Risk Factors Comparison 2024-03-28 to 2023-03-09 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10- K, including our financial statements and the related notes and the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " before deciding to invest in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. We cannot assure you that any of the events discussed below will not occur. If any of the following risks actually occur, our business, prospects, operating results and financial condition could suffer materially. ~~Additionally, to the extent the ongoing COVID- 19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks incorporated by reference or set forth below.~~ In such event, the trading price of our common stock could decline and you might lose all or part of your investment. ~~Summary of Risk~~ **Risks Related** ~~Factors An investment in our common stock involves various risks, and prospective investors are urged~~ to ~~carefully consider the matters discussed in the section titled " Risk Factors " prior to making an investment in our common stock. These risks include, but are not limited to, the following: • If the proposed merger with CaleiMedica is not consummated, our business could suffer materially and our stock price could decline. • If we do not successfully consummate the merger or another strategic transaction, then our Board may decide to pursue a dissolution and liquidation under Delaware law. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities, and it is possible that shareholders would receive significantly less than the current market value of their shares. •~~ Our **Limited Operating History** ~~net cash may be less than $ 18 million at the closing of the merger~~ , **Financial Position** ~~which would cause a condition to CaleiMedica' s obligation to consummate the merger to fail to be satisfied~~ and **Capital Requirements** ~~may result in the termination of the merger agreement. • Some of our officers and directors have conflicts of interest that may influence them to support or approve the merger. • The merger may be completed even though material adverse changes may result from the announcement of the merger, industry- wide changes and other causes. •~~ We are a clinical- stage biopharmaceutical company with ~~no products approved~~ **a limited operating history** . We have incurred **net losses since our inception and anticipate that we will continue to incur** significant losses ~~since inception, and we expect to incur continued and increasing losses over the next several years and may never achieve or maintain profitability. • We will need substantial additional funding to support our operations and pursue our growth strategy. 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. • Our limited operating history may make it difficult~~ for ~~you to evaluate~~ the **foreseeable** ~~success of our business to date and to assess our~~ future ~~viability~~ . ~~• Our approach to the treatment of retinal diseases is unproven, and we do not know whether we will be able to successfully develop any products. • If we do not successfully consummate the merger or another strategic transaction, we will depend heavily on the success of our product candidates. Clinical trials of our product candidates may not be successful. If we are unable to successfully complete clinical development of, and obtain marketing approvals for, our product candidates, or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize these product candidates, our business will be materially harmed. •~~ We have **never generated** ~~not yet successfully initiated or completed~~ any **revenue from** ~~Phase 3 clinical trials nor commercialized any pharmaceutical products, which may make it difficult to evaluate our future prospects. • If clinical trials of GB- 501 or any other~~ product **sales** ~~candidate that we develop fail to demonstrate safety and efficacy to the satisfaction of the FDA, the EMA or other regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be delayed or unable to complete, the development and commercialization of such product candidate. • The ongoing COVID- 19 pandemic may, directly or indirectly, adversely affect our business, results of operations and financial condition. • Gene therapy is an~~ **and** ~~emerging field of drug development that poses many~~ - **may never** ~~scientific and other risks, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval. • We have no prior experience with gene therapy, the sourcing or manufacturing of gene therapy products and components, or the conduct of clinical trials of such products. • Our business and operations would suffer in the event of computer system failures or security breaches. • We could potentially contract with third parties for the production of our product candidates. This could increase the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. • The manufacture of our product development candidates requires outsourced, custom manufacturing and we may encounter difficulties in production, particularly with respect to formulation, process development or scaling up of our manufacturing capabilities. If we, or our contract manufacturing organizations (" CMOs ") encounter such difficulties, our ability to provide supply of our product candidates for preclinical studies, clinical trials or our products for patients, if approved, could~~ be **profitable** ~~delayed or stopped, or we may be unable to maintain a commercially viable cost structure. • Gene therapies are novel, complex and difficult to manufacture. We could experience manufacturing problems that result in delays in our development or commercialization programs or otherwise harm our business. • We have no experience manufacturing any of our product candidates at a commercial scale. We, or our CMOs, may be unable to successfully scale up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any. • Our products may fail to achieve the degree of market acceptance by~~

physicians, patients, third- party payors and others in the medical community necessary for commercial success, and the market opportunity for these products may be smaller than we estimate. • If our patent position does not adequately protect our product candidates, others could compete against us more directly, which would harm our business. • Patents filed by our licensor, University of North Carolina at Chapel Hill (" UNC ") 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.- based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non- U. S. manufacturers. • We may be required, or choose, to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive, the trials are not well- designed, or research participants experience adverse safety outcomes. • If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate significant revenue will be materially impaired. The regulatory approval process is expensive, time- consuming and uncertain. As a result, we cannot predict when or if we, or any collaborators we may have in the future, will obtain regulatory approval to commercialize our product candidates. • Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. • The market price of our stock has been and may continue to be volatile, and you could lose all or part of your investment. • If our stock price does not meet Nasdaq' s minimum bid requirement, it could become subject to delisting. • Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. Risks Related to the Proposed Merger with CalciMedica, Inc. The consummation of the proposed merger with CalciMedica is subject to a number of closing conditions, including the approval by our stockholders, approval by Nasdaq of our application for initial listing of our common stock in connection with the merger, and other customary closing conditions. We are targeting a closing of the transaction in the first quarter of 2023. If the proposed merger is not consummated, we may be subject to a number of material risks, and our business and stock price could be adversely affected, as follows: • We have incurred and expect to continue to incur significant expenses related to the proposed merger with CalciMedica even if the merger is not consummated. • The merger agreement contains covenants relating to our solicitation of competing acquisition proposals and the conduct of our business between the date of signing the merger agreement and the closing of the merger. As a result, significant business decisions and transactions before the closing of the merger are restricted or prohibited. Accordingly, we may be unable to pursue business opportunities that would otherwise be in our best interest as a standalone company. If the merger agreement is terminated after we have invested significant time and resources in the transaction process, we will have a limited ability to continue our current operations without obtaining additional financing to fund our operations. • We could be obligated to pay CalciMedica a $ 1 million or $ 1. 5 million termination fee in connection with the termination of the merger agreement, depending on the reason for the termination. • We could be obligated to pay CalciMedica $ 250, 000 or $ 1 million for expense reimbursement in connection with the termination of the merger agreement, depending on the reason for the termination. • Our collaborators and other business partners and investors in general may view a failure to consummate the merger as a poor reflection on our business or prospects. • Some of our suppliers, collaborators and other business partners may seek to change or terminate their relationships with us as a result of the proposed merger. • As a result of the proposed merger, current and prospective employees could experience uncertainty about their future roles within the combined company. This uncertainty may adversely affect our ability to retain our key employees, who may seek other employment opportunities. Additionally, pursuant to the merger agreement, all Graybug employees will be terminated effective as of the closing. • Our management team may be distracted from day- to- day operations as a result of the proposed merger. • The market price of our common stock may decline to the extent that the current market price reflects a market assumption that the proposed merger will be completed. In addition, if the merger agreement is terminated and our Board determines to seek another business combination, we may not be able to find a third party willing to provide equivalent or more attractive consideration than the value to be provided by each party in the merger. In such circumstances, our Board may elect to, among other things, divest all or a portion of our business, or take the steps necessary to liquidate all of our business and assets, and in either such case, the consideration that we receive may be less attractive than the consideration to be received by us pursuant to the merger agreement. If the proposed merger with CalciMedica is not consummated, CalciMedica may not be able to repay amounts we have loaned to them. Our loans to CalciMedica are in the form of unsecured promissory notes (the " Notes "), so we have no preference ahead of CalciMedica' s other lenders and creditors. In the event that the Merger Agreement is terminated, whether as a result of our shareholders voting against the Merger, the acceptance by our Board of a Superior Offer, the passage of the End Date before the Merger closes, or other reasons, CalciMedica may not be able to repay the Notes in a timely fashion, if at all. If we do not successfully consummate the merger or another strategic transaction, then our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities. There can be no assurance that the merger will be completed. If the merger is not completed, our Board may decide to pursue a dissolution and liquidation of Graybug. In such an event, the amount of cash available for distribution to Graybug' s stockholders will depend heavily on the timing of such decision and, as with the passage of time, the amount of cash available for distribution will be reduced as we continue to fund our operations. The amount of cash available for distribution would also be reduced if we are required to pay a termination fee to CalciMedica pursuant to the merger agreement. In addition, if our Board were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of Graybug, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations, and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and our liquidation. If a dissolution and liquidation were pursued, our Board, in consultation with our advisors, would need to evaluate

these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of Graybug. We are required to have a net cash balance of at least $ 18 million at the closing of the merger as a condition to CalciMedica' s obligation to consummate the merger. For purposes of the merger agreement, net cash is subject to certain reductions, including, without limitation, short- and long- term liabilities accrued and any unpaid change of control payments or severance, termination, accrued paid time off, retention or similar payments at closing. In the event that our net cash falls below this threshold, a condition to the CalciMedica' s obligation to consummate the merger will fail to be satisfied and CalciMedica will have the right to terminate the merger agreement at an outside date of May 21, 2023 (subject to extension as provided in the merger agreement) if our net cash continues to be lower than the $ 18 million threshold. Our officers and directors participate in arrangements that provide them with interests in the merger that are different from yours, including, among others, their continued service as a director of the combined company, retention and severance benefits, the acceleration of option and restricted stock unit vesting, and continued indemnification. These interests, among others, may influence the officers and directors of Graybug to support or approve the merger. In general, either CalciMedica or us can refuse to complete the merger if there is a material adverse change affecting the other party between November 21, 2022, the date of the merger agreement, and the closing. However, some types of changes do not permit either party to refuse to complete the merger, even if such changes would have a material adverse effect on us or CalciMedica, to the extent they resulted from the following: • general business or economic conditions generally affecting the industry in which either company or their subsidiaries operate; • acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes or other natural disasters, health emergencies, including pandemics (including COVID- 19 and any evolutions or mutations thereof) and related or associated epidemics, disease outbreaks or quarantine restrictions; • changes in financial, banking or securities markets; • any change in, or any compliance with or action taken for the purpose of complying with, any law or GAAP (or interpretations of any law or GAAP); • the announcement of the merger agreement or the pendency of the contemplated transactions; • the taking of any action required to be taken by the merger agreement, except in each case with respect to the first three bullets above, to the extent disproportionately affecting either company and its subsidiaries, taken as a whole, relative to other similarly situated companies in the industries in which either company or its subsidiaries operate, as applicable; • our potential asset dispositions under the merger agreement; • any reduction in the amount of our or our subsidiaries' cash and cash equivalents as a result of expenditures made by us or our subsidiaries related to our wind- down activities or our subsidiaries associated with the termination of our research and development activities (including the termination of ongoing contractual obligations relating to our or our subsidiaries' current products or product candidates); • our or our subsidiaries' failure, taken as a whole, to meet internal or analysts' expectations or projections or the results of operations of us and our subsidiaries, taken as a whole; or • any change in the stock price or trading volume of our common stock (it being understood, however, that any effect causing or contributing to any change in stock price or trading volume of our common stock may be taken into account in determining whether a material adverse effect has occurred, unless such effects are otherwise excepted from this definition). If adverse changes occur but CalciMedica and we must still complete the merger, the combined company' s stock price may suffer. The market price of the combined company' s common stock may decline as a result of the merger. The market price of the combined company' s common stock may decline as a result of the merger for a number of reasons including if: • the combined company does not achieve the perceived benefits of the merger as rapidly or to the extent anticipated by financial or industry analysts; • the effect of the merger on the combined company' s business and prospects is not consistent with the expectations of financial or industry analysts; or • investors react negatively to the effect on the combined company' s business and prospects from the merger. Our stockholders may not realize a benefit from the merger commensurate with the ownership dilution they will experience in connection with the merger. If the combined company is unable to realize the strategic and financial benefits currently anticipated from the merger, our stockholders will have experienced substantial dilution of their ownership interest without receiving any commensurate benefit. Significant management attention and resources will be required to integrate the two companies. Delays in this process could adversely affect the combined company' s business, financial results, financial condition and stock price following the merger. During the pendency of the merger, we may not be able to enter into a business combination with another party and will be subject to contractual limitations on certain actions because of restrictions in the merger agreement. Covenants in the merger agreement impede our ability and the ability of CalciMedica to make acquisitions or complete other transactions that are not in the ordinary course of business pending completion of the merger. As a result, if the merger is not completed, the parties may be at a disadvantage to their competitors. In addition, while the merger agreement is in effect and subject to limited exceptions, each party is prohibited from soliciting, initiating, encouraging, inducing or facilitating the communication, making, submission or announcement of certain acquisition inquiries or acquisition proposals or taking any action that could reasonably be expected to lead to certain acquisition inquiries or acquisition proposal, such as certain acquisitions of our common stock, a tender offers for our common stock, and mergers or other business combinations. Such prohibited transactions could otherwise be favorable to our stockholders. Because the lack of a public market for CalciMedica common stock makes it difficult to evaluate the fairness of the merger, CalciMedica' s stockholders may receive consideration in the merger that is greater than or less than the fair market value of CalciMedica common stock. The outstanding share capital of CalciMedica is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of CalciMedica. Since the percentage of our equity to be issued to CalciMedica' s stockholders was determined based on negotiations between the parties, it is possible that the value of our common stock to be issued in connection with the merger will be greater than the fair market value of CalciMedica. Alternatively, it is possible that the value of the shares of our common stock to be issued in connection with the merger will be less than the fair market value of CalciMedica. The combined company will incur significant transaction costs as a result of the merger, including investment banking, legal and accounting fees. In addition, the combined company will incur significant consolidation and integration

expenses which cannot be accurately estimated at this time. These costs could include the possible relocation of certain operations from Redwood, California to other offices of the combined company as well as costs associated with terminating existing office leases and the loss of benefits of certain favorable office leases. Actual transaction costs may substantially exceed CalciMedica' s estimates and may have an adverse effect on the combined company' s financial condition and operating results. CalciMedica may not consummate its private placement or may fail to receive the minimum private placement proceeds of $ 10. 0 million, which could put financial strain on CalciMedica' s ability to consummate the merger as planned. The closing of the private placement is expected to occur immediately prior to the closing of the merger and is subject to certain closing conditions, including the requirement that the private placement investors purchase at least $ 10. 0 million shares of CalciMedica common stock, as specified in CalciMedica' s securities purchase agreement. While the private placement investors have agreed to purchase an aggregate of $ 10. 3 million shares of CalciMedica common stock, there can be no assurances that such purchases will occur. In the event that the private placement is not consummated, CalciMedica may have to look for alternative sources of funding to consummate the merger, including additional capital raising or credit financing transactions that may delay or derail the planned timeline of the merger and entail further transaction costs. Failure of the merger to qualify as a reorganization within the meaning of Section 368 (a) of the Internal Revenue Code could harm the combined company. The parties intend for the merger to qualify as a reorganization within the meaning of Section 368 (a) of the Internal Revenue Code, as amended. Certain requirements must be met for the merger to qualify as a Section 368 (a) reorganization. If such requirements are not satisfied, CalciMedica' s stockholders could be subject to tax liability. The merger is expected to result in a limitation on our ability to utilize our net operating loss carryforwards. Under Section 382 of the Internal Revenue Code, use of our net operating loss carryforwards (" NOLs ") will be limited if we experience an " ownership change. " For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who own at least 5 % of a corporation' s stock increases by more than 50 percentage points over its lowest ownership percentage within a specified testing period. We expect to experience an ownership change as a result of the merger, and therefore our ability to utilize our NOLs and certain credit carryforwards remaining at the effective time will be limited. The annual limitation will be determined by the fair market value of our common stock outstanding prior to the ownership change, multiplied by the applicable federal rate. Limitations imposed on our ability to utilize NOLs could cause U. S. federal and state income taxes to be paid earlier than they would be paid if such limitations were not in effect and could cause such NOLs to expire unused, in each case reducing or eliminating the benefit of such NOLs. Certain of our stockholders could attempt to influence changes which could adversely affect our operations, financial condition and the value of our common stock. Our stockholders may from time to time seek to acquire a controlling stake in Graybug, engage in proxy solicitations, advance stockholder proposals or otherwise attempt to effect changes. Campaigns by stockholders to effect changes at publicly- traded companies are sometimes led by investors seeking to increase short- term stockholder value through actions such as financial restructuring, increased debt, special dividends, stock repurchases or sales of assets or the entire company. Responding to proxy contests and other actions by activist stockholders can be costly and time- consuming, and could disrupt our operations and divert the attention of our Board and senior management from the pursuit of the proposed merger transaction. These actions could adversely affect our operations, financial condition, our ability to consummate the merger and the value of our common stock. We and CalciMedica may become involved in securities litigation or stockholder derivative litigation in connection with the merger, and this could divert the attention of CalciMedica' s or our management and harm the combined company' s business, and insurance coverage may not be sufficient to cover all related costs and damages. Securities litigation or stockholder derivative litigation frequently follows the announcement of certain significant business transactions, such as the sale of a business division or announcement of a business combination transaction. Since the filing of our proxy statement on form PREM 14A on December 14, 2022, four lawsuits have been filed in federal courts against Graybug and the Graybug Board: Bushansky v. Graybug Vision, Inc., et al., 3: 22- cv- 09131 (N. D. Cal.), Connelly v. Graybug Vision, Inc., et al., 3: 23- cv- 00028 (N. D. Cal.), Plumly v. Graybug Vision, Inc., et al., 1: 23- cv- 00169 (D. Del.), and Franchi v. Graybug Vision, Inc., et al., 1: 23- cv- 1390 (S. D. N. Y) (collectively, the " Stockholder Litigation "). In addition, nine purported stockholders of Graybug sent demand letters regarding the proxy statement (the " Demand Letters "). Further details regarding the Stockholder Litigation and the Demand Letters are set forth below in Item 3 " Legal Proceedings ". We and CalciMedica may become involved in this type of litigation in connection with the merger again in the future, and the combined company may become involved in this type of litigation in the future. Litigation often is expensive and diverts management' s attention and resources, which could adversely affect the business of us, CalciMedica and the combined company. Failure to complete the merger may result in us paying a termination fee or expenses to CalciMedica and could harm the price of our common stock and our future business and operations. If the merger is not completed and the merger agreement is terminated under certain circumstances, we may be required to pay CalciMedica a termination fee of either $ 1 million or $ 1. 5 million and / or an expense reimbursement of up to $ 1 million. Even if a termination fee or expense reimbursement is not payable in connection with a termination of the merger agreement, we will have incurred significant fees and expenses, which must be paid whether or not the merger is completed. Further, if the merger is not completed, it could significantly harm the market price of our common stock. The exchange ratio is not adjustable based on the market price of our common stock so the merger consideration at the closing may have greater or lesser value than the market price at the time the merger agreement was signed. Under the terms of the merger agreement, at the effective time of the merger, each share of CalciMedica capital stock (excluding shares held as treasury stock by CalciMedica or held or owned by us, the merger subsidiary or any subsidiary of us or CalciMedica and dissenting shares), after giving effect to (i) CalciMedica' s preferred stock conversion, (ii) CalciMedica warrant exercises and (iii) the conversion of CalciMedica' s convertible notes, will be converted solely into the right to receive a number of validly issued, fully paid and nonassessable shares of our common stock equal to the exchange ratio, which will be calculated based on the total number of shares outstanding of our common stock and CalciMedica common stock immediately prior to the effective time of the merger, in each case, on a fully- diluted basis

