtain the necessary equipment and materials, which may take substantial time and investment. We must also receive FDA approval for the use of any new manufacturers for commercial supply. Any such developments would significantly impact our ability to develop, obtain, and maintain regulatory authorization or approval for or market our

product candidates, if approved. The number of available third- party facilities may also be further limited by natural disasters, such as pandemics, including ~~the~~ **any** ongoing **effects of the** COVID- 19 pandemic, floods, fire, or such facilities could face manufacturing issues, such as contamination or regulatory findings following a regulatory inspection of such facility. In such instances, an appropriate replacement third- party relationship may not be readily available to us or on acceptable terms, which would cause additional delays and increased expense and may have a material adverse effect on our business. We are in an agreement with CanSinoBIO for the development and commercialization of our modifier gene therapy platform ~~and with Bharat Biotech for the development and commercialization of COVAXIN in the North American market~~ . In the future, we may seek to enter into additional collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of other product candidates. We may utilize a variety of types of collaboration, distribution, and other marketing arrangements with third parties to develop and commercialize our product candidates, both inside and outside the United States. In particular, we may enter into arrangements with third parties to perform certain services in the United States or other countries if we do not establish our own sales, marketing, and distribution capabilities in ~~the~~ such countries, or if we determine that such third- party arrangements are otherwise beneficial. We may also consider potential collaborative partnership opportunities for sales, marketing, distribution, development, or licensing or broader collaboration arrangements, including with mid- size and large pharmaceutical companies, regional and national pharmaceutical companies, and biotechnology companies. The success of our current and future collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to collaboration arrangements. Accordingly, with respect to any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend in part on our collaborator' s abilities and efforts to successfully perform the functions assigned to them in these arrangements. Moreover, disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercialization of the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision- making authority. Moreover, collaborations with pharmaceutical companies and other third parties are often terminated or allowed to expire. Any such termination or expiration would adversely affect us financially and could harm our business reputation. Our current and future collaborations may pose a number of additional risks, including the following: • collaborators may not pursue development of product candidates and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing; • collaborators could fail to make timely regulatory submissions for a product candidate; • collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements, which could subject them or us to regulatory enforcement actions; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates; • a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidate or product; • disagreements with collaborators, including disagreements over proprietary rights, contract interpretation, or the preferred course of development, might cause delays or termination of the research, development, or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time consuming and expensive; • collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; • collaborators may infringe the intellectual property rights of third parties or fail to maintain intellectual property rights which they license to us, which may expose us to litigation and potential liability; and • collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. Collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner, or at all. If any collaborations do not result in the successful development and commercialization of our product candidates or if one of our collaborators subsequently terminates our agreement with us, we may not receive any future research funding, milestone, or royalty payments under the collaboration, as applicable. If we do not receive the funding we expect under the agreements, our development of our product candidates could be delayed, and we may need additional resources to develop our product candidates and our product platform. All of the risks relating to product development, regulatory approval, and commercialization described in this report also apply to the activities of our collaborators. Additionally, if any collaborator of ours is involved in a business combination, the collaborator might de- emphasize or terminate development or commercialization of any product candidate licensed to them by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected. Should we desire to pursue a collaboration agreement but are not able to establish collaborations, we may have to alter our development and commercialization plans and our business could be adversely affected. For some of our product candidates, we may decide to collaborate with pharmaceutical