~~using the treasury stock method and excluding out- of- the- money options and warrants, and based on our net cash as of the closing of the merger. Immediately following the effective time of the merger, CalciMedica' s equity holders are expected to own or hold rights to acquire 71. 4 % of the combined company and our equity holders are expected to own or hold rights to acquire 28. 6 % of the combined company, in each case, on a fully- diluted basis using the treasury stock method and excluding out- of- the- money options and warrants, and subject to certain assumptions, including, but not limited to, (a) our net cash as of the closing of the merger being $ 25 million, (b) a closing date of February 15, 2023, and (c) CalciMedica issuing approximately 20. 5 million shares of common stock in the private placement. The post- closing equity split is subject to certain adjustments including based on our net cash at closing, the closing date, the number of shares of CalciMedica' s common stock issued in the private placement and to account for the effect of a reverse stock split. As a result, these ownership percentages may be adjusted upward or downward due to such adjustments and as a result, our stockholders could own less of the combined company than expected. Any changes in the market price of our common stock before the completion of the merger will not affect the number of shares of our common stock issuable to CalciMedica' s stockholders pursuant to the merger agreement. Therefore, if before the completion of the merger the market price of our common stock declines from the market price on the date of the merger agreement, then CalciMedica' s stockholders could receive merger consideration with substantially lower value than the value of such merger consideration on the date of the merger agreement. Similarly, if before the completion of the merger the market price of our common stock increases from the market price of our common stock on the date of the merger agreement, then CalciMedica' s stockholders could receive merger consideration with substantially greater value than the value of such merger consideration on the date of the merger agreement. The merger agreement does not include a price- based termination right. Because the exchange ratio does not adjust as a result of changes in the market price of our common stock, for each one percentage point change in the market price of our common stock, there is a corresponding one percentage point rise or decline, respectively, in the value of the total merger consideration payable to CalciMedica' s stockholders pursuant to the merger agreement. Certain provisions of the merger agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the arrangements contemplated by the merger agreement. The terms of the merger agreement prohibit each of us and CalciMedica from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when, among other things, our Board determines in good faith after consultation with outside financial advisors and outside legal counsel that an unsolicited alternative takeover proposal is or is reasonably likely to result in a superior takeover proposal, and that failure to cooperate with the proponent of the proposal could be reasonably likely to be inconsistent with our Board' s fiduciary duties. If the conditions to the merger are not met, the merger may not occur. Even if the share issuances and amended and restated certificate of incorporation to effect the reverse stock split are approved by our stockholders, specified conditions must be satisfied or waived to complete the merger. These conditions are set forth in the merger agreement. We cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the merger will not occur or will be delayed, and we and CalciMedica each may lose some or all of the intended benefits of the merger. Risks Related to Our Financial Position and Need for Additional Capital We have historically been~~ a clinical- stage biopharmaceutical company with **a limited operating history that may make it difficult to evaluate the success of our business to date and assess our future viability. We commenced operations in October 2006, have** no products approved ~~. We~~ **for commercial sale and** have ~~incurred significant losses since inception, and, if the merger fails to close, we would expect to incur continued and increasing losses over the next several years and may~~ never **generated** ~~achieve or maintain profitability. Since inception, we have incurred significant operating losses. Our net loss was $ 35. 6 million and $ 35. 8 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an~~ **any revenue** ~~accumulated deficit of $ 204. 8 million. To date, we have financed our operations primarily through private placements of convertible preferred stock and convertible promissory notes and the issuance of common stock upon our initial public offering (" IPO ")~~. We have devoted substantially all of our ~~financial~~ resources ~~and efforts~~ to ~~research~~ **organizing** and **staffing** ~~development, including preclinical studies and clinical trials and general and administrative costs to support such efforts. If the merger fails to close, we expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year, such that a period- to- period comparison of our results of operations may not be a good indication of our future performance. We expect to continue to incur substantial and increasing losses before we can consummate the merger. Based on our current operating plan, which would be superseded if the merger closes, we would expect to continue to incur significant and increasingly higher expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we: • conduct pre- clinical activities in connection with the clinical development of our most advanced product candidate, GB- 501; • commence clinical trials of our product candidate GB- 501; • continue the research and development of GB- 701; • seek to identify and develop, or~~ **our company** ~~enter into strategic partnerships or collaborations to develop~~ , **business planning** ~~additional product candidates; • seek marketing approvals for any of our product candidates that successfully complete clinical development; • develop and expand our sales~~ , ~~marketing and distribution capabilities for any of our product candidates for which we obtain marketing approval; • scale up our manufacturing processes and capabilities or, in the future, establish~~ **establishing** and ~~operate a manufacturing facility, to support sales of our product candidates, our ongoing clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval; • maintain~~ **maintaining** ~~, expand and protect~~ our intellectual property portfolio ~~; • expand our operational~~ , **raising capital** ~~financial and management systems and personnel~~ , ~~including personnel to~~ **developing our product candidates, undertaking research and development activities, and providing general and administrative** support **for these operations. We are conducting several clinical trials and preclinical studies for our lead product candidate, Auxora, which is currently in a Phase 2b clinical trial in AP and accompanying SIRS, an ongoing Phase 1 / 2 clinical trial for which the first cohort in pediatric patients with AIPT as a side effect of pediatric acute lymphoblastic leukemia treatment with asparaginase has completed, a Phase**

2 trial in COVID- 19 pneumonia patients with ARDS which has been completed and may inform the further development of Auxora for patients with AHRF and / ~~our~~ or ARDS with a broad range of etiologies, and a Phase 2 clinical trial in AKI which we plan to initiate in the second quarter of 2024. Our other pipeline programs, which include new product candidates, are in preclinical development. We have incurred net losses each year since our inception. As of December 31, 2023, we had an accumulated deficit of $ 146. 1 million and a net loss of $ 34. 4 million for the year ended December 31, 2023. We expect that it will be several years, if ever, before we have a product candidate ready for commercialization. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future as we advance our product candidates through clinical development ~~, manufacturing and commercialization efforts and our operations as a public company; • increase our product liability and clinical trial insurance coverage as we expand our clinical trials and commercialization efforts; and • explore and review a range of strategic alternatives for our company~~ . **Our prior losses, combined** ~~Because of the numerous risks and uncertainties associated~~ with ~~pharmaceutical product development~~ **expected future losses** , **have had and** ~~we are unable to accurately predict the timing or amount of increased expenses or when, or if, we~~ will **continue** ~~be able~~ to **have** ~~achieve profitability. Our expenses will increase if: • we are required by the FDA, the European Medicines Agency (the " EMA ") or any~~ **an adverse effect on** ~~additional international regulatory agency to perform trials or~~ **our stockholders' equity and working capital. To become and remain profitable, we must** ~~studies in addition to those currently expected; • there are any delays in receipt of regulatory clearances or approvals to begin our planned clinical programs; or • there are any delays in enrollment of patients in or completing our clinical trials or the development~~ ~~----~~ **develop** ~~of our~~ **and eventually commercialize** product candidates **with significant market potential** ~~. We have no product sales. We do not expect sales of any product candidate for several years. For us to become profitable, we will need to succeed in developing and commercializing products~~ . This will require us to be successful in a range of challenging activities, including ~~: • successfully~~ completing **preclinical studies and** clinical ~~development~~ **trials** of our product candidates, ~~which may require establishing one or more strategic partnerships; •~~ obtaining marketing approval for these product candidates ~~; •~~ **, finding external** manufacturing ~~at~~ **capacity sufficient to meet** commercial ~~scale~~ **demand, marketing** and selling ~~and distributing~~ those ~~products~~ **product candidates** for which we **may** obtain marketing approval ~~; • achieving an~~ **and satisfying any post** ~~adequate level of market acceptance of and obtaining and maintaining coverage and adequate reimbursement from third~~ **marketing requirements** ~~party payors for our products, which may require establishing a strategic partnership; and • protecting our rights to our intellectual property portfolio~~ . We may never succeed in these activities and **, even if we succeed in commercializing one or more of our product candidates, we** may never generate revenue that is ~~sufficient~~ **significant** or ~~great~~ **large** enough to achieve profitability. ~~Even if~~ **In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. If** we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis **and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates** . Our failure to become and remain profitable would ~~reduce~~ **decrease** the value of ~~our~~ **the** company and could impair our ability to raise capital, ~~expand our business,~~ maintain our research and development efforts, **expand** ~~diversify our product offerings or~~ **our** ~~even~~ **business or** continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment. We will need **to obtain** substantial additional funding to ~~support~~ **complete the development and any commercialization of our product candidates. If we are unable to raise this capital when needed, on acceptable terms,** ~~our~~ **or at all, we may be forced to delay, reduce or eliminate the development of our product candidates or other operations. Since we commenced operations in October 2006, we have primarily financed our operations through private placements of our preferred stock, convertible promissory notes and common stock and through the Merger with Graybug. We have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially for the foreseeable future. The development of drug product candidates is highly capital intensive. As our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our clinical, regulatory and quality capabilities. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing** operations. If we are unable to raise capital when needed ~~, we could be forced to delay, reduce or eliminate our product development programs. We incurred losses from operations and had negative cash flows from operating activities for the years ended December 31, 2022 and 2021, and our accumulated deficit as of December 31, 2022 is $ 204. 8 million. Based on our current operating plan, we would expect to devote substantial financial resources to our ongoing and planned activities, particularly as we conduct pre- clinical studies or clinical trials for GB- 501, preclinical studies or clinical trials for GB- 701, and seek marketing approval for any such product candidate for which we obtain favorable clinical results. Significant financial resources would be required to conduct research and development and to potentially seek regulatory approval for our current product candidates. In addition, substantial financial resources would be required to commercialize our products, if approved, including product manufacturing, sales, marketing and distribution for any of our product candidates for which marketing approval is obtained. Accordingly, substantial additional funding would be required to support our continuing and planned operations. If we are unable to raise or otherwise access capital when needed~~ or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. As of December 31, ~~2022~~ **2023** , we had **$ 11. 2 million in** cash, cash equivalents and short- term investments ~~of $ 39~~ ~~. 1 million, which, based~~ **Based** on our current operating ~~plan~~ **plans** , we believe ~~is~~ **our existing resources, including the funds from a private placement which had closings in January and February of 2024, will be** sufficient to fund our operations ~~beyond~~ **into the second half of 2025 and will allow us to fund the advancement of Auxora in AP, AIPT, and AKI through clinical milestones in 2024 and the first half of 2025. However, our current cash, cash equivalents and short- term investments**

will not be sufficient to fund any of our product candidates through regulatory approval, nor will it be sufficient to pursue additional indications for Auxora like AHRF, nor will it be sufficient to fund clinical trials on ~~the~~ **other** ~~next 12 months~~ **product candidates in our portfolio aside from Auxora, and we will need to raise substantial additional capital to complete the development and any commercialization of our product candidates. We have based these estimates on assumptions that may prove to be incorrect or require adjustment as a result of business decisions, and we could utilize our available capital resources sooner than we currently expect** . Our future funding requirements will depend on many factors, including **, but not limited to** : • the ~~scope,~~ progress, costs and ~~outcome~~ **results** of ~~the~~ **our ongoing** clinical trials of **Auxora and** our **planned trials for our other** product candidates ~~, in particular GB- 501~~ ; • the scope, progress, **results and** costs ~~and outcome~~ of **discovery research,** preclinical development **, laboratory testing** and clinical trials **for our product candidates, including our ongoing clinical trials** of **Auxora** ~~GB- 701~~ ; • the costs, timing and outcome of regulatory review of our product candidates ~~by the FDA, the EMA or other regulatory authorities~~ ; • **our ability to enter into contract manufacturing arrangements for supply of active pharmaceutical ingredient (" API ") and manufacture of drug product for our product candidates and the terms of such arrangements; •** the costs **and timing** of **any future commercialization activities, including product** manufacturing, sales, marketing ~~,~~ **and** distribution **, for** ~~and other commercialization efforts with respect to~~ any **of our** ~~products~~ - **product candidates** for which we ~~obtain~~ **may receive** marketing approval; • ~~subject to receipt~~ **the amount and timing** of **revenue, if any, received from commercial sales of our product candidates for which we receive** marketing approval ~~, revenue received from product sales; • our headcount growth and associated costs as we would need to expand our research and development and establish a commercial infrastructure; • the extent to which we choose to establish collaboration, distribution or other marketing arrangements for our products and product candidates; • the effect of competing technological and market developments~~ ; • the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property **and proprietary** rights and defending any intellectual property- related claims; • the extent to which we acquire or ~~invest~~ in **- license** other ~~businesses,~~ products ~~and~~ **, product candidates,** technologies **or data referencing rights** ; ~~and~~ • **our ability to establish and maintain strategic collaborations, licensing or** ~~the~~ **other** ~~impact~~ **arrangements and the financial terms** of **such arrangements; • the payment or receipt of milestones and receipt of** ~~the~~ **other** ~~COVID~~ **collaboration** - **based revenues** ~~19 pandemic. Conducting preclinical testing and clinical trials is a time- consuming~~ , ~~expensive~~ **if any; • the number of,** and ~~uncertain process~~ **development requirements for, other product candidates** that **we pursue; •** ~~takes years to complete. We may never generate~~ the **impacts** ~~necessary data or results required to obtain regulatory approval~~ of ~~products with~~ the ~~market~~ **ongoing conflicts between Ukraine and Russia and in the Middle East and** potential ~~sufficient to enable us to achieve profitability~~ **future bank failures; and • the costs of operating as a public company** . ~~We would~~ **Because we do** not expect to generate **revenue from product candidate** sales ~~of any commercial product~~ for ~~several~~ **many** years, if at all ~~. Accordingly~~ , we **will** ~~believe that we would~~ need to obtain substantial additional **funding in connection with our continuing operations and expected increases in expenses. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. Accordingly, we will need to continue to rely on additional** financing to achieve our ~~current~~ business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. **The impacts of the ongoing conflicts between Ukraine and Russia and in the Middle East and potential future bank failures on capital markets may affect the availability, amount and type of financing available to us in the future. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could adversely affect our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our proprietary platform or product candidates. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants further limiting or restricting our ability to take specific actions, such as limitations on our ability to incur debt, make capital expenditures or declare dividends. If we raise funds through collaborations or licensing arrangements with third parties, 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. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our proprietary product candidate development process or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Attempting to secure additional financing may also divert our management from our day- to- day activities, which may impair or delay our ability to develop our proprietary platform. In addition, demands on our cash resources may change as a result of**

many factors currently unknown to us including, but not limited to, any unforeseen costs we may incur as a result of preclinical study or clinical trial delays, or disruptions in the manufacturing of our product candidates, due to the ongoing conflicts between Ukraine and Russia and in the Middle East, potential future bank failures or other causes, and we may need to seek additional funds sooner than planned. If we are unable to obtain funding on a timely basis or at all, we may be required to significantly curtail or stop one or more of our research or development programs. Any acquisitions or strategic collaborations may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities or subject us to other risks. From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products and technologies, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including, but not limited to: • increased operating expenses and cash requirements; • the assumption of indebtedness or contingent or unknown liabilities; • assimilation of operations, intellectual property and products or product candidates of an acquired company, including difficulties associated with integrating new personnel; • the diversion of our management' s attention from our existing product candidates and initiatives in pursuing such an acquisition or a strategic partnership; • retention of key employees, the loss of key personnel and uncertainties about our ability to maintain key business relationships; • risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals, and the possibility of disagreements or disputes with such other party; and • our inability to generate revenue from acquired products, product candidates, intellectual property rights, technologies, and / or businesses sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs. In addition, if we engage in acquisitions or strategic partnerships, we may issue dilutive securities, assume or incur debt obligations, incur large one- time expenses or acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our growth or limit access to technology or drugs that may be important to the development of our business. If we are unable to maintain our listing on Nasdaq, it could become more difficult to sell our common stock in the public market. Our common stock was previously delisted from the Nasdaq Stock Market LLC (" Nasdaq ") and on June 12, 2023, Nasdaq approved our application to relist our common stock and we began trading on June 14, 2023 on the Nasdaq Capital Market. If we are unable to continue to meet Nasdaq' s listing standards for any reason, our common stock could be delisted from Nasdaq. If delisted, we may seek to list our securities on a different stock exchange or, if one or more broker- dealer market makers comply with applicable requirements, the OTC. Listing on such other market or exchange could reduce the liquidity of our common stock. If our common stock were to trade in the OTC market, an investor would find it more difficult to dispose of, or to obtain accurate quotations for the price of, the common stock. A delisting from Nasdaq and failure to obtain listing on another market or exchange would subject our common stock to so- called penny stock rules that impose additional sales practice and market- making requirements on broker- dealers who sell or make a market in such securities. Consequently, removal from Nasdaq and failure to obtain listing on another market or exchange could affect the ability or willingness of broker- dealers to sell or make a market in our common stock and the ability of purchasers of our common stock to sell their securities in the secondary market. Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates Our proprietary CRAC channel inhibition science is based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval and we may not be successful in our efforts to use and expand our science to build a pipeline of product candidates. We are **seeking to identify and develop a broad pipeline of product candidates using our proprietary CRAC channel inhibitor science to address acute critical illness and chronic inflammatory and immunologic diseases where there are no effective therapies. Our lead product candidate, Auxora, is currently in Phase 2 clinical development and we have only completed one randomized, blinded placebo- controlled trial with Auxora to date. We are not aware of any FDA approved therapeutics utilizing similar technology. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our proprietary CRAC channel inhibition science is both preliminary and limited. Additionally, there are no drugs currently approved for the treatment of AP and as a result the FDA has not established the endpoints that will be required for approval in this indication. As a result, we are exposed to a number of unforeseen risks and it is difficult to predict the types of challenges and risks that we may encounter during development of our product candidates. Given the novelty of our CRAC channel inhibition science, we intend to work closely with the FDA and comparable foreign regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates; however, due to a lack of relevant experience with the indications that we are pursuing, the regulatory pathway with the FDA and comparable regulatory authorities may be more complex and time- consuming. There can be no assurance as to the length of clinical development, the number of patients that the FDA may require to be enrolled in clinical trials to establish the safety and efficacy of our product candidates, or that the data generated in these clinical trials will be acceptable to the FDA to support marketing approvals. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business. Our business is highly dependent on the success of our product candidates, in particular Auxora, and we may fail to develop Auxora successfully or be unable to obtain regulatory approval. Our future success is dependent on our ability to complete clinical trials in a timely and successful manner and obtain marketing approval for and successfully commercialize Auxora, our lead product candidate. We are**

investing the majority of our efforts and financial resources in the research and development of Auxora for multiple indications. Auxora is currently in several studies: an ~~early~~ **ongoing Phase 2b clinical trial in AP and accompanying SIRS; an ongoing Phase 1 / 2 clinical trial, for which the first cohort, in pediatric patients with AIPT as a side effect of pediatric acute lymphoblastic leukemia treatment with asparaginase has completed; a Phase 2 trial, in COVID- 19 pneumonia patients with ARDS which has completed and may inform the design of clinical development in AHRS and / or ARDS due to a broad range of etiologies; and a Phase 2 trial in AKI expected to be initiated in the second quarter of 2024. We also have additional preclinical product candidates that will need to progress through IND application enabling studies prior to clinical development. None of our product candidates have advanced into a late** - stage ~~company~~ **or pivotal trials for the indications for which we are pursuing development** . Our ~~operations~~ **ability** to ~~date have been limited to organizing and staffing~~ **generate product revenues, which we do not expect will** ~~our~~ **occur** ~~company~~ **for many years** , **if ever** ~~acquiring rights to intellectual property~~ , ~~business planning, raising capital,~~ **will depend heavily on the successful** ~~developing~~ **development and eventual commercialization of** our ~~technology, identifying potential~~ product candidates ~~, undertaking preclinical studies and~~ **. Although certain of our employees have prior experience with** clinical trials **, regulatory approvals** and manufacturing ~~initial quantities~~ of ~~our~~ **pharmaceutical** products **, we have not previously completed any late- stage or pivotal clinical trials or submitted** ~~and~~ - **an NDA to the FDA or regulatory approval filings to comparable foreign authorities for any product candidate, and Auxora may not be successful in clinical trials and may not receive any regulatory approval. The FDA and other comparable global regulatory authorities can delay, limit or deny approval of a product candidate for many reasons. Any delay in obtaining, or inability to obtain, applicable regulatory approval will delay or harm our ability to successfully commercialize Auxora and harm our business, financial condition, results of operations and prospects. Furthermore, because Auxora is our most advanced product candidate, if our clinical trials of Auxora encounter safety, efficacy or manufacturing problems, development delays, regulatory issues or other problems, our development plans for Auxora and our other** product candidates **in** ~~. Consequently, any predictions you make about our future success or~~ **our pipeline** ~~viability in the absence of the merger may not be as accurate as they~~ could be **significantly impaired** ~~if we had a longer operating history. In addition~~ , ~~as a new~~ **which could harm our** business, ~~we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If the merger fails to close, we would need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We expect our~~ financial condition **,** ~~and operating~~ results ~~to continue to fluctuate significantly from quarter- to- quarter and year- to- year due to a variety~~ of **operations and prospects** ~~factors, many of which are beyond our control~~ . **The success** ~~Accordingly, you should not rely upon the results~~ of **our business, including our ability to finance our company and generate** any **revenue in the** ~~quarterly or annual period as an indication of~~ future ~~operating performance. Risks Related to Product Development~~ , ~~Regulatory Approval and Commercialization Our approaches to the treatment of retinal and corneal diseases are unproven, and we do not know whether we~~ will **primarily** ~~be able to successfully develop any products. GB- 501 is a gene therapy that has never been tested in humans and is designed to be a single intrastromal injection. There are currently no FDA- approved therapies that treat corneal diseases with a single gene therapy treatment. If the merger fails to close, our future success currently depends~~ - **depend** on the successful development **, regulatory approval and commercialization** of **our** product candidates, **which may never occur** ~~primarily GB- 501, based on this novel therapeutic approach~~ . We have not yet **succeeded and may not succeed in** ~~demonstrated~~ **demonstrating** efficacy and safety for ~~GB- 501 or GB- 701 in a pivotal trial or obtained marketing approval of~~ any product candidate ~~. GB~~ **in late** - ~~501~~ **stage clinical trials for regulatory approval or in obtaining marketing approval thereafter. Given our early stage of development, it may be several years, if at all, before we have demonstrated the safety and efficacy of a treatment sufficient to warrant approval for commercialization. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we** may not ~~demonstrate in patients any~~ **be able to generate sufficient revenue to continue** ~~or~~ **our business** ~~all of the therapeutic benefits we believe it may possess~~ . ~~If we~~ **Clinical development is a lengthy, expensive and uncertain process. The results of preclinical studies and early clinical trials** are ~~unsuccessful in our development efforts, we may~~ not **always predictive** ~~be able to advance the development~~ of **future results. Any** ~~GB- 501 or any other~~ product candidate **that** ~~, commercialize products, raise capital, expand our business or continue our operations. If the merger fails to close,~~ we **advance into** ~~would depend heavily on the success of our product candidates. Clinical~~ **clinical** trials ~~of our product candidates~~ may not **achieve favorable results in later** ~~be successful. If we are unable to successfully complete~~ clinical **trials** ~~development of~~ , ~~and obtain marketing approvals for, our product candidates, or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize these product candidates, our business will be materially harmed. We have devoted a significant portion of our financial resources and business efforts to the development of our product candidates for diseases and conditions of the eye. In particular, we have historically invested substantial resources to complete the development of GB- 102 for wet AMD, a program that we terminated in August 2022. We cannot accurately predict when or~~ if any ~~of~~ **,** ~~our~~ - **or** ~~ocular disease product candidates will prove effective or safe in humans or whether these product candidates will~~ receive marketing approval. ~~Our ability to generate product revenues sufficient to achieve profitability will depend heavily on obtaining~~ **The research and development of drugs is extremely risky. Only a small percentage of programs that enter the clinical development process ever receive** marketing approval ~~for, and commercialization of, GB- 501. The success of GB- 501 and GB- 701 will depend on many factors, including: • successful completion of preclinical studies and clinical trials that demonstrate to the satisfaction of the FDA, the EMA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications; • our ability to raise additional capital to fund future clinical trials for GB- 501; • acceptance of our products, if and when approved, by patients, the medical community and third- party payors; • effectively competing with other therapies; • applying for and receiving marketing approvals from applicable regulatory authorities for our product candidates; • scaling up~~

~~our manufacturing processes and capabilities to support additional or larger clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval; • developing, validating and maintaining a commercially viable manufacturing process that is compliant with current good manufacturing practices; • maintaining a continued acceptable safety profile of our products following approval; • obtaining and maintaining coverage and adequate reimbursement from third- party payors; • developing and expanding our sales, marketing and distribution capabilities and launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; • minimizing and managing any delay or disruption to our ongoing or planned clinical trials, and any adverse impacts to the U. S. and global market for pharmaceutical products, including as a result of the ongoing COVID- 19 pandemic; • obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and • protecting our rights in our intellectual property portfolio. If the merger fails to close and we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. We have not yet initiated or completed any Phase 3 clinical trials nor commercialized any pharmaceutical products, which may make it difficult to evaluate our future prospects. Our operations to date have been limited to financing and staffing our company, developing our technology and conducting preclinical research and Phase 1 and Phase 2 clinical trials for our product candidates. We have not yet demonstrated an ability to initiate or complete Phase 3 clinical trials, obtain marketing approvals, manufacture a commercial- scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by clinical- stage biopharmaceutical companies such as ours. Any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. If the merger fails to close, we may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We would eventually need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. If clinical trials of GB- 501 or any other product candidate that we develop fail to demonstrate safety and efficacy to the satisfaction of the FDA, the EMA or other regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be delayed or unable to complete, the development and commercialization of such product candidate .~~ Before obtaining marketing approval from regulatory authorities for the sale of ~~any~~ **our** product ~~candidate~~ **candidates** ~~, including GB- 501 ,~~ we must ~~complete preclinical development and then~~ conduct extensive clinical trials to demonstrate the safety and efficacy of ~~our~~ **the** product ~~candidates~~ **candidate** in humans. Clinical testing is expensive, ~~difficult to design and implement,~~ can take many years to complete and **its outcome** is uncertain ~~as to outcome. A failure of one or more clinical trials can occur at any stage of testing. GB- 501 has not yet been tested in humans, and because it is a gene therapy, it cannot be tested in healthy volunteers, so the first time it will be tested on humans will be in a Phase 3 clinical trial. In addition, because mucopolysaccharidosis type 1 (" MPS1 ") is a rare disease, the number of patients enrolled in the Phase 3 clinical trial will be very small, making it difficult to predict whether the favorable results from such a trial will be repeatable in the larger patient population .~~ Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their ~~products~~ **product candidates** . **The results of preclinical studies and early clinical candidates, ~~Even~~ even those with the same or similar mechanisms of action, may not be predictive of the results of later- stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. While we have previously received results, some preliminary, from one randomized, blinded placebo- controlled trial, one small blinded randomized SOC controlled trial, one small randomized open- label placebo- controlled trial, and one small open- label single site trial, we do not know how Auxora will perform in the ongoing Phase 2 clinical trials or in future clinical trials with larger sample sizes. Results of clinical trials with smaller sample sizes, such as our completed SOC- controlled Phase 2a clinical trial of Auxora in 21 patients with AP and accompanying SIRS plus hypoxemia, can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the features of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. In general, clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the biopharmaceutical industry have suffered setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. To date, we have not completed any late- stage or pivotal clinical trials for any of our product candidates. We cannot guarantee that any clinical trials will be initiated or conducted as planned or completed on schedule, if at all. We also cannot be sure that submission of an IND or similar application will result in the FDA or ~~the~~ other regulatory authority, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Any of these events could cause delays and interruptions in our clinical trials, which could adversely affect our business. We may experience delays in site initiation and patient enrollment, failures to comply with study protocols, delays in the manufacture of our product candidates for clinical testing and other difficulties in starting or completing our clinical trials. Other events that may prevent successful or timely completion of clinical development include: • inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to**

support the initiation or continuation of clinical trials; • delays in reaching a consensus with regulatory agencies, the FDA or foreign regulatory authorities, on trial design or implementation; • delays in reaching agreement on acceptable terms with prospective clinical research organizations (" CROs "), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • delays in identifying, recruiting and training suitable clinical investigators; • delays in obtaining required institutional review board (" IRB ") or independent ethics committee (" IEC ") approval at each clinical trial site; • delays in recruiting suitable patients to participate in our clinical trials; • imposition of a clinical hold by regulatory agencies for a number of reasons, including after review of an IND or amendment or equivalent foreign application or amendment, as a result of a new safety finding that presents unreasonable risk to clinical trial participants, or after a negative finding from an inspection of our clinical trial operations or study sites; • failure by our CROs, other third parties or us to adhere to the trial protocol or good clinical practice (" GCP "); • third- party contractors or clinical investigators becoming debarred or suspended or otherwise penalized by the FDA or other comparable foreign regulatory authorities for violations of applicable regulatory requirements; • delays in the testing, validation, manufacturing and delivery of our product candidates to the treatment sites, including due to supply or manufacturing related delays, being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practices (" cGMP "), regulations or other applicable requirements, or infections or cross- contaminations of our product candidates in the manufacturing process; • delays in having subjects' complete participation in a study or return for post- treatment follow- up; • changes to the clinical trial protocols; • clinical trial sites or subjects deviating from the trial protocol or dropping out of a study; • changes in the SOC on which a clinical development plan was based, which may require new or additional trials; • selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data; • the cost of clinical trials of our product candidates being greater than we anticipate; • clinical trials of our product candidates producing negative or inconclusive results **, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development** of **such product candidates; • transfer of manufacturing processes to larger- scale facilities operated by a contract manufacturing organization, and delays or failure by our such manufacturers or us to make any necessary changes to such manufacturing process; • occurrence of adverse events (" AEs ") associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of an AE in a trial of the same class of agents as our product candidate conducted by other companies; • we have expanded to and plan to conduct a significant portion of our ongoing CARPO trial in India and, to the extent that we conduct clinical trials in foreign countries, the failure of enrolled subjects in foreign countries to adhere to clinical protocol as a result of differences in SOC, provision of healthcare services or cultural customs; • patients in different geographies, including foreign countries, may show differences in clinical outcomes than expected due to differences in underlying disease etiologies or genetic factors; • conducting clinical trials in a foreign country may also present additional administrative burdens or delays associated with foreign regulatory schemes including different requirements for clinical trial protocols; • conducting clinical trials in a foreign country may introduce political and economic risks relevant to such foreign countries; • receiving untimely or unfavorable feedback from applicable regulatory authorities regarding the trial or requests from regulatory authorities to modify the design of a trial; • suspensions or terminations by us, the IRBs (or the IECs) of the institutions at which such trials are being conducted, by the data safety monitoring board (" DSMB "), for such trial or by regulatory authorities due to a number of factors, including those described above; • lack of adequate funding; or • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols. In addition, disruptions caused by the ongoing conflicts between Ukraine and Russia and in the Middle East may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to raise capital, generate revenues from product candidate sales and enter into or maintain collaboration arrangements. For example, if enrollment in a clinical trial is slowed, certain of our expenses related to the trial would not decrease and therefore the overall costs to complete the trial would increase. In addition, if we make manufacturing changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring product candidates to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. One of our product candidates is, and potential** future **product candidates may be, developed for the treatment of a pediatric population, for which safety concerns may be particularly scrutinized by regulatory agencies. Trials involving pediatric populations can be difficult to conduct, can be quite costly and, like other clinical trials, may not yield the anticipated results. In addition, pediatric trials are more dependent on a smaller number of specialized clinical trial sites, which in turn can limit site availability and make the trials more expensive to conduct. In addition, as interest in pediatric indications grows as a result of the RACE Act and other market forces, trial recruitment may become even more difficult due to competition for eligible patients. Moreover, it may be challenging to ensure that pediatric or adolescent patients adhere to clinical trial protocols. Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and an investigator** ~~Phase~~ **has** ~~3~~ **created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of**

the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates. We have expanded to and plan to conduct a significant portion of our ongoing CARPO trial in India, and regulatory authorities may not accept data from such trial or any future clinical trials we conduct outside the United States or the applicable foreign jurisdiction. We have expanded to and plan to conduct a significant portion of our ongoing CARPO trial in India. The acceptance of trial data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable non- U. S. regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from non- U. S. clinical trials are ~~positive~~ **intended to serve as the basis for marketing approval in the United States** , ~~we may~~ **the FDA will generally not approve the application on the basis of non- U. S. data alone unless (i) the data are applicable to the U. S. population and U. S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA' s clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many non- U. S. regulatory authorities** have **similar approval requirements. In addition, such non- U. S. trials would be subject** to ~~commit substantial~~ **the applicable local laws of the non- U. S. jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable non- U. S. regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable non- U. S. regulatory authority does not accept such data or believes that additional data is necessary to supplement such data, it would result in the need for additional trials, which would be costly and** time **- consuming** and **delay aspects of our business plan, and which may result in product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction. Conducting clinical trials outside the United States also exposes us to** additional ~~resources~~ **risks, including risks associated with: • additional foreign regulatory requirements; • foreign exchange fluctuations; • compliance with foreign manufacturing, customs, shipment and storage requirements; • the failure of enrolled subjects in foreign countries** to ~~conducting~~ **adhere to clinical protocol as a result of differences in SOC; • cultural differences in medical practice and clinical research; and • diminished protection of intellectual property in some countries. We depend on enrollment of patients in our clinical trials for our product candidates. If we experience delays or difficulties enrolling patients in our clinical trials, our research and development efforts and business, financial condition, results of operations and prospects could be adversely affected. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients to participate in each study. These trials may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, subject withdrawal from the trial or AEs. These types of developments could cause us to delay the trial or halt** further **development. Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. In addition, there may be limited patient pools from which to draw for clinical studies. In addition to the rarity of some diseases, the eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a clinical trial. Participant enrollment in clinical trials depends on many factors, including: • the size and nature of the patient population; • the severity of the disease under investigation; • eligibility criteria for the trial; • the proximity of patients to clinical sites; • the design of the clinical protocol; • the ability to obtain and maintain research subject consents; • the ability to recruit clinical trial investigators with the appropriate competencies and experience; • the availability of competing clinical trials; • patients' perceptions of risk in traveling to clinical sites (for patients in non- hospitalized clinical trial settings); • the availability of new drugs approved for the indication the clinical trial is investigating; and • clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies. These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost- effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Preliminary, interim and topline data from our clinical trials may change as more participant data become available, and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary, interim or topline data from our** preclinical studies and clinical trials ~~before~~ **, which is based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change as participant enrollment and treatment continues and more data become available. Our data to date is based on a small number of subjects, and as a result, data from additional subjects can have a significant impact on the overall data viewed as a whole. Adverse differences between previous preliminary or interim data and future interim or final data could significantly harm our business prospects. We may also announce topline data following the completion of a preclinical study or clinical trial, which may be subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or**

had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, topline and preliminary data should be viewed with caution until the final data are available. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine to be material or otherwise appropriate information to include in our disclosure. If the interim, top- line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to ~~obtaining --- obtain FDA~~ approval for , and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects. SAEs, undesirable side effects or other unexpected properties of our product candidates could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate. As we continue developing Auxora and initiate clinical trials of our additional product candidates, SAEs, undesirable side effects, relapse of disease or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the SAEs or undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective or in which efficacy is more pronounced or durable. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to our therapies. Because of our planned dose escalation design for our clinical trials, undesirable side effects could also result in an expansion in the size of our clinical trials, increasing the expected costs and timeline of our clinical trials. Additionally, results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, which may stem from our product candidates specifically or may be due to an illness from which the clinical trial subject is suffering. If unacceptable side effects arise in the development of our product candidates such that there is no longer a positive benefit risk, we, the FDA, the IRBs at the institutions in which our trials are conducted or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any ~~of our -~~ or ~~drug~~ all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, and inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Even if we believe our product candidates initially show promise in early clinical trials, side effects of product candidates may only be detectable after they are tested in larger, longer and more extensive clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor . If serious adverse or ~~unacceptable~~ unexpected side effects are identified during ~~the~~ development or after approval (including pursuant to any toxicity studies, including reproductive toxicity studies) and are determined to be attributed to our product candidates, we may be required to develop a Risk Evaluation and Mitigation Strategy (“ REMS ”) to ensure that the benefits of ~~GB~~ treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. Product - ~~501~~ related side effects could also result in potential product liability claims. Any of these occurrences may harm ~~or~~ our business, financial condition, results of operations and prospects. In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such product candidates, a number of potentially significant negative consequences could result, including: • regulatory authorities may suspend, withdraw or limit approvals of such product candidate, or seek an injunction against its manufacture or distribution; • regulatory authorities may require additional warnings on the label, including “ boxed ” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product candidate; • we may be required to create a medication guide outlining the risks of such side effects for distribution to patients; • we may be required to change the way a product candidate is administered or conduct additional clinical trials; • the product candidate may become less competitive; • we may decide to remove the product candidate from the marketplace; and • we may be subject to fines, injunctions or the imposition of civil or criminal penalties. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could seriously harm our business. We may seek special designations by the regulatory authorities to expedite regulatory approvals, but may not be successful in receiving such designations, and even if received, they may not benefit the development and regulatory approval process. We may seek various designations by the regulatory authorities for any product candidates that we develop, such as Fast Track designation or