or biotechnology companies for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate collaborators and whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical 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, if approved, 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. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time- consuming to negotiate and document. Should we desire to pursue a collaboration agreement but are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform and our business may be materially and adversely affected. Risks Related to Legal and Compliance Matters We are currently, and may in the future be, subject to securities litigation, which is expensive and could divert management attention. In June 2021, a securities class action lawsuit was filed against us and certain of our agents in the U. S. District Court for the Eastern District of Pennsylvania (~~"~~ **“** Court ~~"~~ **”**) (Case No. 2: 21- cv- 02725) that purported to state a claim for alleged violations of Sections 10 (b) and 20 (a) of the Exchange Act and Rule 10b- 5 promulgated thereunder, based on statements made by us concerning the announcement of our decision to pursue the submission of a BLA for COVAXIN for adults ages 18 years and older rather than pursuing an EUA for the vaccine candidate. In July 2021, a second securities class action lawsuit was filed against us and certain of our agents in the Court (Case No. 2: 21- cv- 03182) that also purported to state a claim for alleged violations of Sections 10 (b) and 20 (a) of the Exchange Act and Rule 10b- 5 promulgated thereunder, based on the same statements as the first complaint. In March 2022, the Court consolidated these two related securities class action lawsuits and appointed Andre Galan Bernd Benayon to serve as lead plaintiff. The lead plaintiff' s amended complaint was filed in June 2022. ~~We filed a~~ **In March 2023, the Court granted the Company' s** motion to dismiss **with prejudice. The lead plaintiff appealed to** the ~~amended complaint~~ **United States Court of Appeals for the Third Circuit (" Third Circuit") regarding the order that was entered** in ~~August~~ **March** ~~2022~~ **2023 , which dismissed the action with prejudice** . The lead plaintiff' s ~~opposition to the motion to dismiss~~ **appellant’ s brief and joint appendix were filed in July 2023. Our appellees’ brief** was filed in ~~October~~ **August** ~~2022~~ **2023** ~~. We~~ **, and the lead plaintiff' s reply brief was** filed **in September 2023. In March 2024, the Third Circuit affirmed the** ~~our~~ **Court ' s decision** ~~reply in support of the motion~~ to dismiss ~~in November 2022. Oral argument on the motion to dismiss took place in January 2023 and no decision has been made to date by the Court. As~~ with ~~any litigation, we cannot predict~~ **prejudice** the **consolidated securities class action lawsuits** ~~outcome with certainty, but we expect to provide further updates on the status of the motion to dismiss as available~~ . In August 2021, a stockholder derivative lawsuit was filed derivatively on behalf of **us** ~~our company~~ against certain of our agents and the nominal defendant Ocugen in the Court (Case No. 2: 21- cv- 03876) that purported to state a claim for breach of fiduciary duty and contribution for violations of Sections 10 (b) and 21 (d) of the Exchange Act, based on facts and circumstances relating to the securities class action lawsuits and seeking contribution and indemnification in connection with claims asserted in the securities class action lawsuits. In September 2021, a second stockholder derivative lawsuit was filed derivatively on behalf of **us** ~~our company~~ against certain of our agents and the nominal defendant Ocugen in the Court (Case No. 2: 21- cv- 04169) that purported to state a claim for breach of fiduciary duties, unjust enrichment, abuse of control, waste of corporate assets, and contribution for violations of Sections 10 (b) and 21 (d) of the Exchange Act, based on the same allegations as the first complaint. The parties to both stockholder derivative lawsuits have stipulated to the consolidation of the two stockholder derivative lawsuits and also have submitted to the Court in each action a proposed order requesting a stay of the litigation pending a decision on any motion to dismiss filed in the securities class action lawsuits, which the Court entered in April 2022. **In March 2023, the Court in the securities class action lawsuits granted our motion to dismiss with prejudice. The parties to the stockholder derivative lawsuits stipulated to extend the stay of litigation pending resolution of any appeal filed in the securities class action lawsuits, which the Court entered in March 2023. In April 2024, a securities class action lawsuit was filed against us and certain of our agents in the Court (Case No. 2: 24- cv- 01500) that purported to state a claim for alleged violations of Sections 10 (b) and 20 (a) of the Exchange Act and Rule 10b- 5 promulgated thereunder, based on statements made by us concerning our previously- issued audited consolidated financial statements for each fiscal year beginning January 1, 2020 and our previously- issued unaudited interim condensed consolidated financial statements for each of the first three quarters in such years and the effectiveness of our disclosure controls and procedures during each such period.** The complaints seek unspecified damages, interest, attorneys ~~’~~ **'** fees, and other costs. We believe that ~~the~~ **these** lawsuits are without merit and intend to vigorously defend against them. At this time, no assessment can be made as to their likely outcome or whether the outcome will be material to us. We may also become subject to additional securities class action lawsuits in the future. This risk is especially relevant for us because life sciences companies have experienced significant stock price volatility in recent years. The cost of defending against these types of claims against us or the ultimate resolution of such claims, whether by settlement or adverse court decision, may **divert management’ s attention and** harm our business. Further, potential claimants may be encouraged to bring lawsuits based on a settlement from us or adverse court decisions against us. We cannot currently assess the likely outcome of such lawsuits, but the commencement and / or

resolution of such lawsuits (particularly if the outcome were negative), could have a material adverse effect on our reputation, results of operations, financial condition, and cash flows. They could also cause a decline in the market price of our common stock. If we fail to comply with federal and state healthcare laws, including fraud, abuse, and health and other information privacy and security laws, we could face substantial penalties and our business, financial condition, results of operations, and prospects could be adversely affected. As a biotechnology company, we are subject to many federal and state healthcare laws, such as the federal Anti- Kickback Statute, the federal civil and criminal FCA, the civil monetary penalties statute, the Medicaid Drug Rebate statute and other price reporting requirements, the VHCA, the HIPAA, the FCPA, the ACA, and similar state laws. We may also be subject to laws regarding transparency and patient privacy. Even though we do not and will not control referrals of healthcare services or bills directly to Medicare, Medicaid, or other third- party payors, certain federal and state healthcare laws, and regulations pertaining to fraud and abuse, reimbursement programs, government procurement, and patients' rights are and will be applicable to our business. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud, abuse, or other healthcare laws and regulations. If we or our operations are found to be in violation of any federal or state healthcare law, or any other governmental laws or regulations that applies to us, we may be subject to penalties, including civil, criminal, and administrative penalties, damages, fines, imprisonment, disgorgement, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in U. S. federal or state health care programs, corporate integrity agreements, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, reimbursement, and fraud laws may prove costly. Any action against us for the violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. The United States government, state legislatures, and foreign governments also have shown significant interest in implementing cost- containment programs to limit the growth of government- paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription products. In recent years, Congress has considered reductions in Medicare reimbursement levels for products administered by physicians. CMS, the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for some products. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payers. The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The ACA is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. ~~Among other things, the Affordable Care Act expanded manufacturers' rebate liability under the MDRP by increasing the minimum Medicaid rebate for both branded and generic products, expanded the 340B program, and revised the definition of AMP, which could increase the amount of Medicaid rebates manufacturers are required to pay to states. The legislation also extended Medicaid rebates, previously due only on fee- for- service Medicaid utilization, to include the utilization of Medicaid managed care organizations as well and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those products. On February 1, 2016, CMS issued final regulations to implement the changes to the MDRP under the ACA. These~~ **There** ~~regulations became effective on April 1, 2016. Since that time, there~~ have been significant ongoing **administrative, executive, and legislative** efforts to modify or eliminate the ACA. ~~The~~ **For example, the** Tax **Cuts and Jobs** Act **,** enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the ~~Internal Revenue Code of 1986, as amended, of the~~ Code, commonly referred to as the individual mandate. Other legislative changes have been proposed and adopted since ~~the~~ passage of the ACA. The **ACA has also been subject to challenges in the courts. Other legislative changes have been proposed and adopted since the passage of the ACA. For example, the** Budget Control Act of 2011, among other things, ~~created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than $ 1. 2 trillion for the fiscal years 2012 through 2021, triggering the legislation' s automatic reductions to several government programs. These reductions included~~ **includes** aggregate reductions to Medicare payments to healthcare providers of up to 2. 0 % per fiscal year, which ~~went into effect~~ in **connection with** ~~April 2013. Subsequent~~ **subsequent** legislation **are** extended ~~the 2. 0 % reduction, on average,~~ to ~~2030~~ **2032** unless additional Congressional action is taken. **Further** ~~However, pursuant to the CARES Act, the 2. 0 % Medicare sequester reductions were suspended from May 1, 2020 through March 31, 2022 due to the COVID- 19 pandemic. As of July 1, 2022, the 2. 0 % sequester reduction resumed. The sequester will remain in place through 2030. On January 2~~ , 2013, the American Taxpayer Relief Act **of 2012** ~~was signed into law, which,~~ among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The IRA **also** contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U. S. Department of Health and