Breakthrough Therapy designation. If a product candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for Fast Track designation from the FDA. The sponsor of a product candidate with Fast Track designation has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the candidate may be eligible for priority review if the relevant criteria are met. A product candidate with Fast Track designation may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. We have received Fast Track designation for Auxora for the treatment of AP, and we may receive Fast Track designation for other product candidates **in the future; however, we may not experience a faster development process, review or approval compared to conventional FDA approval timelines, and the FDA may still decline to approve Auxora or our other designated product candidates. The FDA may rescind the Fast Track designation if it believes** that ~~we may develop, we may need to abandon~~ **the designation is no longer supported by data from** ~~or~~ **our clinical** ~~limit our~~ development **program or for any other reason. A Breakthrough Therapy is defined by the FDA as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the drug, may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. The designation also includes all of the Fast Track designation benefits, including eligibility for rolling review of an NDA submission. Seeking and obtaining these designations is dependent upon results of our clinical program, and whether and when we may have the data from our clinical programs to support an application to obtain any such designation is uncertain. Even if we do receive the designations we may apply for, we may not experience a faster development process, review or approval compared to conventional FDA or similar foreign regulatory authorities' procedures, as applicable. The FDA or similar foreign regulatory authorities, as applicable, may rescind any granted designations if it believes that the designation is no longer supported by data from our clinical development program. We may seek orphan drug designation for our product candidates, and we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually in the United States, or a patient population greater than 200, 000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user- fee waivers. Similarly, in the European Union, the European Commission grants orphan drug designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan drug designation application. Orphan drug designation is intended to promote the development of drugs that are (1) intended for the diagnosis, prevention or treatment of life- threatening or chronically debilitating conditions; (2) either (a) affecting not more than five in 10, 000 persons in Europe, or (b) when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug; and (3) for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or if such a method exists, the product will be of significant benefit to those affected by the condition). In Europe, orphan drug designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor. We have received orphan drug designation for Auxora for the treatment of AP in the European Union, and we may receive orphan drug designation for other product candidates in the future; however, we may not experience a faster development process, review or approval compared to conventional approval timelines, and the European Commission and EMA may still decline to approve Auxora or our other designated product candidates. The European Commission and EMA may rescind the orphan drug designation if it believes that the designation is no longer supported by data from our clinical development program or for any other reason. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same or similar drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if, at the end of the fifth year, it is established that the drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified. Even if we obtain orphan drug exclusivity for any of our product candidates that obtain approval, that exclusivity may not effectively protect those product candidates from competition because different therapies can be approved for the same condition. Even after an orphan drug is approved, the FDA or comparable foreign authorities can subsequently approve another drug for the same condition if the relevant authority concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug**

may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek orphan drug designation for applicable indications for our product candidates, we may never receive such designations. Even if we do receive such designations, we may not enjoy the benefits of those designations. We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post- marketing requirements, the FDA may seek to withdraw accelerated approval. We may in the future seek an accelerated approval for our one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life- threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that such product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor' s agreement to conduct, in a diligent manner, additional post- approval confirmatory studies to verity and describe the drug' s clinical benefit. If such post- approval studies fail to confirm the drug' s clinical benefit, the FDA may withdraw its approval of the drug. Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e. g., breakthrough therapy designation) for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates would result in a longer time period to commercialization of such product candidates **, if any, could increase the cost of development of such candidates and could harm our competitive position in the marketplace** . ~~If GB~~ **Our product candidates must meet extensive regulatory requirements before they can be commercialized and any regulatory approval may contain limitations or conditions that require substantial additional development expenses or limit our ability to successfully commercialize our product candidates. The clinical development, manufacturing, labeling, storage, record** - ~~501~~ **keeping, advertising, promotion, import, export, marketing and distribution of** ~~or~~ **our** ~~any of our other~~ product candidates are **subject to extensive regulation by** ~~associated with serious adverse events (" SAEs ") or other~~ -- **the FDA** ~~undesirable side effects~~ in ~~clinical trials or have characteristics that~~ **the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we** are **not permitted** ~~unexpected, we may need~~ to **market** ~~abandon their development or limit development to more narrow uses or subpopulations in which the SAEs, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective. There are potential side effects that are related to ocular injection procedures, including intrastromal injections. These side effects are shared by any treatment that uses injection as a means of delivering medication. These can include conjunctival hemorrhage, punctate keratitis, eye pain, conjunctival hyperemia, intraocular pressure rise, intraocular inflammation, retinal detachment and endophthalmitis. Clinical trials by their nature utilize a sample of the potential patient population. However, with a limited number of patients and limited duration of exposure, rare and severe side effects of~~ our product candidates **until we receive regulatory approval from** ~~may only be uncovered when a significantly larger number of patients are exposed to the product. If safety problems occur or are identified after one of our products reaches the market,~~ the FDA ~~, the EMA or other regulatory authorities may require that we amend the labeling of our product, recall our product or even withdraw approval for our product~~ . ~~Moreover, with regard to GB- 501, additional or unexpected adverse side effects could develop, as gene therapy is still a relatively new approach to disease treatment. There~~ -- **The process** ~~also is the potential risk~~ of ~~delayed adverse events following exposure to gene therapy products due to persistent biologic activity of the genetic material or other components of products used to carry the genetic material. Possible adverse side effects that could occur with treatment with gene therapy products include an immunologic reaction early after administration which, while not necessarily adverse to the patient' s health, could substantially limit the effectiveness of~~

~~the treatment. Gene therapy is an emerging field of drug development, which makes it difficult to predict the time and cost of product candidate development and subsequently~~ obtaining regulatory approval ~~. Currently~~ **is expensive** , ~~only a limited number~~ **often takes many years following the commencement** of ~~gene therapy~~ **clinical trials and can vary substantially based upon the type, complexity and novelty of the** ~~products~~ **product candidates involved, as well as the target indications and patient population. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. To date, we** have ~~been~~ **not submitted an NDA or other marketing authorization application to the FDA or similar drug** ~~approved~~ **approval submissions to comparable foreign regulatory authorities for any product candidates. Prior to obtaining approval to commercialize a product candidate** in the United States **or abroad, we or our potential future collaborators must demonstrate with substantial evidence from adequate** and ~~in~~ **well- controlled clinical trials, and to the satisfaction of the FDA or comparable** foreign ~~countries. The future success of GB- 501, a recombinant AAV gene therapy designed to treat corneal clouding caused by MPS1, depends on the successful development of this novel therapeutic approach. The~~ regulatory ~~requirements~~ **authorities,** that **such** ~~govern any novel gene therapy~~ product candidates ~~we develop~~ are **safe** ~~not entirely clear~~ and ~~are subject to change~~ **effective for their intended uses** . ~~The~~ **Even if we believe the preclinical or** clinical **data** ~~study requirements of the FDA and the criteria regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process~~ for ~~novel~~ **our** product candidates **are promising,** such **data** ~~as ours~~ may **not** be **sufficient to support approval by** ~~more expensive and take longer than for other~~ -- **the FDA and comparable foreign regulatory authorities. In particular** , ~~better known or extensively studied~~ **because we are seeking to identify and develop** product candidates **using** ~~. Further, as we are developing novel treatments for diseases in which there is little clinical experience with~~ new **technologies** ~~endpoints and methodologies~~ , there is heightened risk that the FDA or **other regulatory authorities may impose additional requirements prior to granting marketing approval, including enhanced safety studies or monitoring. Furthermore, as more product candidates within a particular class of products proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. The FDA or** comparable foreign regulatory ~~bodies~~ **authorities can delay, limit or deny approval of a product candidate for many reasons, including: • such authorities may disagree with the design or implementation of our clinical trials; • negative or ambiguous results from our clinical trials or results** may not ~~consider~~ **meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval; • serious and unexpected product candidate- related side effects may be experienced by participants in our clinical trials; • serious and unexpected results from preclinical toxicity studies that will be completed in conjunction with late stage clinical trials; • the population studied in** the clinical trial ~~endpoints~~ **may not be sufficiently broad or representative** to **assure safety in** ~~provide clinically meaningful results, and~~ the ~~resulting~~ **full population for which we seek approval; • such authorities may not accept** clinical data **from trials which are conducted at clinical facilities or** ~~and results may be more difficult to analyze. To date, only a limited number of gene therapy products have been approved~~ in **countries where the SOC is potentially different from that of** the United States **; • we may be unable to demonstrate that a product candidate' s clinical** and **other benefits outweigh** ~~foreign countries, which makes it~~ **its** ~~difficult to determine how long it will take~~ **safety risks; • such authorities may disagree with** ~~or~~ **our** ~~how~~ **interpretation of data from preclinical studies or clinical trials; •** ~~much~~ **such** ~~it will cost~~ **authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of an application for regulatory approval or other submissions or** to obtain regulatory ~~approvals~~ **approval in the United States or elsewhere and such authorities may impose requirements** for **additional preclinical studies or clinical trials; • such authorities may disagree regarding the formulation, labeling and / or the specifications of** our product candidates ~~in the United States~~ **; • approval may be granted only** ~~or~~ **for indications that are significantly more limited than what we apply for and / or with** other ~~jurisdictions. Further,~~ **significant restrictions on distribution and use; • such authorities may fail to** ~~approvals~~ **approve** ~~by~~ any ~~ex~~ **required companion diagnostics to be used with our product candidates; • such authorities may find deficiencies in the manufacturing processes or facilities of our or our third** ~~- U. S.~~ **party suppliers or manufacturers with which we or any of our potential future collaborators contract for clinical and commercial supplies; or • the approval policies or** ~~regulatory~~ **regulations** ~~agency may not be indicative~~ of **such authorities** ~~what the FDA~~ may ~~require~~ **significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient** for approval **. With respect to foreign markets** , **approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product candidate testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new products based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Even if we eventually complete clinical trials and receive approval to commercialize** ~~or~~ **our** ~~vice versa~~ **product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, and / or the implementation of a REMS** . ~~Gene therapy~~ **The FDA or the comparable foreign regulatory authority also may approve a product candidate for a more limited indication or patient population than we originally requested or may not approve the labeling that we believe** is **necessary or desirable for the successful commercialization of a product candidate. Manufacturers of our product candidates** ~~an~~ **and** ~~emerging field of drug development that poses many scientific~~ **manufacturers' facilities are also required to comply with cGMP regulations** and other **similar regulatory requirements, which include requirements related** ~~risks. Our lack of experience with gene therapy and the limited patient populations for our newly acquired gene therapy programs may limit our ability~~ to **quality control** ~~be successful or may delay our development efforts. Gene therapy is an~~ **and quality assurance** ~~emerging field of drug development with only a small~~

number of gene replacement therapies having received FDA approval to date. GB- 501 is our first gene therapy program , and it is based entirely on technology that we acquired in March 2022 through our purchase of RainBio, Inc. (" RainBio "). We did not acquire any employees or manufacturing assets from RainBio, only the intellectual property rights that RainBio had in- licensed as well as the preclinical data **corresponding maintenance of records and documentation. Further, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture our product candidates, if approved, and these facilities are subject to continual review and periodic inspections by the FDA and other comparable foreign regulatory authorities for compliance with cGMP regulations and other similar regulatory requirements. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of** that they had generated. We did not acquire any raw materials or finished drug product **candidate and could adversely impact our business, financial condition, results of operations and prospects** . We will need to rely entirely on third- party providers **obtain FDA approval of any proposed product names, including Auxora, and any failure** for - **or delay associated** all aspects of process development, manufacturing, and analytical methods for GB- 501. We have no prior experience with **such** any of these specialty providers, so we may not be able to negotiate acceptable supply terms, including pricing or timing of delivery, if at all. As a result, there are several areas of drug development risk, including translational science, manufacturing processes and materials, safety concerns, regulatory pathway and clinical trial design and execution, which pose particular uncertainty for our gene therapy program given the relatively limited development history of, and our limited prior experience with, gene therapies. Furthermore, the medical community' s understanding of the genetic causes of many diseases continues to evolve and further research may change the medical community' s views on what therapies and approaches are most effective for addressing certain diseases. As we pursue our first gene therapy research program and any subsequent programs, we expect we may need to grow our own gene therapy scientific and technical capabilities through hiring internally and seeking assistance from outside service providers. We believe that gene therapy is an area of significant investment by biotechnology and pharmaceutical companies and that there may be a scarcity of talent available to us in these areas. If we are not able to expand our gene therapy capabilities, we may not be able to develop, in the way that we intend or desire, any of our gene therapy research programs into product candidates. We have not previously conducted any clinical development involving gene therapies and, if and when we are ready to conduct our first gene therapy clinical trial, we will need to build our internal and external capabilities in designing and executing a gene therapy clinical trial. There are many known and unknown risks involved in translating preclinical development of gene therapies to clinical development, including selecting appropriate endpoints and dosage levels for dosing humans based on preclinical data. Many of the indications for which we are pursuing our gene therapy programs have limited natural history data and a limited number of therapies in clinical development, which may make selecting an appropriate endpoint difficult. Furthermore, our gene therapy programs are targeting orphan diseases with relatively small populations, which limits the pool of potential patients for our gene therapy clinical trials. Because gene therapy trials generally require patients who have not previously received any other therapy for the same indication, we will also need to compete for the same group of potential clinical trial patients with our competitors who are also developing therapies for these same indications. If we are unable to initiate and conduct our gene therapy clinical trials in a manner that satisfies our expectations or regulatory requirements, the value of our gene therapy programs may be diminished. Adverse public perception of genetic medicines may negatively impact regulatory approval of, and / or demand for, our potential products. Regulatory approval of and / or demand for our potential products will depend in part on public acceptance of the use of genetic medicine for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that genetic medicines are unsafe, unethical or immoral, and consequently, our products may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop. There have been several significant adverse side effects reported in genetic medicine treatments in the past. SAEs in our clinical trials, or other clinical trials involving gene therapy by us or our competitors, even if not ultimately attributable to the relevant product candidates, and the resulting publicity, could result in increased government regulation, unfavorable public perception and potential regulatory delays in the clinical testing or approval of our product candidates. The COVID- 19 pandemic may, directly or indirectly, adversely affect our business , results of operations and financial condition . **Any name we intend to** Our business could be materially adversely affected, directly or indirectly, by the widespread outbreak of contagious disease, including the ongoing COVID- 19 pandemic. The COVID- 19 pandemic caused us **use** to modify our business practices (including but not limited to curtailing or modifying employee travel, moving to full remote work for **our current** many employees, and cancelling physical participation in meetings, events and conferences). The majority of our - **or** office- based employees have been working from home since March 2020. Further, we decommissioned our laboratories in Baltimore, MD in October 2022 and the lease for our administrative offices in Redwood City, California expired on January 31, 2023, resulting in the need for all of our employees to work remotely, which exposes us to greater risks related to cybersecurity and our information technologies systems. In addition, we have experienced and will continue to experience disruptions to our business operations resulting from quarantines, self- isolations and other restrictions on the ability of our employees to perform their jobs. The COVID- 19 pandemic has disrupted business operations. The extent and severity of the impact on our business and clinical trials will be determined largely by the extent of future disruptions in the supply chains for GB- 501 and our future product candidates and delays in **will require approval from** the **FDA regardless of whether we have secured a formal trademark registration from the United States Patent and Trademark Office (" USPTO "). The FDA typically** conduct **conducts a review** of current **proposed product names, including** and - **an evaluation of** future clinical trials. Further, our ability to conduct our future clinical trials may be adversely affected, directly or indirectly, by the **potential** COVID- 19 pandemic, which has been known to cause disruptions in the ability to monitor patients in person due to clinics and hospitals closing sites or diverting the resources that are necessary to conduct clinical trials to care for **confusion with** COVID- 19 patients. Further, our

~~suppliers, vendors and manufacturing and clinical trial partners have been adversely affected by the COVID- 19 pandemic, including by adversely impacting the ability of their~~ **other product names** ~~employees to get to their places of work and maintain the continuity of their on- site operations~~. **The** ~~In addition, the impact of the COVID- 19 pandemic on the operations of the~~ FDA ~~and~~ **may also object to a product name if it believes** ~~other~~ **the name inappropriately implies medical claims** ~~health authorities may delay potential approvals of GB- 501 and our~~ **or** ~~future~~ **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. ~~The COVID- 19 pandemic has also impacted~~ **If we adopt alternative names, we would lose any goodwill or** ~~and~~ **brand** ~~may further impact the global economic~~ **recognition developed for previously used names** and ~~capital markets~~ **marks as well as the benefit of our 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** ~~, including by negatively impacting capital markets~~ **not infringe 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 ~~may adversely affect our business, liquidity and access to capital. We could~~ **would limit** ~~experience any of a number of possible unforeseen events in connection with our future clinical trials, potential marketing approval or~~ **our ability to** ~~commercialization~~ **commercialize** ~~of~~ our product candidates ~~could be delayed or prevented~~. **Even if** ~~If the merger fails to close,~~ we ~~may experience numerous unforeseen events in connection with our future clinical trials that could delay or prevent our ability to~~ receive ~~marketing~~ **regulatory** approval ~~or for commercialize~~ **any of** our ~~ocular disease~~ product candidates **, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally,** ~~or~~ **our** ~~any other~~ product candidates ~~that we may develop~~, **if approved** ~~including: • clinical trials of our product candidates may not produce statistically significant~~, **could be subject** ~~positive results, and we may decide, or regulators may require us,~~ to **labeling** ~~conduct additional clinical trials or amend~~ **and** ~~product development programs, or abandon product development programs entirely; • the~~ **other restrictions and market withdrawal and** ~~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~~ **subject to penalties if** we ~~anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate; • our contractors may~~ fail to comply with regulatory requirements or **experience unanticipated problems with** ~~meet their obligations to us in a timely manner, or~~ **our** ~~at all;~~ **• product candidates. If the FDA, EMA or any other comparable foreign** ~~regulators~~ **regulatory authority approves any of** ~~or~~ **our** ~~institutional review boards may not authorize us~~ **product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping** ~~or~~ **for** ~~our investigators~~ **the drug product will be subject** to ~~commence a~~ **extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration requirements and continued compliance with cGMPs and GCP requirements, for any** clinical ~~trial~~ **trials** ~~or~~ **that we** conduct ~~a~~ **post- approval. In addition, any regulatory approvals that we receive for our present or future product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4** clinical ~~trial~~ **trials** ~~at a prospective trial site; • we~~ **and surveillance to monitor the safety and efficacy of the product candidate. The FDA** may ~~experience delays in reaching,~~ **also require REMS as a condition of approval of** ~~or~~ **our product candidates** ~~fail to reach~~, **which could entail requirements** ~~agreement on acceptable clinical trial contracts or~~ **for** ~~clinical trial protocols~~ **long- term patient follow- up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Later discovery of previously unknown problems** with **a product candidate** ~~prospective trial sites; • we may decide, or regulators or institutional review boards may require us, to suspend or terminate clinical research for various reasons~~ , including ~~noncompliance~~ **AEs of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply** with regulatory requirements ~~or a finding that~~ **, may result in, among** ~~the~~ **other things:** ~~participants are being exposed to unacceptable health risks; •~~ **restrictions on** ~~the cost of clinical trials of our product candidates may be greater than we anticipate; and • the supply or~~ **our ability** ~~quality of our clinical trial material or other materials necessary~~ to conduct clinical trials ~~of~~ **, including full** ~~our~~ **or partial clinical holds on ongoing or planned trials; • restrictions on the marketing or manufacturing of the product candidate, withdrawal of the product candidate from the market, or voluntary or mandatory product candidate recalls; • fines, untitled or warning letters or holds on clinical trials; • refusal by the FDA, the EMA or any other comparable foreign regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product candidate approvals; • product candidate seizure or detention, or refusal to permit the import or export of** product candidates **; and • injunctions or the imposition of civil or criminal penalties. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above** may **inhibit** ~~be insufficient or~~ **our** ~~inadequate~~ **or our collaborators' ability to commercialize our product candidates, and harm our business, financial condition, results of operations and prospects** . ~~If we~~ **Manufacturers and manufacturers' facilities** are required to ~~conduct additional clinical trials or~~ **comply with extensive FDA and** other **regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, other marketing application and previous responses to inspectional observations made by regulatory authorities. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action,**

either in the United States or abroad. If we are slow or unable to adapt to changes in ~~testing~~ existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. If any of our product candidates ~~beyond~~ are approved and we are found to have improperly promoted off- label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that ~~we currently foresee~~ may be made about prescription products , such as ~~if we are unable to successfully complete clinical trials of~~ our product candidates ~~or other testing~~ , if ~~the results of these trials~~ approved. In particular, a product may not be promoted ~~or for tests~~ uses that are not ~~favorable~~ approved by the FDA or such ~~are only modestly favorable or if there~~ other regulatory agencies as reflected ~~are safety concerns, we may: • be delayed~~ in ~~obtaining or unable to obtain~~ the product' s approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off- label uses, we may become subject to significant liability. The U. S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off- label use and has enjoined several companies from engaging in off- label promotion. The government has also required that companies enter into consent decrees ~~our~~ or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which could adversely affect our business, financial condition, results of operations and prospects. Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, or approved or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA' s ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA' s ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies such as the EMA, following its relocation to Amsterdam and corresponding staff changes, that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown or slowdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. We may not identify or discover other product candidates and may fail to capitalize on our proprietary platform or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success. Our business depends upon our ability to identify, develop and commercialize product candidates. A key element of our strategy is to discover and develop additional product candidates based upon our CRAC channel inhibitor science. We are seeking to do so through our internal research programs, and may also explore strategic collaborations for the discovery of new product candidates. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. In addition, targets for different indications may require changes to our manufacturing processes, which may slow down development or make it impossible to manufacture our product candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following: • the research methodology or technology platform used may not be successful in identifying potential product candidates; • competitors may develop alternatives ~~obtain approval for indications or patient populations~~ that render ~~are not as broad as intended or~~ our ~~desired~~ product candidates obsolete or less attractive ; • ~~obtain approval with labeling~~ we may choose to cease development if we determine that clinical results do not show promise ~~includes significant use or distribution restrictions or safety warnings~~ ; • ~~be subject to additional post- marketing testing requirements; or • have the product removed from the market after obtaining marketing approval. Our product development costs would also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials would begin as expected, would need to be restructured or would be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our~~ product candidates ~~or allow~~ we develop may nevertheless be covered by third parties' patents ~~our~~ or ~~competitors to bring~~ other exclusive rights; • a ~~products~~ product candidate may be shown to have harmful side effects ~~market before we do and impair our~~ or ~~ability~~ other characteristics that indicate it is unlikely to ~~successfully commercialize~~ be effective ~~our~~ or otherwise does not meet applicable regulatory criteria; and • a product candidate may not be accepted as safe and effective by patients, the medical community or third- party payors. Because we have limited resources, we must choose to pursue and fund the development of specific types of treatment, or treatment for a specific indication, and we may forego or delay pursuit of opportunities with certain programs or product candidates ~~. We could experience delays or difficulties in the enrollment of patients in clinical trials, our~~ or ~~receipt of necessary regulatory approvals could be delayed or prevented. We may not be able to initiate clinical trials~~ for ~~GB- 501 or our other product candidates that we may develop if we~~

~~are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the EMA or similar regulatory authorities outside the United States. Although there is a significant prevalence of disease in the areas of ophthalmology in which we are focused, we may nonetheless experience unanticipated difficulty with patient enrollment. A variety of factors affect patient enrollment, including: • the prevalence and severity of the ophthalmic disease or condition under investigation; • the eligibility criteria for the trial in question; • the perceived risks and benefits of the product candidate under study; • the perceived risks and benefits of switching patients from treatment with eye drops to intravitreal therapy, in the case of certain glaucoma patients; • the efforts to facilitate timely enrollment in clinical trials; • any delay or disruption to enrollment or attendance for injections, including as a result of the ongoing COVID- 19 pandemic; • the patient referral practices of physicians; • the ability to monitor patients adequately during and after treatment; • the proximity and availability of experienced clinical trial sites for prospective patients; • the conduct of clinical trials by competitors for product candidates that treat the same indications as our product candidates; and • the lack of adequate compensation for prospective patients. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and 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 **estimates regarding the potential** ~~resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable~~ market **for our** ~~opportunities. Our spending on current and future research and development programs and~~ product candidates **could be inaccurate, and if** ~~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 **strategic** collaboration, licensing ~~,~~ **or** other ~~royalty~~ arrangements ~~, or strategic transactions~~ in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. **Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement. If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate. Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop.** We **face an inherent risk of product liability exposure related to the testing of our product candidate programs in clinical trials and** may ~~need~~ **face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against claims that any such product candidate programs caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any product candidate that we may develop; • loss of revenue; • substantial monetary awards to trial participants or patients; • significant time and costs to defend the related litigation; • withdrawal of clinical trial participants; • increased insurance costs; • the inability to commercialize any product candidate that we may develop; and • injury to our reputation and significant negative media attention. Any such outcomes could adversely affect our business, financial condition, results of operations and prospects. Risks Related to Manufacturing, Commercialization and Reliance on Third Parties We rely on third parties** to conduct **and perform most of our research, preclinical studies and clinical trials. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements, fail to meet projected clinical trial enrollment schedules or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects. We do not have the ability to conduct most aspects of our preclinical studies or clinical trials in-house. As a result, we are and expect to remain dependent on third parties to conduct or otherwise support our ongoing clinical trials and any** future clinical trials ~~for~~ **of our** product candidates ~~at sites outside~~ **. Specifically, CROs, clinical investigators, and consultants play a significant role in the conduct** of ~~the~~ **these trials** ~~United States,~~ and **the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by** the FDA **,** ~~may not accept data from trials conducted in such locations. Although~~ the ~~FDA may accept data from~~ **Competent Authorities of the member states of the EEA, and comparable foreign regulatory authorities for all of our product candidates in** clinical **development. Regulatory authorities enforce these GCP requirements through periodic inspections of** ~~trials~~ **trial sponsors** ~~conducted outside the United States~~ , ~~acceptance of this data is subject to conditions imposed by the FDA. For example, the~~ clinical trial ~~must be well- designed and conducted and performed by qualified~~ investigators ~~in accordance with ethical principles. 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 applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U. S. laws and regulations. If the FDA does not accept the data from any 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 delay or permanently halt our development of the applicable product candidates. Other risks inherent in conducting international clinical trials include: • foreign regulatory requirements that could~~

~~restrict or limit our ability to conduct our clinical trials; • administrative burdens of conducting clinical trials under multiple sets of foreign regulations; • failure of enrolled patients to adhere to clinical protocols as a result of differences in healthcare services or cultural customs; • foreign exchange fluctuations; • diminished protection of intellectual property in some countries; and • political and economic risks relevant to foreign countries. The FDA and other regulatory agencies have demonstrated caution in their regulation of gene therapy treatments. Ethical and legal concerns about gene therapy and genetic testing may result in additional regulations or restrictions on the development and commercialization of our product candidates, which may be difficult to predict. The FDA and other regulatory agencies at both the federal and state level in the United States, U. S. congressional committees, and foreign governments, have expressed interest in further regulating the biotechnology industry, including gene therapy and genetic testing. Any such further regulation may delay or prevent commercialization of some or all of our product candidates. Regulatory requirements in the United States and abroad governing gene therapy products have changed frequently and may continue to change in the future. In addition to the FDA, the Institutional Biosafety Committee and institutional review boards, or IRBs, of each institution at which we conduct or will conduct our planned clinical trials, would need to review the proposed~~ clinical trial ~~to assess the safety~~ **sites. If we or any** of ~~the~~ **our CROs or clinical** trial ~~. Within the FDA, the Office of Tissues and Advanced Therapies (" OTAT ") within the Center for Biologics Evaluation and Research (" CBER ") consolidates the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee advises CBER on its~~ **sites fail** ~~review. Adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other oversight 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 or trials, 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 product candidates, we will be required to consult with these regulatory and advisory groups and~~ comply with applicable **GCP requirements** ~~guidelines. If we fail to do so~~ , ~~we~~ **the data generated in our clinical trials** may be **deemed unreliable, and the FDA or comparable foreign regulatory authorities may** ~~required~~ - **require us** to **perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with investigational product produced under cGMP regulations (and similar foreign requirements). Our failure to comply with these regulations may require us to stop and / or repeat clinical trials, which would** delay **the marketing** ~~or discontinue development of such product candidates. These additional processes may result in a review and~~ approval process ~~that is longer than we otherwise would have expected~~ . **CROs,** ~~Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete~~ clinical ~~trials~~ - **trial investigators** ~~and commercialize our~~ - **or** ~~current and future product candidates in a timely manner, if at all. In the ordinary course of our business, we collect, store and transmit confidential information, including intellectual property, proprietary business information, health information and personal information. Despite the implementation of security measures, our internal computer systems, and those of our contract research organizations, or CROs, and~~ other third parties on which we rely **may not devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines** , **adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow- up information on subjects enrolled in such clinical trials unless we** are ~~vulnerable~~ **able** to ~~damage~~ **transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trials may serve as scientific advisors or consultants to us** from **time to time** ~~computer viruses, unauthorized access, cyberattacks, natural disasters, fire, terrorism, war~~ and **may receive cash or equity compensation** ~~telecommunication and electrical failures. Cyberattacks are increasing~~ in **connection with such** ~~their frequency, sophistication and intensity. Cyberattacks could include the deployment of harmful malware, denial- of- service~~ **services** ~~attacks, social engineering~~ **. If these relationships** and **any related compensation result in perceived or actual conflicts of interest, or** ~~other~~ -- **the** ~~means to~~ **FDA or any comparable foreign regulatory authority concludes that the financial relationship may have** ~~affect~~ **affected** ~~service reliability and threaten~~ the ~~confidentiality~~ **interpretation of the trial** , **the** integrity ~~and availability~~ of ~~information. Significant disruptions of our information technology systems or security breaches could adversely affect our business operations and / or result in the loss, misappropriation, and / or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other~~ -- **the** ~~intellectual property, proprietary business information~~ **data generated at the applicable clinical trial site may be questioned** and ~~personal information)~~ **the utility of the clinical trial itself may be jeopardized** , ~~and~~ **which** could result in ~~financial, legal, business and reputational harm to~~ **the delay or rejection of any marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent** us **from commercializing our product candidates** . If **any of** ~~such disruptions were to occur~~ -- **our** ~~and cause interruptions in~~ **relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms,** ~~our~~ - **or at all** ~~operations, it could result in a material disruption of our product development programs~~ . **Further** ~~For example~~ , **under certain circumstances,** ~~the~~ **these** ~~loss of~~ **third parties may terminate their agreements with us upon as little as 30 days prior written notice. Entering into arrangements with alternative CROs,** clinical trial **investigators or other third parties involves additional cost and requires management focus and time, in addition to requiring a transition period when a new CRO, clinical trial investigator or other third party begins work. If third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory**

requirements or for other reasons, any clinical trials such third parties are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed. In addition, with respect to investigator- sponsored trials that are being conducting and may be conducted in the future, we do not and would not control the design or conduct of these trials, and it is possible that the FDA will not view these investigator- sponsored trials as providing adequate support for future clinical trials or market approval, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. We expect that such arrangements will provide us certain information rights with respect to the investigator- sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory submissions, resulting from the investigator- sponsored trials. However, we would not have control over the timing and reporting of the data from ~~completed~~ **investigator- sponsored trials** , ~~ongoing or~~ **nor** ~~planned~~ **would we own the data from the investigator- sponsored trials. If we are unable to confirm or replicate the results from the investigator- sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the firsthand knowledge we might have gained had the investigator- sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future** clinical trials ~~could result in delays in~~ **ourselves may be adversely affected. The investigators may design clinical trials with clinical endpoints that are more difficult to achieve,** ~~our~~ **or in other ways that** ~~regulatory approval efforts and significantly~~ increase ~~our costs~~ **the risk of negative clinical trial results compared** to ~~recover~~ **clinical trials that we may design on** ~~or~~ **our own** ~~reproduce the data~~ . ~~Further, the COVID~~ **Negative results in investigator** - **sponsored** ~~19 pandemic has resulted in a significant number of our employees and partners working remotely, which increases the risk of a data breach or issues with data and cybersecurity. To the extent that any disruption or security breach results in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our future product candidates could be delayed. In addition, our remediation efforts may not be successful. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information. Moreover, if a computer security breach affects our systems or results in the unauthorized access, use or disclosure of personal information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media and / or affected individuals pursuant to various federal, state and international privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996 (" HIPAA ") as amended by the Health Information Technology for Economic and Clinical~~ **clinical trials** ~~Health Act of 2009 (" HITECH ") and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. We would also be exposed to a risk of loss or litigation and potential liability under laws, regulations and contracts that protect the privacy and security of personal information. As described below in " We are subject to stringent and changing privacy laws, regulations and standards as well as contractual obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could harm our reputation, subject us to significant fines and liability, or otherwise adversely affect our business or prospects, " the California Consumer Privacy Act (" CCPA ") provides a private right of action for security breaches, which could lead to some form of remedy including regulatory scrutiny, fines, private right of action settlements, and other consequences. The financial exposure from the events referenced above could either not be insured against or not be fully covered through any insurance that we may maintain, and there can be no assurance that the limitations of liability in any of our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above. Any of the foregoing~~ could have a material adverse effect on our **efforts** ~~business, reputation, results of operations, financial condition and prospects. Risks Related~~ to **obtain regulatory approval for our product candidates and the public perception of our product candidates. Additionally, the FDA may disagree with the sufficiency of our right of reference to the preclinical or clinical data generated by these investigator- sponsored trials, or our interpretation of preclinical,** ~~Manufacturing~~ **manufacturing or clinical data from these investigator-** sponsored **trials** ~~database,ClinicalTrials.gov,within specified timeframes.Failure to do so can result in fines,adverse publicity and civil and criminal sanctions~~ .If ~~we engage~~ **so,the FDA may require us to obtain and submit additional preclinical or clinical data.Furthermore,these** third parties ~~and they~~ **may also have relationships with other entities,some of which may be our competitors.If these third parties** do not successfully carry out their contractual duties,meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols,we will not be able to obtain,or may be delayed in obtaining,marketing approvals for our product candidates and will not be able to,or may be delayed in our efforts to,successfully commercialize our product candidates. ~~Risks Related to Our Intellectual Property We own and exclusively license a number of U.S.~~ We ~~currently~~ **contract with third parties for the manufacturing and supply of certain goods and services for our product candidates for use in preclinical studies and clinical trials, which supply may become limited or interrupted or may not be of satisfactory quality and quantity. We do not have any manufacturing facilities. We produce in our laboratory relatively small quantities of product for evaluation in our research programs. We** rely on third parties for the ~~production~~ **manufacture** of ~~both~~ **most** of our product candidates **for preclinical testing and all of our product candidates for clinical testing and we will continue to rely on such third parties for commercial manufacture if any of our product candidates are approved. We currently have limited manufacturing arrangements for preclinical and clinical trial materials for each of our product candidates, including Auxora, and one**