Human Services that would require manufacturers to charge a negotiated " maximum fair price " for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the IRA. The IRA could have the effect of reducing the prices we can charge and reimbursement we receive for our products, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations, and growth prospects. The **drug price negotiations of the IRA are currently subject to several constitutional challenges. The outcomes of this litigation and the** effect of IRA on our business and the pharmaceutical industry in general ~~is~~ **are** not yet known. The ACA has **also** been subject to challenges in the courts. **In** ~~On December 14, 2018, a Texas U. S. District Court Judge ruled that~~ the ~~ACA is unconstitutional~~ **most recent challenge** in ~~its entirety because the " individual mandate " was repealed by Congress. On December 18, 2019, the Fifth Circuit U. S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire ACA. An appeal was taken to the U. S. Supreme Court. On June 17,~~ 2021 **, for example** , the Supreme Court ruled that ~~the~~ plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions. Further changes to and under the ACA remain possible, but it is unknown what form any such changes or any law proposed to replace or revise the ACA would take, and how or whether it may affect our business in the future. We expect that changes to the ACA, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing, or other legislation in individual states, could have a material adverse effect on the healthcare industry. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical 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. We expect that additional federal, state, and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement, and reduced demand for our products, once approved, or additional pricing pressures. Our employees, independent contractors, consultants, commercial partners, principal investigators, or CDMOs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business. We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, manufacturers, investigators, or CDMOs could include intentional, reckless, negligent, or unintentional failures to (i) comply with FDA regulations or other similar regulatory requirements, (ii) comply with manufacturing standards, including current GMP requirements, (iii) comply with applicable fraud and abuse laws, (iv) comply with federal and state data privacy, security, fraud and abuse, and other healthcare laws and regulations in the United States and abroad, (v) provide accurate information to the FDA, (vi) properly calculate pricing information required by federal programs, (vii) comply with federal procurement rules or contract terms, (viii) report financial information or data accurately, or (ix) disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter this type of misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws, and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, or be precluded from developing, manufacturing, and selling certain products outside the United States, which could adversely affect our business, results of operations, and financial condition. If we expand our operations outside of the United States, we must dedicate additional resources to comply with anti- corruption laws, including the Bribery Act, the FCPA, and other anti-corruption laws that apply to countries where we do business and may do business in the future. The Bribery Act, FCPA, and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed, or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. The FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. We may in the future operate in jurisdictions

that pose a high risk of potential Bribery Act or FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA, or local anti- corruption laws. We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom, the United States, Canada, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements, and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations, and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non- U. S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs. If we are not in compliance with the Bribery Act, the FCPA, and other anti- corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations, and liquidity. The SEC also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA' s accounting provisions. Any investigation of any potential violations of the Bribery Act, the FCPA, other anti- corruption laws or Trade Control laws by U. K., U. S., or other authorities could also have an adverse impact on our reputation, our business, results of operations, and financial condition. Risks Related to Our Intellectual Property Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries, with respect to our proprietary technology and product candidates. We have sought to protect our proprietary position by filing in the United States and in certain foreign jurisdictions, patent applications related to our novel technologies and product candidates. The patent prosecution process is expensive and time- consuming, and we may not have filed, maintained, or prosecuted and may not be able to file, maintain, and prosecute all necessary or desirable patents or 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. The patent position of pharmaceutical and biotechnology companies generally is highly 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 fail to result in issued patents in the United States or in other foreign countries which **may impact** ~~protect~~ **protection of** our technology or product candidates, or which **may** effectively prevent others from commercializing competitive technologies and products. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, unlike patent law in the United States, European patent law precludes the patentability of methods of treatment of the human body and imposes substantial restrictions on the scope of claims it will grant **. In addition** , ~~of broader than~~ **unlike the U. S. the European Patent Office typically limits the claims to those commensurate in scope with** specifically disclosed embodiments. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Databases for patents and publications, and methods for searching them, are inherently limited so we may not know the full scope of all issued and pending patent applications. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon our ability to generate additional preclinical or clinical data that support the patentability of our proposed claims. We may not be able to generate sufficient additional data on a timely basis, or at all. Moreover, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection for our proprietary technology and product candidates, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non- infringing manner. In some instances, we may need to license additional patents and trade secrets to commercialize our product candidates in certain territories. The issuance of a patent is not conclusive as to our inventorship, ownership, scope, validity, or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In 2011, the Leahy- Smith America Invents Act (the" Leahy-Smith Act") was signed into law. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO

developed new regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first to file provisions, became effective in 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. The Leahy- Smith 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, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. For example, the Leahy- Smith Act created a new administrative tribunal known as the Patent Trial and Appeals Board (" PTAB"), that provides a venue for companies to challenge the validity of competitor patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long term impact the PTAB proceedings will have on the operation of our business, the outcome of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U. S. patent claims. The availability of the PTAB as a lower- cost, faster, and potentially more potent tribunal for challenging patents could therefore increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining, defending, and enforcing them. If we are not able to obtain patent term extension in the United States under the Hatch- Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for our product candidates, our business may be materially harmed. Depending upon the timing, duration, and specifics of FDA marketing approval of our product candidates, one of the U. S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Hatch- Waxman Act. The Hatch- Waxman Act allows a maximum of one patent to be extended per FDA approved product to account for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it, or a method for manufacturing it may be extended. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product may be shortened and our competitors may obtain approval of competing products following our patent expiration sooner, and our revenue could be reduced, possibly materially. It is possible that we will not obtain patent term extension under the Hatch- Waxman Act for a U. S. patent covering one of our product candidates even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for our licensed patents, we do not have the right to control prosecution, including filing with the USPTO, a petition for patent term extension under the Hatch- Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch- Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO. Competitors and other third parties may infringe, misappropriate, or otherwise violate our owned and licensed patents, trade secrets, or other intellectual property. As a result, to **discourage, prevent, or** counter infringement, misappropriation, or unauthorized use, we may be required to file infringement or misappropriation claims or other intellectual property related proceedings, which can be expensive and time- consuming. Any claims we assert against perceived infringers could provoke such parties to assert counterclaims against us alleging that we infringed their patents or that our asserted patents are invalid. In addition, in a patent infringement or other intellectual property related proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent' s claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly ~~, and could put any of our patent applications at risk of not yielding an issued patent~~ . Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information or trade secrets could be compromised by disclosure during this type of litigation. We may be subject to a third- party **pre-** ~~preissuance~~ --- **issuance** submission of prior art to the USPTO, or become involved in other contested proceedings such as opposition, derivation, reexamination, inter partes review, post- grant review, or interference proceedings in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding, or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates. In the United States, the FDA does not prohibit clinicians from prescribing an approved product for uses that are not described in the product' s labeling. Although use of a product directed by off- label prescriptions may infringe our method- of- treatment patents, the practice is common across medical specialties, particularly in the United States, and such infringement is difficult to detect, prevent, or prosecute. Third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability to develop, manufacture, market, and sell our product candidates and use our proprietary technologies without infringing, misappropriating, or otherwise violating the intellectual property and other proprietary rights of third parties. There is a considerable amount of intellectual property litigation in the

biotechnology and pharmaceutical industries. We may become party to, or threatened with, infringement litigation claims regarding our products and technology, including claims from competitors or from non- practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. Moreover, we may become party to future adversarial proceedings or litigation regarding our patent portfolio or the patents of third parties. Such proceedings could also include contested post- grant proceedings such as oppositions, inter partes review, reexamination, interference, or derivation proceedings before the USPTO or foreign patent offices. The legal threshold for initiating litigation or contested proceedings is low, so even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can ~~also~~ be expensive and time- consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we do. The risks of being involved in such litigation and proceedings may increase as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. We may not be aware of all such intellectual property rights potentially relating to our product candidates and their uses. Thus, we do not know with certainty that any of our product candidates, or our development and commercialization thereof, do not and will not infringe or otherwise violate any third party' s intellectual property. If we are found to infringe, misappropriate, or otherwise violate a third party' s intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing its products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent, and could be forced to indemnify our customers or collaborators. A finding of infringement could also result in an injunction that prevents us from commercializing our product candidates or forces us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign our product candidates, seek new regulatory approvals, and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated confidential information or trade secrets of third parties could have a similar negative impact on our business. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance, renewal, and annuity fees on any issued patent must be paid to the USPTO and foreign patent agencies in several stages or annually over the lifetime of our owned and licensed patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In certain circumstances, we rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of the relevant patent agency. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non- payment of fees, and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, it would have a material adverse effect on our business. A substantial portion of our patent portfolio is in- licensed. As such, we are party to license agreements and certain aspects of our business depend on patents and / or patent applications owned by other companies or institutions. For example, we hold exclusive licenses for patent families relating to OCU400, OCU410, OCU410ST, and OCU200, and an exclusive license in the United States, ~~Canada, and Mexico with respect to COVAXIN, an exclusive license in the United States,~~ Europe, Japan, South Korea, Australia, ~~and~~ China **, and Hong Kong** with respect an inhaled mucosal COVID- 19 vaccine, and exclusive licenses for patent families related to NeoCart. Pursuant to the CU Agreement, which primarily relates to OCU200, we are responsible for and control the patent prosecution of all patent families licensed under the CU Agreement. Pursuant to the SERI Agreement, which relates to NHR genes NR1D1, NR2E3 (OCU400), RORA (OCU410 and OCU410ST), NUPR1, and NR2C1, from and after December 19, 2017, we have the right to assume responsibility and control patent prosecution of licensed patent families relating to these NHR genes. Additionally, we are responsible for and control patent prosecution for any patent applications developed in connection with the SERI Agreement filed after December 19, 2017 that are owned jointly by us and SERI, or solely by us. Pursuant to the WU Agreement, which relates to inhaled mucosal COVID- 19 vaccines, Washington University maintains control of patent preparation, filing, prosecution, and maintenance, subject to our right to negotiate with WU after the first anniversary of the effective date of the WU Agreement to assume responsibility for and control of the prosecution and maintenance of the patent rights throughout the Mucosal Vaccine Territory in Washington University' s name. Our rights with respect to in- licensed patents and patent applications may be lost if the applicable license agreement expires or terminates. We are likely to enter into additional license agreements to in- license patents and patent applications as part of the development of our business in the future, under which we may not retain control of the preparation, filing, prosecution, maintenance, enforcement, and defense of such patents. If we are unable to maintain these patent rights for any reason, our ability to develop and commercialize our product candidates could be materially harmed. Our licensors may not successfully prosecute certain patent applications, the prosecution of which they control, under which we are licensed and on which our business depends. Even if patents are issued from these applications, our licensors may fail to maintain these patents, may decide not to pursue litigation against third- party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability. In some cases, our licensors may in- license certain patents licensed to us. If our licensors were to fail to maintain such licenses, we