component of the latter is provided by a single source supplier in China, and will continue to be for the intermediate future. In addition, our single source supplier in China and any other foreign suppliers we may utilize in the future may be subject to U. S. legislation, including the proposed BIOSECURE Act, sanctions, trade restrictions and other foreign regulatory requirements, which may limit, delay, prevent or impair our ability to obtain preclinical and clinical trial materials for our product candidates . This ~~could~~ **reliance** ~~increase~~ **increases** the risk that we will not have sufficient quantities of our product candidates **or products, if approved,** or such quantities at an acceptable cost **or quality** , which could delay, prevent or impair our development or commercialization efforts. **Furthermore, all entities involved in the preparation of product candidates for clinical trials or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing.** We ~~currently rely~~ **or our contract manufacturers must supply all necessary documentation in support of an NDA** on **a timely basis and must adhere to the FDA' s GLP regulations and cGMP regulations enforced by the FDA through its facilities inspection program. Comparable foreign regulatory authorities may require compliance with similar requirements. Our facilities and quality systems, and those of our third- party contract manufacturers, must pass a pre- approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product candidates. We do not control the manufacturing activities of, and are completely dependent on, our contract manufacturers for compliance with cGMP regulations, although the FDA will hold us responsible for any such non- compliance with respect to our product candidates and any future approved products. In the event that any of our contracted** third parties **fails to comply with such requirements or to perform their obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted** for ~~the~~ **other** ~~production of GB~~ **reasons, including due to the ongoing conflicts between Ukraine and Russia and in the Middle East or other geopolitical or macroeconomic, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third** ~~- 501 and GB~~ **party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of a third** - **party** ~~701. While we believe that our existing manufacturing partners have facilities that will be sufficient to meet our requirements for manufacturing GB- 501 and GB- 701, we may in the future need to rely on additional contract~~ **contractor** ~~development~~ **could require significant effort** and ~~manufacturing organizations (" CDMOs ") for~~ **expertise because there may be a limited number of qualified replacements. In** some ~~aspects of~~ **cases,** the **technical skills or technology required to** manufacture **a certain aspect** of our product candidates ~~. Reliance on~~ **may be unique or proprietary to the** third ~~parties~~ **- party performing such process and we may have difficulty transferring such skills** ~~for -~~ **or** ~~aspects of the supply~~ **technology to another third- party and a feasible alternative may not exist. In addition, certain** of our product candidates ~~entails additional risks~~ **and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if we attempt to establish new third- party arrangements for these product candidates or methods. If we are required to or voluntarily change a third- party contractor for any reason, we will be required to verify that the new third party maintains facilities, processes and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget. Our or a third- party' s failure to execute on our manufacturing and supply requirements, do so on commercially reasonable terms and comply with cGMP could adversely affect our business in a number of ways** , including: • ~~lack~~ **in the event** of ~~direct control over regulatory compliance and quality assurance~~ **approval, to initiate or continue clinical trials of our product candidates** ; • ~~the possible misappropriation of~~ **delays in submitting regulatory applications,** ~~our -~~ **or** ~~proprietary information~~ **receiving marketing approvals** , ~~including~~ **for** our **product candidates** ~~trade secrets and know- how~~ ; • **loss** ~~the possible breach~~ of ~~an agreement by~~ the ~~third party~~ **cooperation of future collaborators** , ~~and~~ • **subjecting** ~~the possible termination or~~ **our** ~~nonrenewal of an agreement by the third party at a time that is costly or inconvenient for -~~ **or any** ~~us. We, or our~~ third- party ~~suppliers or CDMOs, may not be able to comply with quality assurance standards, current good~~ manufacturing **facilities** ~~practices regulations or similar regulatory requirements outside the United States. If we or our CDMOs cannot successfully manufacture material that conforms~~ to **additional inspections by** ~~our specifications and the strict regulatory requirements of the FDA and comparable~~ regulatory authorities **;** ~~in other jurisdictions, if the quality and accuracy of the manufacturing and quality control data is compromised due to failure to adhere to protocols~~ or **•** ~~to regulatory~~ requirements ~~or if we or our CDMOs fail~~ to **cease development** ~~maintain a compliance status acceptable~~ to **market** ~~the FDA or comparable regulatory authorities in other jurisdictions, we may not be able to secure~~ and **commercialize** ~~/ or maintain regulatory approval for~~ our product candidates ~~. In addition~~ , ~~we or our CDMOs must maintain adequate quality control, quality assurance and -~~ **an** ~~qualified personnel. If we or our CDMOs cannot maintain a compliance status acceptable to the FDA or a comparable regulatory authority in another jurisdiction, we may need to find alternative manufacturing facilities, which would significantly impact our ability~~ **inability** to **meet commercial demands** ~~develop, obtain regulatory approval~~ for ~~or~~ **our** ~~market~~ **current** ~~our -~~ **or any other future** product candidates, if approved. Any **approved** ~~failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our~~ product candidates ~~and that obtained approvals could be revoked, which would adversely affect our business and reputation. Our failure, or the failure of our suppliers or CDMOs, to comply with applicable regulations could result in sanctions being imposed on us, including clinical~~

holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates. The same risks, however, would also apply to any internal manufacturing facilities, should we in the future decide to build internal manufacturing capacity. Our potential future dependence upon others for the manufacture of our product candidates may **fail** adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis. The manufacture of our product development candidates requires outsourced, custom manufacturing and we may encounter difficulties in production, particularly with respect to formulation, process development or scaling up of our manufacturing capabilities. If we, or our CDMOs, encounter such difficulties, our ability to provide supply of our product candidates for preclinical studies, clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure. As product candidates are developed, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned preclinical studies or future clinical trials. Any of these challenges could delay completion of preclinical studies or clinical trials, require bridging studies or trials, or the repetition of one or more studies or trials, increase development costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and growth prospects. The competition for gene therapy contract development, manufacturing and testing services is intense. Additionally, these manufacturers do not have experience producing our product candidates at commercial levels and may not achieve the necessary regulatory approvals or produce our product candidates at the quality, quantities, locations and timing needed to support commercialization. We do not currently plan to independently manufacture the gene therapy material for our planned clinical programs. We currently rely, and expect to continue to rely, on third parties for the production of our preclinical study and planned clinical trial materials, including the materials used to administer our product candidates and, therefore, we can control only certain aspects of their activities. The competition for gene therapy contract development, manufacturing and testing is intense. Reliance on third- party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves, including but not limited to potential competition from other gene therapy companies for the use of such third- party manufacturers. We have no experience manufacturing any of our product candidates at a commercial scale. We, or our CDMOs, may be unable to successfully scale up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any. In order to conduct clinical trials of, and commercialize, our product candidates, we would need to manufacture them - **the degree** in large quantities. We may, in the future, establish and operate our own manufacturing facility, which would require significant amounts of additional capital and adequate personnel infrastructure. We, or any manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost- effective manner, or at all. In addition, quality issues may arise during scale- up activities. If we, or any manufacturing partners, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. Our current operations are conducted entirely remotely, and we or the third parties upon whom we depend, may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. We no longer occupy our facilities located in Baltimore, Maryland and Redwood City, California, and our remaining employees all work remotely. Any unplanned event, such as earthquake, flood, fire, explosion, extreme weather condition, medical epidemic or pandemic, including COVID- 19, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to remotely access our systems or telecommunications or fully utilize the manufacturing facilities of our CDMOs, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these systems or CDMO facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, operating results and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our critical infrastructure, such as the manufacturing facilities of our CDMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. In addition, the long- term effects of climate change on general economic conditions, and the pharmaceutical industry in particular, are unclear and may heighten or intensify existing risk of natural disasters. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If the manufacturing facilities of our CDMOs are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption could have a material and adverse effect on our business, financial condition, operating results and prospects. Risks Related to Commercialization GB- 501 or any of our product candidates that receives marketing approval may fail to gain market acceptance by physicians, patients, **hospitals, healthcare payors and others in the medical community necessary for commercial success. If any of our product candidates receives marketing approval, they may nonetheless fail to gain**

sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. Our CRAC channel inhibitors are a relatively novel technology, and no CRAC channel inhibitor- based therapy has been approved to date. Public perception may be influenced by third- party ~~payors~~ **claims, such as claims that CRAC channel inhibitors are unsafe, ineffective** and ~~others in~~ **, consequently, our approach may not gain the acceptance of the public or** the medical community. **The degree of** ~~We have not received marketing --- market acceptance approval and have not commercially launched GB- 501 or any~~ of our product candidates **, if approved** ~~and cannot yet accurately predict whether it or they will gain market acceptance and become commercially successful. The degree of market acceptance of GB- 501 or any product candidate~~ for **commercial sale,** ~~which we obtain marketing approval~~ will depend on a number of factors, including: • ~~the~~ efficacy and potential advantages compared to alternative treatments; • our ability to offer our ~~products~~ **product candidates** for sale at competitive prices ~~, particularly in light~~ **; • convenience and ease** of **administration compared to** ~~the lower cost of~~ alternative treatments ~~; • the clinical indications for which the product is approved; • the convenience and ease of administration compared to alternative treatments, including the retention of any of our products as preferred treatment by patients and doctors~~ ; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • the **availability of coverage and adequate reimbursement by third- party payors, including government payors, for our products, if approved by applicable regulatory authorities; • the** strength of ~~our~~ marketing and distribution support; **and** • the ~~timing~~ **prevalence and severity** of ~~market introduction of competitive~~ **any side effects. For example, Auxora is an injectable emulsion drug** ~~products~~ **product** ~~; • the availability~~ **that must be administered intravenously over four hours, and this dosing regimen may be inconvenient for physicians or patients. If our product candidates do not achieve an adequate level** of **acceptance, we may not generate significant product revenue and we may not become profitable. We may not be able to successfully commercialize our product candidates due to unfavorable pricing regulations or** third- party coverage and ~~adequate~~ reimbursement **policies, which could** ~~; • the prevalence and severity of any side effects; and • any restrictions on the use of our products together with other medications. Our assessment of the potential market --~~ **make** ~~opportunity for GB- 501 and our other product candidates is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. 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. If the actual market for GB- 501 or any of our product candidates is smaller than we expect, our product revenue may be limited, and~~ it ~~may be more~~ difficult for us to **sell** ~~achieve or maintain profitability. If we are unable to secure a partner that can establish and maintain adequate sales, marketing and distribution capabilities, we may not be successful in commercializing any of~~ our product candidates ~~if and when they~~ **profitably. Patients who** are **prescribed medications** ~~approved. If we are unable to establish and maintain our own adequate sales, marketing and distribution capabilities, we may not be successful in commercializing our other product candidates if and when they are approved. We have no experience in the sales, marketing and distribution of drug and device products, or in building a commercial team to do so. Furthermore, we lack sufficient capital resources to complete development of GB- 501 without a partner, and we will be dependent on such partner, should we secure one,~~ for the **treatment** ~~successful sales, marketing and distribution~~ of ~~GB- 501. To achieve commercial success for any other~~ **their conditions** ~~product candidate for which we obtain marketing approval~~ , ~~we will need to establish~~ and ~~maintain adequate sales, marketing and distribution capabilities, either ourselves or through collaborations or other~~ **their prescribing physicians** ~~arrangements with third parties. If any of our product candidates are approved for marketing~~ , **generally** ~~and our future capital resources permit retention of marketing rights to such products, we would evaluate the attractiveness of commercializing them through our own specialty sales force. Alternatively, we may~~ rely on ~~a network of independent distributors across the United States to sell such products. We expect that a direct sales force may be required to effectively market and sell such products. We cannot be certain when, if ever, we would recognize revenue from commercialization of our product candidates in any international market. If we decide to commercialize our potential products outside of the United States, we would expect to utilize a variety of collaboration, distribution and other marketing arrangements with one or more third parties. These may include independent distributors, pharmaceutical companies or our own direct sales organization. There are risks involved with both establishing our own sales, marketing, and distribution capabilities and with entering into arrangements with third parties to perform these services. We may not be successful in entering into arrangements with third parties to sell, market and distribute our products or may be unable to do so on terms that are most beneficial to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to market, sell and distribute our products effectively. Our product revenues and our profitability, if any, under third- party collaboration, distribution or other marketing arrangements may also be lower than if we were to sell, market and distribute a product ourselves. On the other hand, recruiting and training a sales force is expensive and time- consuming and could delay any product launch. If the commercial launch of any product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Other factors that may inhibit our efforts to commercialize products on our own include: • our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to use or prescribe our products; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and • unforeseen costs and expenses associated with creating an independent sales and marketing organization. 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 our product candidates. We face substantial competition, which may result in others discovering, developing,**

~~or commercializing products before or more successfully than we do. The development and commercialization of new drug and device products is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to our product candidates that we may seek to develop or commercialize. Potential competitors also include 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. Our commercial opportunity 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 our products. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, certain of these products may be available on a biosimilar basis, and our product candidates may not demonstrate sufficient additional clinical benefits to physicians, patients or payors to justify a higher price compared to generic products. In many cases, insurers or other~~ third- party payors ~~, particularly Medicare, seek~~ to ~~encourage~~ **reimburse all or part of the costs associated with** ~~the~~ **those medications. Patients are unlikely to** use **our product candidates unless coverage is provided and reimbursement is adequate to cover all or a significant portion** of ~~biosimilar~~ **the cost of our product candidates. Therefore, coverage and adequate reimbursement are critical to a new product' s acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new** products ~~. Many of the companies against which we~~ **when more established or lower cost therapeutic alternatives** are ~~competing~~ **already available** or **subsequently become available. There is** ~~against which we may compete in the future have significantly --~~ **significant** ~~greater financial resources~~ **uncertainty related to the insurance coverage** and **reimbursement of newly** ~~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~~ **In the United States,** ~~the~~ **there is no uniform policy** ~~pharmaceutical and biotechnology industries may result in even more resources being concentrated~~ among ~~a smaller number of our competitors. Smaller and other 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, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Any product candidate for which we obtain marketing approval may become subject to unfavorable pricing regulations, third- party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business. Our ability to commercialize our product candidates that we may develop successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers, managed care plans and other organizations. Government authorities and~~ third- party payors ~~, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third- party payors are requiring that drug and device companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for GB- 501 or any other product that we commercialize and, even if they are available, the level of reimbursement may not be satisfactory. Inadequate reimbursement may adversely affect the demand for, or the price of, GB- 501 or any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize GB- 501 or any other product candidates for which we obtain marketing approval. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility~~ for coverage and reimbursement does not imply that a drug will..... lower prices than in the United States . Third- party payors often rely upon Medicare coverage policy and payment limitations in setting **reimbursement policies, but also have** their own **methods and approval process apart from Medicare coverage and** reimbursement ~~policies~~ **does not imply that a drug will be paid for** in all cases or at a rate that covers our costs,including research,development, ~~intellectual property,~~ manufacture,sale and distribution expenses.Interim reimbursement levels for new ~~products~~ **drugs** ,if applicable,may also not be sufficient to cover our costs and may not be made permanent.Reimbursement rates may vary according to the use of the ~~product~~ **drug** and the clinical setting in which it is used,may be based on reimbursement levels already set for lower cost ~~products~~ **drugs** and may be incorporated into existing payments for other services.Net prices for ~~products~~ **drugs** may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors ~~,by any future laws limiting drug prices~~ and by any future relaxation of laws that presently restrict imports of ~~product~~ **drugs** from countries where they may be sold at lower prices than in the United **States** . Our inability to promptly obtain coverage and adequate reimbursement rates from both government- funded and private payors for any ~~FDA~~ **approved product candidates that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates and our overall financial condition. Further, coverage policies and third** - **party reimbursement rates may change at any time** ~~approved products that we develop would compromise our ability to generate revenues and become profitable~~ . **Even if favorable** ~~Regulations that govern marketing approvals, pricing,~~ coverage and **reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. Additionally, separate** reimbursement for **the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or**

procedure in which our product is used. Further, from time to time, the Centers for Medicare & Medicaid Services (" CMS ") revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Hospital Outpatient Prospective Payment System, which may result in reduced Medicare payments. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new ~~drug and device~~ products ~~vary widely from country to country~~ . ~~Current~~ **Further, the adoption** and **implementation of any** future ~~legislation may significantly change~~ **governmental cost containment or** ~~the~~ **other** ~~approval requirements~~ **health reform initiative may result** in ~~ways~~ **additional downward pressure on the price** that **we may receive for any approved product** ~~could involve additional costs and cause delays in obtaining approvals~~ . ~~Some~~ **Outside of the United States, many** countries require approval of the sale price of a ~~drug~~ **product** before it can be marketed ~~. In many countries~~ , **and** the pricing review period **only** begins after marketing or product licensing approval is granted **. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Member states are free to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement, and to control the prices and reimbursement levels of pharmaceutical products for human use. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost- effectiveness of a particular product candidate to currently available therapies. To obtain reimbursement or pricing approval in some of these countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidate to other available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, new products are facing increasingly high barriers to entry. In addition, in some countries, cross- border imports from low- priced markets exert a commercial pressure on pricing within a country** . In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product **candidate** in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the ~~revenues~~ - **revenue, if any,** we are able to generate from the sale of the product in that country ~~. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidate to other available therapies~~ . Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if ~~our~~ **such** product candidates obtain marketing approval. ~~Any~~ **If any of our product candidates are approved for marketing and commercialization and we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved. We have no sales, marketing or distribution capabilities or experience. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization, which would be expensive and time consuming, or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved. There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a** product candidate for which we ~~obtain~~ **recruit a sales force and establish** marketing **capabilities is delayed** ~~approval in the United States~~ or **does** ~~in other countries may~~ not ~~be considered medically reasonable and necessary for a specific indication, may not be considered cost- effective by third- party payors, coverage and an adequate level of reimbursement may not be available and reimbursement policies of third- party payors may adversely affect our~~ **occur** ~~ability to sell our product candidates profitably. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we develop. We face an inherent risk of product liability exposure related to the use of our product candidates that we develop in clinical trials. We face an even greater risk~~ for any ~~products~~ **reason,** we ~~develop~~ **would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly,** and ~~sell commercially~~ **our investment would be lost if we cannot retain or reposition our sales and marketing personnel** . If we ~~cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any product candidates that we develop; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • significant costs to defend the related litigation; • substantial monetary awards to trial participants or patients; • loss of revenue; • reduced time and attention of our management to pursue our business strategy; and • the inability to commercialize any products that we develop. We currently hold $ 10 million in product liability insurance coverage, with a per incident limit of $ 250, 000, which may not be adequate to cover all liabilities that we may incur. We will need to increase our insurance coverage as we conduct additional or larger clinical trials and should we eventually realize sales of any product candidate 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. Risks Related to Our Dependence on Third Parties We intend to enter into collaborations with third parties in which they may complete or~~