may need to obtain additional licenses with respect to the applicable product candidates. Risks with respect to parties from whom we have obtained intellectual property rights may also arise out of circumstances beyond our control. In spite of our best efforts, our licensors might conclude that we have materially breached our intellectual property agreements and might therefore terminate the intellectual property agreements, thereby removing our ability to market products covered by these intellectual property agreements. If our intellectual property agreements are terminated, or if the underlying patents fail to provide the intended market exclusivity, our competitors **may severely impact** ~~would have the freedom to seek regulatory approval of, and to market, products similar or identical to ours~~ **our business** . Moreover, if our intellectual property agreements are terminated, our former licensors and / or assignors may be able to prevent us from utilizing the technology covered by the licensed or assigned patents and patent applications. This could have a ~~material~~ **materially** adverse effect on our competitive business position and our business prospects. Some intellectual property which we own or have licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as " march- in " rights, certain reporting requirements, and a preference for U. S. industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements, and limit our ability to contract with non- U. S. manufacturers. Some of the licenses or intellectual property rights that we own have been generated through the use of U. S. government funding and may therefore be subject to certain federal regulations under the Bayh- Dole Act. To the best of our knowledge, our intellectual property for OCU400 for the treatment of ~~NR2E3~~ **RHO and other gene- agnostic** ~~mutation~~ **mutations** - associated **with RP,** ~~inherited retinal degenerative disease and other inherited retinal degenerative diseases~~ is subject to the Bayh- Dole Act. As a result, the U. S. government may have certain rights to intellectual property embodied in these patents and patent applications. In general, the Bayh- Dole Act provides the U. S. government certain rights in inventions developed using a government funded program, such as U. S. government' s right to a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, under the Bayh- Dole Act, the U. S. government has the right to require any invention developed using U. S. government funding to be granted exclusive, partially exclusive, or non- exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as " march- in rights "). Under the Bayh- Dole Act, the U. S. government also has the right to take title to inventions developed using a U. S. government funded program, if one fails to disclose the invention to the government and fails to file an application to register the intellectual property within specified time limits. In addition, the U. S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements. In addition, the Bayh- Dole Act requires that any products subject to the Bayh- Dole Act be manufactured substantially in the United States. However, under the Bayh- Dole Act, this manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable efforts to manufacture the product substantially in the United States were unsuccessful, or that under the circumstances, domestic manufacture is not commercially feasible. Any exercise by the government of any of the foregoing rights under the Bayh- Dole Act may affect our competitive position, business, financial condition, results of operations, and prospects. If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business. Our agreements under which we license certain of our patent rights and a significant portion of the technology for our product candidates, impose royalty and other financial obligations on us and other substantial performance obligations. We may also enter into additional licensing and funding arrangements with third parties that may impose diligence, development, and commercialization timelines and milestone payment, royalty, insurance, and other obligations on us. If we fail to comply with our obligations under current or future license and collaboration agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture, or market any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could diminish the value of our products and product candidates. Termination of these agreements or reduction or elimination of our rights under these agreements may result in us having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. In addition, ~~it is possible that our licensors may conclude that we have materially breached the applicable license agreement and might therefore terminate the agreement, thereby removing our ability to market products covered by such agreements. If any license is terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to ours. Moreover, if any of our license agreements are terminated, the counterparty and / or its assignors may be able to prevent us from utilizing the technology covered by the licensed or assigned patents and patent applications. This could have a materially adverse effect on our competitive business position and our business prospects. In addition,~~ the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. We may not be able to protect our intellectual property and proprietary rights throughout the world. Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to

the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not being issued, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property. Many of our and our licensors' employees and contractors were previously employed at other biotechnology, medical device, or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and contractors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee' s former employer. Litigation may be necessary to defend against these claims. In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Furthermore, we are unable to control whether our licensors have obtained similar assignment agreements from their own employees and contractors. Our and their assignment agreements may not be self- executing or may be breached, and we or our licensors may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we or our licensors fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products, which may not be available on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management. Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patents for our technology and product candidates, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a

competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. Risks Related to Our Common Stock We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock. We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that the common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares. Sales of a substantial number of common stock by our stockholders in the public market could cause our stock price to fall. If our existing stockholders sell, or indicate an intention to sell, substantial amounts of common stock in the public market, the market price of our common stock could decline. We had ~~221~~ **256** . 6 million shares of common stock outstanding as of December 31, ~~2022~~ **2023** , which were all freely tradable, without restriction, in the public market. If a substantial number of shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline and we are unable to predict the effect that sales may have on the prevailing market price of our common stock. Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our Board of Directors. The provisions in our charter documents include the following: • a classified Board of Directors with three- year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our Board of Directors; • no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; • the exclusive right of our Board of Directors, unless the Board of Directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the Board of Directors or the resignation, death, or removal of a director, which prevents stockholders from being able to fill vacancies on our Board of Directors; • the prohibition on removal of directors without cause due to the classified Board of Directors; • the ability of our Board of Directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror; • the ability of our Board of Directors to alter our amended and restated bylaws without obtaining stockholder approval; • the required approval of at least 66- 2 / 3 % of the shares entitled to vote to adopt, amend, or repeal our amended and restated bylaws or repeal certain provisions of our amended and restated certificate of incorporation; • a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders; • an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings; • the requirement that a special meeting of stockholders may be called only by the chairman of the Board of Directors, the Chief Executive Officer, or the Board of Directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and • advance notice procedures that stockholders must comply with in order to nominate candidates to our Board of Directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror' s own slate of directors or otherwise attempting to obtain control of us. We are also subject to the anti- takeover provisions contained in Section 203 of the Delaware General Corporation Law (" DGCL"). Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15 % or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction. Our sixth amended and restated certificate of incorporation, as amended, provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Our sixth amended and restated certificate of incorporation, as amended, provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Securities Act of 1933, as amended, or any other claim for which the federal courts have exclusive jurisdiction. These 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. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. ~~General Risk Factors~~ **Our failure to meet the continued listing requirements of The Nasdaq Capital Market (" Nasdaq ") could result in a delisting of our common stock. We must continue to satisfy Nasdaq continued listing requirements, including, among other things, certain corporate governance requirements and a minimum closing bid price requirement of $ 1. 00 per share. If a company fails for 30 consecutive business days to meet the $ 1. 00 minimum closing bid price requirement, Nasdaq will send a deficiency notice to the company, advising that it has been afforded a" compliance period" of 180 calendar days to regain compliance with the**