~~fund the clinical development, secure the regulatory approval, and conduct the commercialization of GB- 501, and may also do so for our other product candidates. If we are unable to secure such our collaborations or they are not successful, we may not be able to capitalize on the market potential of GB- 501 or other product candidates. We may utilize a variety of types of collaboration arrangements with third parties to develop or commercialize GB- 501 and any of our other product candidates, including merger, license, or sale. We also may~~ enter into arrangements with third parties to perform **sales, marketing and distribution services, our product revenue or the profitability of** these ~~services in the United States~~ **product revenue to us are likely to be lower than** if **we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. If** we do not establish **sales and marketing capabilities successfully, either on** our own ~~sales, marketing and distribution capabilities in the United States for~~ **or in** ~~our product candidates or if we determine that such arrangements are otherwise beneficial. We also may seek collaborators for development and commercialization of other product candidates. Our likely collaborators for any sales, marketing, distribution, development, licensing or broader~~ collaboration ~~arrangements include large and mid- size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We are not currently party to any such arrangement. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations that we enter into may pose a number of risks, including the following: • collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations; • collaborators may not perform their obligations as expected; • collaborators may not pursue development and commercialization of our product candidates that receive marketing approval or may elect not to continue or renew development or commercialization programs based on results of clinical trials or other studies, 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 independently develop, or develop~~ with third parties, **we will not be successful in commercializing our product candidates. Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such product candidates outside of the United States, which would limit our ability to realize their full market potential. In order to market any product candidates outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our product candidates will be harmed. Risks Related to Our Industry and Business Operations We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan. Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in- licensing or acquisition of new assets and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We conduct substantially all of our operations at our facility in La Jolla, California. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with certain of our key employees, these employment agreements provide for at- will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain " key person " insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid- level and senior managers as well as junior, mid- level and senior scientific and medical personnel. Dr. Rachel Leheny,**

our Chief Executive Officer and a member of our Board of Directors, and Eric W. Roberts, our Chief Business Officer and a member of our Board of Directors, also provide services for Valence, an investment fund that is one of our significant stockholders. Our Chief Executive Officer and member of our Board of Directors, Dr. Leheny, and our Chief Business Officer and member of our Board of Directors, Mr. Roberts, are the co- founders of Valence Life Sciences (" Valence "), are employed as managing directors of Valence and beneficially own the shares of the company held by Valence. Entities affiliated with Valence together with Dr. Leheny and Mr. Roberts beneficially owned approximately 14. 3 % of our common stock as of March 21, 2024. Although we expect that each of Dr. Leheny and Mr. Roberts will devote on average at least 40 hours per week to our company and remain highly active in our management, they will also continue to devote time to Valence. Because Dr. Leheny and Mr. Roberts are not required to work exclusively for us, their attention to other activities could slow our operations, which could adversely affect our business. In addition, although we do not believe Valence currently has any investments that conflict with our interests, in the future Valence may invest in companies that may compete with us for business opportunities or develop products that **are** ~~compete~~ **competitive** ~~directly or indirectly~~ with ~~our~~ **ours** ~~products~~ **. As a result, Dr. Leheny' s and Mr. Roberts' interests may not be aligned with the interests of** ~~or~~ **our other stockholders, and they may from time to time be incentivized to take certain actions that benefit their other interests and that our other stockholders do not view as being in their interest as investors in our company. We expect to expand our development, regulatory and operational capabilities and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. As of December 31, 2023, we employed 14 full- time employees, seven of whom were primarily engaged in research and development activities. We also engage various consultants that are primarily engaged in research and development activities. As we advance our research and development programs, we may be required to further increase the number of our employees, particularly in the areas of clinical development, quality, regulatory affairs and, if any of 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~~ **receives marketing approval, sales, marketing and distribution. To manage any future growth, we must: • identify, recruit integrate, maintain and motivate additional qualified personnel** ; • **manage our development efforts effectively, including the initiation and conduct of clinical trials for our** product candidates **, both** ~~discovered in collaboration with us may be viewed by our collaborators~~ as ~~competitive with their own~~ **a monotherapy and combination therapy; and • improve our operational, financial and management controls, reporting systems and procedures. Our need to effectively execute our growth strategy requires that we: • discover new** product candidates **, develop the process and analytical methods** ~~or~~ **for** ~~products~~ **IND- enabling studies and regulatory submissions** , ~~which may cause collaborators to cease to devote resources to~~ **complete the required IND- enabling studies for each, and receive approval from the FDA and** ~~the~~ **other** ~~commercialization of our~~ **regulatory authorities to initiate clinical trials for such** product candidates; • ~~a collaborator~~ **manage our clinical trials effectively; • identify, recruit, retain, incentivize and integrate additional employees; • maintain sufficient quantities of drug product for clinical supply and establish manufacturing capabilities or arrangements** with **third- party manufacturers for commercial supply, if and when approved; and • continue to improve our operational, financial and management controls, reports systems and procedures. Our future financial performance and our ability to develop, manufacture and commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day- to- day activities in order to devote a substantial amount of time, to managing these growth activities. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals. Furthermore, the United States is currently experiencing an increasingly competitive labor market and we are uncertain as to the employment environment in the future, or how that environment will impact our workforce, including our ability to hire or retain qualified employees, consultants, contractors or other key personnel to facilitate our growth. We face substantial competition, which may result in others discovering, developing or commercializing product candidates more quickly or** marketing **them** ~~and distribution rights to one or~~ more **successfully than us. The development and commercialization** of **new product candidates is highly competitive. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop therapies for the treatment of acute critical illnesses. Our commercial opportunity could be reduced** ~~our~~ **or eliminated if our competitors develop and commercialize** product candidates that **are safer** ~~achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products; • disagreements with collaborators~~ , **more effective** ~~including disagreements over proprietary rights~~ , ~~contract interpretation~~ **have fewer** or **less severe side effects** ~~the preferred course of development~~ , **are more convenient** ~~might cause delays or termination of the research~~ , ~~development~~ or ~~commercialization of~~ **are less expensive than any** product candidates **that we may develop** ~~, might lead to additional responsibilities for~~ **or** ~~us with respect to~~ **that would render any** product candidates ~~,~~ **that we may develop obsolete or non- competitive. Our competitors also may obtain marketing approval** ~~or~~ **for** ~~might~~ **their products more rapidly than we may obtain approval for ours, which could** result in ~~litigation or~~ **our competitors establishing** ~~arbitration, any of which would divert management attention and resources and 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~~ **strong market position before we are able to enter the market. Moreover, with the proliferation of new drugs and therapies into critical illnesses, we expect to face increasingly intense competition** as **new technologies become available. If** ~~to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; • collaborators may infringe the intellectual property rights of third parties,~~

~~which may expose us to litigation and potential liability; and • collaborations may be terminated for the convenience of the collaborator and, if terminated,~~ we **fail** ~~could be required~~ to **stay at** ~~raise additional capital to pursue further development or commercialization of~~ the ~~applicable~~ **forefront of technological change, we may be unable to compete effectively. Any** product candidates **that we successfully** ~~. Collaboration agreements, including merger, license, or sale, may not lead to development ----~~ **develop** ~~or~~ **and** ~~commercialization~~ **commercialize will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature** of **and rapid technological changes in the biotechnology and pharmaceutical industries could render our** product candidates **or** ~~in the most efficient manner, or~~ **our** ~~at all~~ **technology obsolete, less competitive or uneconomical** . ~~If any collaborations~~ **The amount and type of clinical data** that ~~we enter into do not~~ **may be required by regulatory authorities may increase or change. Consequently, the** ~~result~~ **results** ~~in the successful development and commercialization~~ of ~~products or~~ **our clinical trials** ~~if one of our collaborators terminates its agreement with us, we or~~ **for** ~~our shareholders may not receive any future research funding or milestone or royalty payments under the collaboration. If the funding or performance we expect under these agreements does not occur, further development of our~~ product candidates **will likely** ~~could be delayed or we may~~ need ~~additional resources~~ to ~~develop~~ **show a risk benefit profile that is competitive with or more favorable than products approved prior to** ~~our~~ **ours in order to obtain marketing approval or, if approved, a product label that is favorable for commercialization. If the risk benefit profile is not competitive with those** product candidates ~~. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10- K also apply to the activities of our~~ **or** ~~collaborators. Additionally, subject to its contractual obligations to us, if a collaborator of ours were to be involved in a future business combination, it might deemphasize or terminate the development or commercialization of any~~ product candidate **candidates, we may have developed a product that** ~~acquired from or licensed to it by us. If one of our collaborators terminates its~~ **is** ~~agreement with us~~ **not commercially viable** , **that** ~~we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be harmed. If~~ we are not able to **sell profitably or that is unable to achieve favorable pricing or reimbursement. In such circumstances, our future product business, financial condition, results of operations and prospects could be adversely affected. There is significant investment across the biotechnology and pharmaceutical industries in developing novel and proprietary therapies for acute critical illnesses. We face substantial and increasing competition on multiple fronts, including from larger companies with access to more resources and capital, as well as more experience in research and development, clinical trials and commercialization. Smaller or earlier- stage companies as well as academic institutions, government agencies and public and private research institutions may also prove to be significant competitors. Additionally, we may face competition in hiring scientific and management personnel, establishing clinical trial sites, recruiting patients to participate in clinical trials and acquiring technologies complementary to, or necessary for our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidates that we may develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety, convenience, price and degree of reimbursement. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and** ~~establish~~ **established** ~~additional~~ **companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and subject enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. The key competitive factors affecting the success of all of our programs are likely to be the possibility of other companies developing drugs that address the same illnesses that we are aiming to address. Some of these markets are limited and significant competition could reduce the number of patients we are able to reach. If we are not successful in developing, commercializing and achieving higher levels of reimbursement than our competitors, we will not be able to compete against them and our business would be adversely affected. We may wish to form** collaborations **in the future with respect to our product candidates** , ~~we~~ **but** may ~~have~~ **not be able to do so or realize the potential benefits of such transactions, which may cause us** to alter **or delay** our development and commercialization plans ~~and our business could be adversely affected~~ . ~~For~~ **The development and potential commercialization of** our ~~current~~ product candidates **will require substantial additional capital** ~~, if our proposed merger fails~~ to ~~close~~ **fund expenses. We may** , **in** ~~then~~ - **the** ~~we would intend~~ **future, decide** to ~~transact~~ **collaborate** with **other** ~~pharmaceutical~~ **biopharmaceutical** ~~, biotechnology or medical device~~ companies for the development and potential commercialization of those product candidates **, including in territories outside the United States or for certain indications** . We **will** face significant competition in seeking appropriate **collaborators** ~~transaction counterparties~~ . ~~Whether~~ **We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when** we **collaborate with a third- party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third- party. Our ability to** reach a definitive agreement for a ~~transaction~~ **collaboration** will depend, among other things, upon our assessment of the ~~counterparty~~ **collaborator** ' s resources and expertise, the terms and conditions of the proposed ~~transaction~~ **collaboration** and the proposed ~~counterparty~~ **collaborator** ' s evaluation of ~~a number of factors. Those factors may include the design or~~ **our technologies** ~~results of clinical trials~~ , **product candidates and the**

~~likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential~~ market **opportunities** ~~for the product candidate, the costs and complexities of manufacturing and delivering a product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally~~ . The ~~counterparty~~ **collaborator** may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the ~~transaction~~ **one with us** for our product ~~candidate~~ **candidates** . We may also be restricted under ~~future~~ **any** license agreements from entering into agreements on certain terms **or at all** with potential ~~counterparties~~ **collaborators** . **Collaborations** ~~Such transactions~~ are complex and time- consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future ~~counterparties~~ **collaborators and changes to our strategies** . ~~If~~ **As a result,** we ~~are~~ **may not be** ~~unable~~ -- **able** to **negotiate collaborations** ~~reach agreements with suitable counterparties~~ on a timely basis, on acceptable terms **,** or at all **. If we are unable to do so** , we may have to curtail the development of ~~a~~ **such** product candidate, reduce or delay ~~its development program or~~ one or more of our other development programs, delay ~~its~~ **the** potential commercialization or reduce the scope of any **planned** sales or marketing activities **for such product candidate** , or increase our expenditures and undertake development **, manufacturing** or commercialization activities at our own expense. If ~~our merger fails to close,~~ we ~~may need~~ **elect to increase our expenditures** to fund ~~and undertake~~ development **, manufacturing** or commercialization activities on our own, we may need to obtain ~~additional expertise and~~ additional capital, which may not be available to us on acceptable terms or at all. If we **do not have** ~~fail to enter into such transactions that provide~~ 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 **and generate** ~~or continue to develop our~~ product ~~platform~~ **revenue** . **Our** ~~We have relied, and may continue to rely, on third parties for certain aspects of our clinical development, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials. We have relied and may continue to rely on third parties, such as CROs, to conduct clinical trials of our~~ product candidates ~~. If we deem necessary, we~~ may **also require specific components** ~~engage CROs, clinical data management organizations, medical institutions and clinical investigators~~ to ~~conduct or assist~~ **work effectively and efficiently, and rights to those components may be held by others. We may be unable to** in ~~our clinical trials~~ **- license any compositions, methods of use, processes** or other ~~clinical development work. If we are unable to enter into an agreement with a service provider when required, our product development activities would be delayed. Our reliance on~~ third ~~parties for development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices (" 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. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government~~ - sponsored database, ClinicalTrials. gov,..... Our success depends in large part **party** ~~on our ability to obtain and maintain patent protection both in the United States and in other countries for our product candidates. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical and gene therapy- based inventions and the scope of claims made under these patents, our ability to maintain, obtain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes. We cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. The patent prosecution process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions. Under the laws of certain jurisdictions, patents or other~~ intellectual property rights ~~may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. We currently solely own or exclusively license patents and patent applications that encompass our current product candidates. We do not control the prosecution of the exclusively licensed patents and patent applications from the University of North Carolina at Chapel Hill (" UNC ") which encompass our GB- 501 product, although we have input into the prosecution. In the future, we may choose to license additional patents or patent applications~~ from third parties that we **identify** ~~conclude are useful or necessary for our business goals~~ . We may **fail** ~~not have the right~~ to **obtain any** ~~control the preparation, filing, prosecution or maintenance~~ of ~~such additional licensed patent applications. Therefore, if we do license additional patents or patent applications in the future,~~ these ~~patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U. S. Patent and Trademark Office (" PTO ") for the entire time prior to issuance as a U. S. patent. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Consequently, we cannot be certain that we or our licensors~~ **licenses at a reasonable cost** ~~were the first to invent,~~ or ~~the first to file patent applications~~ on **reasonable terms** ~~, our product candidates or their intended uses. Furthermore, we may not have identified all U. S. and foreign patents or published applications that affect our business either by blocking our ability to commercialize our products or by covering similar technologies that affect our product market or patentability, or all prior art that could be considered relevant to our patent claims. On October 3, 2022, we provided written notification to Johns Hopkins University (" JHU ") of our complete~~