applicable requirements. On May 1, 2023, we received a deficiency letter from Nasdaq notifying us that, for the last 30 consecutive business days, the closing bid price for our common stock was below the minimum $ 1. 00 per share required for continued listing on Nasdaq pursuant to the minimum closing bid price requirement. The Nasdaq deficiency letter had no immediate effect on the listing of our common stock. In accordance with Nasdaq Listing Rule 5810 (c) (3) (A), we have been given 180 calendar days, or until October 30, 2023, to regain compliance with the minimum closing bid price requirement by causing our stock to close above $ 1. 00 for a minimum of 10 consecutive trading days. If we do not regain compliance with the minimum closing bid price requirement by October 30, 2023, we may be afforded a second 180 calendar day period to regain compliance. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for Nasdaq, except for the minimum bid price requirement. In addition, we would be required to notify Nasdaq of our intent to cure the deficiency during the second compliance period. On October 31, 2023, we received a letter from Nasdaq stating that, although we had not regained compliance with the minimum bid price requirement, Nasdaq determined that we are eligible for an additional 180- day period, or until April 29, 2024, to regain compliance with the minimum bid price requirement. On March 28, 2024, we received written notice from Nasdaq stating that we have regained compliance with Nasdaq Listing Rule 5550 (a) (2) (" Rule 5550 (a) (2) ") by maintaining a minimum closing bid price of our common stock of at least $ 1. 00 per share for the ten consecutive business days from March 13, 2024 to March 27, 2024 and that this matter is now closed. We can provide no assurance that we will be able to remain in compliance with other Nasdaq continued listing requirements. A delisting of our common stock from Nasdaq could materially reduce the liquidity of our common stock, impairing your ability to sell or purchase shares of our common stock when you wish to do so, and could result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors and employees. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow the common stock to become listed again, stabilize the market price or improve the liquidity of the common stock, prevent the common stock from dropping below the Nasdaq minimum bid price requirement, or prevent future non- compliance with Nasdaq' s listing requirements. Our stock price has been, and will likely continue to be volatile. The stock market in general and the market for stock of biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above their purchase price. The market price for our common stock may be influenced by those factors discussed in this" Risk Factors" section and many others, including: • our ability to enroll subjects in our ongoing and planned clinical trials; • the results of our clinical trials and preclinical studies, and the results of trials of our competitors or those of other companies in our market sector; • regulatory approval of our product candidates, or limitations to specific label indications or patient populations for use, or changes or delays in the regulatory review process; • the level of expenses related to any of our product candidates or clinical development programs; • regulatory developments in the United States and foreign countries; • reports of adverse events in any of our products, competing biologics, or gene therapy products; • changes in the structure of healthcare payment systems, especially in light of current reforms to the U. S. healthcare system; • the success or failure of our efforts to acquire, license, or develop additional product candidates; • innovations or new products developed by us or our competitors; • announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments; • manufacturing, supply, or distribution delays or shortages; • any changes to our relationship with any manufacturers, suppliers, licensors, future collaborators, or other strategic partners; • achievement of expected product sales and profitability; • variations in our financial results or those of companies that are perceived to be similar to ours; • market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations; • trading volume of our common stock; • an inability to obtain additional funding; • sales of our stock by insiders and stockholders or the perception that such sales could occur; • our ability to effectively manage our growth; • ineffectiveness of our internal control over financial reporting; • additions or departures of key personnel, including major changes in our board or management; • intellectual property, product liability, or other litigation against us; and • general economic, industry, market conditions, and other events or factors, many of which are beyond our control. In addition, in the past, stockholders have initiated class action lawsuits against biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, including the litigation instituted against us in our current class action lawsuit, could cause us to incur substantial costs and divert management' s attention and resources, which could have a material adverse effect on our business, financial condition, and results of operations. If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline. The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market, or our competitors. We currently have research coverage by six securities and industry analysts. If one or more of the analysts who currently or in the future may cover us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline. **General Risk Factors** We are highly dependent on the research and development, clinical, and business development expertise of Shankar Musunuri, Ph. D., MBA, our Chief Executive Officer, Chairman of the Board, and Co- Founder, as well as the other principal members of our management, scientific, and clinical teams. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain" key person" insurance for any of our executives or other employees. Recruiting and retaining qualified scientific, clinical, manufacturing, legal, financial, and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development, and

commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of, and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain, or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited. We expect to expand our development, regulatory, and manufacturing capabilities and potentially implement sales, marketing, and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, clinical, regulatory affairs, manufacturing, sales, marketing, and distribution. For example, we ~~are~~ **have completed** renovating an existing facility into a current GMP facility in accordance with the FDA' s regulations in support of NeoCart manufacturing for Phase 3 clinical trial material. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of our attention to managing these growth activities. Due to our limited financial resources and our limited experience in managing such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our inability to manage the expansion of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced, and we may not be able to implement our business strategy, including the successful commercialization of our product candidates. We incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives and corporate governance practices. As a public company we have incurred, and will continue to incur, significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes- Oxley Act of 2002 (" Sarbanes- Oxley"), the Dodd- Frank Wall Street Reform, the Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We have had to hire additional accounting, finance, and other personnel in connection with our efforts to comply with the requirements of being a public company and our management and other personnel devote a substantial amount of time towards maintaining compliance with these requirements. These requirements increase our legal and financial compliance costs and make some activities more time- consuming and costly. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. In addition, Sarbanes- Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes- Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory" say on pay" voting requirements that are applicable to us. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs could impact our results of operations, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our board committees, or as executive officers. If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and

any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third- party facilities. We also could incur significant costs associated with civil or criminal fines and penalties. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological agents coverage and our commercial general liability policy specifically excludes coverage for damages and fines arising from biological agents. Accordingly, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws, regulations, and permitting requirements. These current or future laws, regulations, and permitting requirements may impair our research, development, or production efforts. Failure to comply with these laws, regulations, and permitting requirements also may result in substantial fines, penalties, or other sanctions or business disruption, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Any third- party contract manufacturers and suppliers we engage will also be subject to these and other environmental, health, and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. **We have identified material weaknesses in our internal control over financial reporting as of December 31, 2023 as well as of and for the fiscal year ended December 31, 2022, and the quarters ended September 30, 2022, June 30, 2022, March 31, 2022, September 30, 2023, June 30, 2023, and March 31, 2023, with respect to the design and operating effectiveness of controls over the accounting for collaborative arrangement revenue. If we are unable to develop and maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results in a timely manner, which may adversely affect investor confidence in us and materially and adversely affect our business and operating results. Our management is responsible for establishing and maintaining adequate internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Our management is likewise required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any changes and material weaknesses identified through such evaluation in those internal controls. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. As discussed elsewhere in this Report under " Controls and Procedures " as well as " Restatement of Previously Issued Consolidated Financial Statements, " our management has concluded that, as of December 31, 2023, we had a material weakness in our internal control over financial reporting with respect to the design and operating effectiveness of controls over the accounting for collaborative arrangement revenue. This includes controls over the determination of the transaction price, calculating the progress towards the satisfaction of the performance obligations under the collaborative arrangements, and determining the value of the non- cash consideration received. Effective internal controls are necessary for us to provide reliable financial reports and prevent fraud. Any failure to maintain such internal control could adversely impact our ability to report our financial position and results from operations on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations. Likewise, if our financial statements are not filed on a timely basis, we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities. In either case, there could result a material adverse effect on our business. Failure to timely file will cause us to be ineligible to utilize short form registration statements on Form S- 3, which may impair our ability to obtain capital in a timely fashion to execute our business strategies or issue shares to effect an acquisition. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock. We may discover additional weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our combined and consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. 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. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. We continue to evaluate steps to remediate the identified material weaknesses. The material weakness cannot be considered remediated until the newly designed controls operate effectively for a sufficient period of time and management has concluded, through testing, that the control is operating effectively. These remediation measures may be time consuming and costly and there is no assurance that these initiatives will ultimately have the intended effects. If we identify any new material weaknesses in the future, any such newly identified material weakness could limit our ability to prevent or detect a misstatement of our accounts or disclosures that could result in a material misstatement of our annual or interim financial statements. In such case, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting and our stock price may decline as a result. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to avoid potential future**

material weaknesses. We can give no assurance that the measures we have taken and plan to take in the future will remediate the material weakness identified or that any additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our financial statements. We have restated our prior consolidated financial statements, which may lead to additional risks and uncertainties, including loss of investor confidence and negative impacts on our stock price. In this Annual Report on Form 10- K, we restated our consolidated financial statements as of and for the fiscal year ended December 31, 2022, and the quarters ended September 30, 2022, June 30, 2022, March 31, 2022, September 30, 2023, June 30, 2023, and March 31, 2023 (the " Restated Periods "). The determination to restate the financial statements for the Restated Periods was made by our Audit Committee of the Board of Directors upon management' s recommendation following the identification of errors related us not appropriately accounting for the estimated non- cash consideration and expense in one of our collaboration arrangements. These identified errors resulted in a restatement of the following financial statements line items captions: Collaborative arrangement revenue, Research and development expenses, Other income (expense), net and Accrued expense and other current liabilities. Our management, after consultation with our independent registered accountants, concluded that our previously issued financial statements for the Restated Periods should no longer be relied upon. The restatement of our previously issued financial statements has been time- consuming and expensive and could expose us to additional risks that could materially adversely affect our financial position, results of operations and cash flows, including unanticipated costs for accounting and legal fees in connection with or related to the restatement and the risk of potential stockholder litigation. If lawsuits are filed, we may incur additional substantial defense costs regardless of the outcome of such litigation. Likewise, such events might cause a diversion of our management' s time and attention. If we do not prevail in any such litigation, we could be required to pay substantial damages or settlement costs. In addition, the restatement may lead to a loss of investor confidence and have negative impacts on the trading price of our common stock. If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting, and the trading price of our common stock may decline. Pursuant to Section 404 of Sarbanes- Oxley, our management is required to report upon the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. If we are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline. We 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, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock 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 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. We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for our product candidates and may have to limit our commercialization. The use of our product candidates in clinical trials, and the sale of any of our product candidates for which we obtain regulatory approval, exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical or biotechnology companies, or others selling or otherwise coming into contact with our products. For example, we may be sued if any product candidate we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourself against these claims, we will incur substantial liabilities or be required to limit development or commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of merit or eventual outcome, liability claims may result in: • loss of revenue from decreased demand for our products and / or product candidates; • impairment of our business reputation or financial stability; • costs of related litigation; • substantial monetary awards to patients or other claimants; • exhaustion of any available insurance and our capital resources; • diversion of management attention; • withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs; • the inability to commercialize our product candidates; • significant negative media attention; • decrease in our stock price; • initiation of investigations and enforcement actions by regulators; or • product recalls, withdrawals, revocation of approvals, or labeling, marketing, or promotional restrictions. While we currently hold product liability insurance coverage in an amount that we believe is customary for similarly situated companies, the amount of that coverage may not be adequate. We may need to increase our insurance coverage as we continue to conduct our clinical trials. We will need to further increase our insurance coverage if we commence commercialization of any of our product candidates for which we obtain marketing approval. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. On occasion, large judgments have been awarded in class action lawsuits based on therapeutics that had unanticipated side effects. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. A successful product liability claim or series of claims

brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business and our prospects. Our internal computer systems or those of our development collaborators, third- party CDMOs, or other contractors or consultants may fail or suffer cybersecurity or other security breaches, which could result in a material disruption of our product development programs and cause our business and operations to suffer. We face risks related to our collection and use of data, which could result in investigations, inquiries, litigation, fines, legislative and regulatory action, and negative press about our privacy and data protection practices. Our internal computer systems and those of our CDMOs and other contractors and consultants are vulnerable to cybersecurity breaches and damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. While we have not experienced any such material system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our business operations and product candidate development and, if any of our product candidates are approved, commercialization programs. Likewise, we intend to rely on third parties to manufacture our product candidates and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business and operations. To the extent that any disruption or cybersecurity or other 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, the further development and commercialization of our product candidates could be delayed, and our reputation could be harmed. In addition, there are known cyberattacks against biotechnology companies engaged in the development of therapeutic or vaccine products addressing COVID- 19. Our ~~COVAXIN and OCU500 programs~~ **inhaled mucosal vaccine platform** could attract the attention of cyberattackers. Additionally, our business processes personal data, including some data related to health. When conducting clinical trials, we face risks associated with collecting trial participants' data, especially health data, in a manner consistent with applicable laws and regulations. We also face risks inherent in handling large volumes of data and in protecting the security of such data. We could be subject to attacks on our systems by outside parties or fraudulent or inappropriate behavior by our service providers or employees. Third parties may also gain access to our systems using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks, or other means, and may use such access to obtain personal data. Data breaches could subject us to individual or consumer class action litigation and governmental investigations and proceedings by federal, state, and local regulatory entities in the United States and by international regulatory entities, resulting in exposure to material civil and / or criminal liability. As our operations and business grow, we may become subject to or be affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities, including various domestic and international privacy and security regulations. The legislative and regulatory landscape for privacy and data protection continues to evolve. In the United States, certain states may adopt privacy and security laws and regulations that may be more stringent than applicable federal law. For example, California enacted the California Consumer Privacy Act (" CCPA"), which took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. Furthermore, it is anticipated that the California Privacy Rights Act of 2020 (" CPRA"), effective January 1, 2023, will expand the CCPA' s requirements, including applying to personal information of business representatives and employees and establishing a new regulatory agency to implement and enforce the law. We may also in the future be subject to data protection laws and regulations of other jurisdictions, such as the EU' s General Data Protection Regulation (" GDPR"), which provides data subjects with certain rights and requires organizations to adopt technical and organizational safeguards to protect personal data. In the event that we are subject to or affected by privacy and data protection laws, including the CCPA, CPRA, or GDPR and other domestic or international privacy and data protection laws, we may expend significant resources to comply with such laws, and any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. The increasing use of social media platforms presents new risks and challenges. Social media is increasingly being used to communicate about our research, product candidates, and the diseases those product candidates and investigational medicines are being developed to treat. Social media practices in the biotechnology industry and the FDA' s regulation of social media continues to evolve. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, our employees or agents may use social media channels to inadvertently provide inaccurate or misleading information about our product candidates. If regulators become aware of such disclosures, they may take administrative or enforcement action against us. There is also a risk that third parties will use social media to disseminate inaccurate or misleading information about us or our product candidates. If this occurs, we may not be able to adequately defend our business or the public' s perception of us or our product candidates, particularly given restrictions on what we may say about our product candidates prior to FDA approval. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business. Evolving expectations around corporate responsibility practices, specifically related to environmental, social and governance (" ESG") matters, may expose us to reputational and other risks. Investors, stockholders, customers, suppliers and other third parties are increasingly focusing on ESG and corporate social responsibility endeavors and reporting. Certain institutional investors, investment funds, other influential investors, customers, suppliers and other third parties are also increasingly focused on ESG practices. Companies that do not adapt to or comply with the evolving investor or stakeholder expectations and standards, or which are perceived to have not responded appropriately, may suffer from reputational damage and result in the business, financial condition, and / or stock price of a company being materially and adversely affected. Further, this increased focus on ESG issues may result in new regulations and / or third party requirements that could adversely impact our business, or certain shareholders reducing or eliminating their holdings of our stock. Additionally, an allegation or perception that we have not taken sufficient action in these areas could negatively harm our reputation. **We are and expect to continue to be a " smaller reporting company " as defined in the Exchange Act, and have elected and expect to continue to elect to take advantage of certain of the scaled disclosures available to smaller**

reporting companies, including reduced disclosure obligations regarding executive compensation. We are and expect to continue to be a " smaller reporting company " as defined in the Exchange Act, and have elected and expect to continue to elect to take advantage of certain of the scaled disclosures available to smaller reporting companies, including reduced disclosure obligations regarding executive compensation. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are not required to audit our internal control over financial reporting for so long as we report less than $ 100 million in annual revenues for the most recent fiscal year and may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock price may be more volatile. We will remain a smaller reporting company until our public float exceeds $ 250 million or our annual revenues exceed $ 100 million with a public float greater than $ 700 million.