~~termination of our exclusive license agreement to all licensed patent rights owned by JHU that are relevant to our GB- 102 and GB- 401 programs. The termination became effective 30 days from the date of notice. The claims of any patents which have already issued or may issue in the future and are owned by or licensed to us, may not confer on us significant commercial protection against competing products. Additionally, our patents may be challenged by third parties, resulting in the patent being deemed invalid, cancelled, unenforceable or narrowed in scope, or the third party may circumvent any such issued patents. Our patents may be challenged, for example, in a U. S. federal court or alternatively challenged in an adversarial proceeding at the Patent Trial and Appeals Board (" PTAB ") at the PTO, using an inter partes Review or Post Grant Review process. The cost of these procedures is often substantial, and it is possible that our efforts would be unsuccessful resulting in a loss of our U. S. patent position. Further, even if a U. S. federal court or PTAB rules that a patent owned by us is valid and enforceable, if the other venue takes a contrary position, the patent can be considered invalid and not enforceable. Therefore, a party seeking to invalidate a patent owned by or licensed to us in the United States has the procedural advantage of two alternative venues. To date, the PTAB has cancelled over 60 % of the patent claims it has reviewed and is considered to be a forum of choice for infringers for patent cancellation. Also, our pending patent applications may not issue, and we may not receive any additional patents. Our patents might not contain claims that are sufficiently broad to prevent others from utilizing our technologies. For instance, GB- 501 is a recombinant AAV- based construct encoding L- iduronidase for use in treating Mucopolysaccharidosis type 1 (" MPS1 ") corneal clouding. If a competitor develops a product that uses a non- AAV construct or delivery mechanism to deliver L- iduronidase to the cornea, then it may be able to compete with our GB- 501 product without infringing our licensed patent claims. Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual property. To the extent a competitor can develop similar products using a different delivery system, microparticle or molecule, our patents may not prevent them from directly competing with us. Furthermore, as a result of our decision to terminate further development of GB- 102 and GB- 401 in August 2022, we initiated the process of winding down our non- US patent filing footprint that covers our GB- 102 and GB- 401 programs, including the abandonment of certain patents and patent applications in certain non- US jurisdictions. The Leahy- Smith America Invents Act (" America Invents Act ") was signed into law in September 2011, and many of the substantive changes became effective in March 2013. The America Invents Act revised U. S. patent law in part by changing the standard for patent approval from a " first to invent " standard to a " first to file " standard and developing a post- grant review system. This legislation changes U. S. patent law in a way that may weaken our ability to obtain patent protection in the United States for those applications filed after March 2013. For example, if we were the first to invent a new product or its use, but another party is the first to file a patent application on this invention, under the new law the other party may be entitled to the patent rights on the invention. The America Invents Act created for the first time new procedures to challenge issued patents in the United States, including post- grant review and inter partes review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with a priority date of March 16, 2013 or later, a petition for post- grant review can be filed by a third party in a nine- month window from issuance of the patent. A petition for inter partes review can be filed immediately following the issuance of a patent if the patent was filed prior to March 16, 2013. A petition for inter partes review can be filed after the nine- month period for filing a post- grant review petition has expired for a patent with a priority date of March 16, 2013 or later. Post- grant review proceedings can be brought on any ground of challenge, whereas inter partes review proceedings can only be brought to raise a challenge based on published prior art. These adversarial actions at the PTO review patent claims without the presumption of validity afforded to U. S. patents in lawsuits in U. S. federal courts and use a lower burden of proof than used in litigation in U. S. federal courts. The PTO issued a Final Rule on November 11, 2018, announcing that it will now use the same claim construction currently used in the U. S. federal courts to interpret patent claims, which is the plain and ordinary meaning of words used. If any of our, or our licensors', patents are challenged by a third party in such a PTO proceeding, there is no guarantee that we or our licensors will be successful in defending the patent~~, which would **harm** ~~result in a loss of the challenged patent right to us. The U. S. Supreme Court --~~ **our business. Even if we** ~~has issued opinions in patent cases in the last few years that many consider may weaken patent protection in the United States, either by narrowing the scope of patent protection available in certain circumstances, holding that certain kinds of innovations~~ are ~~not patentable or generally otherwise making~~ **able to obtain a license,** it ~~easier to invalidate patents in court. For example, recent Federal Circuit rulings such as Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F. 3d 1336, 1340 (Fed. Cir. 2010) (en banc), Wyeth & Cordis Corp. v. Abbott Labs, 720 F. 3d 1380 (Fed. Cir. 2013), Enzo Life Scis., Inc. v. Roche Molecular Sys., 928 F. 3d 1340 (Fed. Cir. 2019), and Idenix Pharms. LLC v. Gilead Scis. Inc., 941 F. 3d 1149 (Fed. Cir. 2019), and Amgen Inc. v. Sanofi, 987 F. 3d 1080 (Fed. Cir. 2021) have significantly heightened the standard for securing broad claims to pharmaceutical and biological products. In addition to heightened patentability requirements, recent Supreme Court and Federal Circuit cases relating to biosimilar product approval under the Biologics Price Competition and Innovation Act or BPCIA, have held that the " patent dance " provisions of the statute, which are intended to resolve any patent infringement issues before the approval of a biosimilar, are discretionary, and a biosimilar applicant can opt out by refusing to provide a copy of its application and manufacturing information to the biologic sponsor (see Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664 (2017)). It may be that we do not learn of a biosimilar application until after FDA publishes its approval (see Immunex v. Samsung Bioepsis, 2: 19- cv- 117555- CCC- MF (D. N. J. Apr. 30, 2019)). In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the United States federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U. S. Congress,~~

the U. S. courts, the PTO and the relevant law- making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many - **may** companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed. For example, we could become a party to foreign opposition proceedings, such as at the European Patent Office, or patent litigation and other proceedings in a foreign court. If so, uncertainties resulting from the initiation and continuation of such proceedings could have a material adverse effect on our ability to compete in the marketplace. The cost of foreign adversarial proceedings can also be substantial, and in many foreign jurisdictions, the losing party must pay the attorney fees of the winning party. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization of our product candidates, thereby reducing or eliminating any advantages of the patent. To the extent our product candidates based on that technology are not commercialized significantly ahead of the date of any applicable patent, or to the extent we have no other patent protection on such product candidates, those product candidates would not be protected by patents, and we would then rely solely on other forms of exclusivity, such as regulatory exclusivity provided by the Federal Food, Drug, and Cosmetic Act (" FDCA ") or trade secret protection. Patents filed by our licensor, University of North Carolina at Chapel Hill, 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.- based companies. Compliance with such regulations may limit our exclusive rights and may limit our ability to contract with non- U. S. manufacturers. Any patents licensed from UNC that cover inventions generated in whole or part through the use of U. S. government funding are subject to certain federal regulations. As a result, the U. S. government may have certain rights to licensed patents embodied in our current or future product candidates pursuant to the Bayh- Dole Act of 1980 (" Bayh- Dole Act "). These U. S. government rights in certain inventions developed under a government- funded program include a non-exclusive, non- transferable **thereby giving our competitors access to the same technologies licensed to us. In that event** , irrevocable worldwide **we may be required to expend significant time and resources to develop or** license **replacement technology. Failure** to use inventions **comply with applicable data protection laws, regulations, and other obligations could lead to government enforcement actions (which could include civil** for - **or criminal penalties), private litigation and mass arbitration demands, and / or adverse publicity and could negatively affect our operating results and business. We and** any governmental purpose **potential collaborators may be subject to federal, state, and foreign data protection laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations that address privacy and data security** . In addition, the U. S. government has the right, under certain limited circumstances, to require UNC, and thus us, to grant 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 "). The U. S. government also has the right to take title to these inventions if UNC fails to disclose the invention to the government or fails to file an application to register the patents within specified time limits. Patents generated under a government- funded program are also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U. S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States . The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U. S. manufacturers may limit our ability to contract with non- U. S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U. S. government funding , **numerous federal** the provisions of the Bayh- Dole Act may similarly apply. If we infringe or are alleged to infringe intellectual property rights of third parties , **state** our business could be harmed. Our research , development or commercialization activities **and local laws and regulations** , including **federal** any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents or other proprietary rights owned by third parties and **state health information privacy laws** to which we do not hold licenses or other rights. We may not be aware of third- party patents that a third party might assert against us. For example , **state data breach notification laws** there may be third- party applications that have been filed but not published that , **personal data** if issued, could be asserted against us. If a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Further, if we are found to have infringed a third- party patent, we could be obligated to pay royalties and / or other payments to the third party for the sale of our product, which may be substantial, or we could be enjoined from selling our product. We could also incur substantial litigation costs. Litigation regarding patents, intellectual property and other proprietary rights may be expensive and time- consuming. If we are involved in such litigation, it could cause delays in bringing product candidates to market and harm our ability to operate. Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Although we are not currently aware of any litigation or other proceedings or third- party claims of patent infringement against us related to our product candidates, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization.

Likewise, third parties may challenge or infringe upon our existing or future patents. Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding: • the patentability of our inventions relating to our product candidates; and / or • the enforceability, validity or scope of protection **laws** offered by our patents relating to our product candidates. Even if we are successful in these proceedings , **federal** we may incur substantial costs and divert management time and attention in pursuing these proceedings , **state** which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others , we may be required to seek a license, defend an **and local consumer protection laws** infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non- infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may: • incur substantial monetary damages; • encounter significant delays in bringing our product candidates to market; and / or • be precluded from participating in the manufacture, use or sale of our product candidates or methods of treatment requiring licenses. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed. Because one of our current clinical candidates is based on a small molecule, it will be subject in the United States to the patent litigation process of the Hatch- Waxman Amendments after commercialization, which allows a generic company to submit an Abbreviated New Drug Application (**e** " ANDA ") to the FDA to obtain approval to sell our drug using bioequivalence data only . **g** Under the Hatch- Waxman Amendments, we will have the opportunity to list all of our patents that cover our drug product or its method of use in the FDA' s compendium of " Approved Drug Products with Therapeutic Equivalence Evaluation, " sometimes referred to as the FDA' s Orange Book . Currently , in the United States, the FDA may grant three years of exclusivity to a new formulation, for which none of our current product candidates would qualify, and other changes to a drug, such as the addition of a new indication to the package insert, if the application contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to the approval of the application. The FDA also may grant five years of exclusivity for new chemical entities (" NCEs ") for which GB- 701 would qualify. An NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. A generic company can submit an ANDA to the FDA four years after approval of GB- 701. The submission of an ANDA by a generic company is considered a technical act of patent infringement. The generic company can certify that it will wait until the natural expiration date of our listed patents to sell a generic version of our product or can certify that one or more of our listed patents are invalid, unenforceable or not infringed. If the latter, we will have 45 days to bring a patent infringement lawsuit against the generic company. This will initiate a challenge to one or more of our Orange Book listed patents based on arguments from the generic company that either our patent is invalid, unenforceable or not infringed. Under the Hatch- Waxman Amendments, if a lawsuit is brought, the FDA is prevented from issuing a final approval on the generic drug until 30 months after the end of the data exclusivity period, or a final decision of a court holding that our asserted patent claims are invalid, unenforceable or not infringed. If we do not properly list our relevant patents in the Orange Book, or timely file a lawsuit in response to a certification from a generic company under an ANDA, or if we do not prevail in the resulting patent litigation, we can lose our proprietary market, which can rapidly become generic. Further, even if we do correctly list our relevant patents in the Orange Book, bring a lawsuit in a timely manner and prevail in that lawsuit, it may be at a very significant cost to us of attorneys' fees and employee time and distraction over a long period. Further, it is common for more than one generic company to try to sell an innovator drug at the same time, and so we may be faced with the cost and distraction of multiple lawsuits. We may also determine it is necessary to settle the lawsuit in a manner that allows the generic company to enter our market prior to the expiration of our patent or otherwise in a manner that adversely affects the strength, validity, or enforceability of our patent. Our GB- 501 product, if approved under a Biologics License Application (" BLA ") may qualify under the provisions of the Biologics Price Competition and Innovation Act (" BPCIA "). Under the BPCIA, innovator manufacturers of biologic products may be granted 12 years of exclusive use before biosimilar versions of such products can be licensed for marketing in the U. S. This means that the FDA may not approve an application for a biosimilar version of our GB- 501 product until 12 years after the date our product is approved for sale (with a potential six- month extension of exclusivity if certain pediatric studies are conducted and the results accepted by the FDA), although a biosimilar application may be submitted four years after the date we receive approval from the FDA to sell our GB- 501 product. Additionally, the BPCIA establishes procedures by which potentially relevant patents may be shared and litigation over patents may proceed in advance of approval. The BPCIA also provides incentives to biosimilar applicants by providing a period of exclusivity to the first biosimilar of a product approved by the FDA. The 12- year data exclusivity provision of the BPCIA does not prevent a competitor from seeking marketing approval of our GB- 501 product, or a product similar thereto, by submitting its own, original BLA. Furthermore, there is a risk that this exclusivity could be shortened due to congressional action **Section 5** or otherwise, or that the FDA will not consider our GB- 501 product to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for GB- 501 in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If a generic competitor seeks a biosimilar approval to our GB- 501 product and engages in the " patent dance " provisions of the BPCIA, which are intended to resolve any patent infringement issues before the approval of a biosimilar, it may be at a very significant cost to us of attorneys' fees and employee time and distraction over a long period. We may also determine it is necessary to settle the lawsuit in a manner that allows the generic company to enter our market prior to the expiration of our patent or otherwise in a manner that adversely affects the strength, validity, or enforceability of our patent. A number of

~~pharmaceutical companies have been the subject of intense review by the U. S.~~ Federal Trade Commission **Act), and** ~~or a corresponding agency in another~~ -- **other** ~~country based~~ **similar laws that govern the collection, use, disclosure, and protection of health- related and other personal data could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under federal HIPAA, as amended by the HITECH. Depending** on ~~how they~~ -- **the** ~~have conducted~~ **facts and circumstances, we could be subject to significant penalties if we obtain, use, or disclose individually identifiable protected information provided by a HIPAA-covered entity or business associate in a manner that is not authorized or permitted by HIPAA. Additionally, new privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened.** ~~or~~ **For** ~~settled drug patent~~ **example, the CCPA requires covered companies to provide certain disclosures to California consumers (including business representatives and employees who are California residents) and provide such consumers data protection and privacy rights, including the ability to opt- out of certain sales or sharing of personal data. The CCPA provides for administrative penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal data. This private right of action may increase the likelihood of, and risks associated with, data breach** litigation ~~, and certain reviews have led to an allegation of an anti- trust violation, sometimes resulting in a fine or loss of rights. We cannot be sure that we would not also be subject to such a review or that the result of the review would be favorable to us, which could result in a fine or penalty~~. The **CPRA expanded** ~~U. S. Federal Trade Commission (" FTC ") has brought a number of lawsuits in federal court in the past few years to challenge Hatch- Waxman ANDA litigation settlements between innovator companies and generic companies as anti- competitive. The FTC has taken an aggressive position that anything of value is a payment, whether money is paid or not. Under their~~ -- **the CCPA** ~~approach, if an innovator as part of a patent settlement agrees not to launch or delay launch of an authorized generic during the 180- day period granted to the first generic company to challenge an Orange Book listed patent covering an innovator drug, or negotiates a delay in entry without payment, the FTC may consider it an unacceptable reverse payment. The biopharmaceutical industry has argued that such agreements are rational business decisions to dismiss risk and are immune from antitrust attack if the terms of the settlement are within the scope of the exclusionary potential of the patent. In 2013, the U. S. Supreme Court, in a five- to- three decision in FTC v. Actavis, Inc. rejected both the biopharmaceutical industry~~ ' s **requirements** ~~and the FTC' s arguments with regard to so-called reverse payments~~ , **including by adding** ~~and held that whether~~ a **new right** ~~" reverse payment " settlement involving the exchange of consideration~~ for **consumers** ~~a delay in entry is subject~~ to **correct** ~~an anticompetitive analysis depends on five considerations: (a) the potential for genuine adverse effects on competition; (b) the justification of payment; (c) the patentee' s ability to bring about anticompetitive harm; (d) whether the size of the payment is a workable surrogate for the patent' s weakness; and (e) that antitrust liability for large unjustified payments does not prevent litigating parties from settling~~ their **personal information** ~~lawsuits, for example, by allowing the generic to enter the market before the patent expires without the patentee' s paying the generic. Furthermore, whether a reverse payment is justified depends upon its size, its scale in relation to the patentee' s anticipated future litigation costs, its independence from other services for which it might represent payment, as was the case in Actavis, and the lack of any other convincing justification. The Court held that reverse payment settlements can potentially violate antitrust laws and are subject to the standard antitrust rule- of- reason analysis, with the burden of proving that an~~ **and establishing** ~~agreement is unlawful on the FTC and leaving to lower courts the structuring of such rule of reason analysis. If we are faced with drug patent litigation, including Hatch- Waxman litigation or BPCIA litigation with~~ a **new** ~~generic company, we could be faced with such an FTC challenge based on that activity, including how or whether we settle the case, and even if we strongly disagree with the FTC' s position, we could face a significant expense or penalty. We may not be able to enforce our intellectual property rights throughout the world. Filing, prosecuting, and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. 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 may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, may not favor the enforcement of our patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights in certain foreign countries. A number of foreign countries have stated that they are willing to issue compulsory licenses to patents held by innovator companies on approved drugs to allow the government or one or more third- party companies to sell the approved drug without the permission of the innovator patentee where the foreign government concludes it is in the public interest. India, for example, has used such a procedure to allow domestic companies to make and sell patented drugs without innovator approval. There is no guarantee that patents covering any of our drugs will not be subject to a compulsory license in a foreign country, or that we will have any influence over if or how such a compulsory license is granted. Further, Brazil allows its~~ regulatory agency ~~ANVISA~~ to **implement** ~~participate in deciding whether to grant a drug patent in Brazil,~~ and ~~patent grant decisions~~ **enforce the law. Moreover, other states such as Virginia and Colorado, have enacted data protection laws, and similar laws** are **being considered** ~~made based on several factors, including whether the patent meets the requirements for a patent and whether such a patent is deemed~~ in ~~the country' s interest. In addition,~~ several

other ~~countries have created~~ **states, as well as at the federal and local levels. Although these** laws **may exempt some data processed in the context of clinical trials, these evolving compliance and operational requirements impose significant costs** that ~~make it more difficult to enforce drug patents than patents on other kinds of technologies. Further, under the treaty on the Trade- Related Aspects of Intellectual Property (" TRIPS ") as interpreted by the Doha Declaration, countries in which drugs~~ are **likely** ~~manufactured are required~~ to **increase** ~~allow exportation of the drug to a developing country that lacks adequate manufacturing capability. Therefore, our drug markets in the United States or foreign countries may be affected by the influence of current public policy on patent issuance, enforcement or involuntary licensing in the healthcare area. In addition, in November 2015, members of the World Trade Organization (" WTO ") which administers TRIPS, voted to extend the exemption against enforcing pharmaceutical drug patents in least developed countries until 2033. We currently have no patent applications filed in least developed countries, and our current intent is not to file in these countries in the future, at least in part due to this WTO pharmaceutical patent exemption. Furthermore, in late 2022, we began the process of winding down our non-US patent filing footprint that covers our now- terminated GB- 102 and GB- 401 programs, including the abandonment of certain patents and patent applications in certain non- US jurisdictions. To the extent a patent and / or patent application has been abandoned in a specific jurisdiction, we will be unable to assert such patent right against an alleged infringer if the alleged infringer practices those claims. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and / or applications will be due to be paid to the PTO and various governmental patent agencies outside of the United States in several stages~~ over **time** ~~the lifetime of the patents and / or applications. We have systems in place to remind us to pay these fees~~ , and we employ an outside firm and..... our patents; however, some jurisdictions may require us to **modify** ~~grant licenses to third parties. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities. Many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties, in certain circumstances. For example, compulsory licensing, or~~ **our data processing** ~~the threat of compulsory licensing, of life- saving products and expensive products is becoming increasingly popular in developing countries, either through direct legislation or international initiatives. Compulsory licenses could be extended to include some of our product candidates, if they receive marketing approval, which may limit our potential revenue opportunities. Consequently, we may not be able to prevent third parties~~ **practices** ~~from practicing our inventions in certain countries outside the United States~~ and **policies** ~~Europe. Competitors may also use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and~~ , ~~further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. 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. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and~~ divert ~~our efforts and~~ resources from other ~~aspects~~ **initiatives and projects, and could restrict the way products and services involving data are offered, all** of **which may harm** our business ~~. Furthermore~~ , ~~while we intend to~~ **financial condition, results of operations and** ~~protect~~ **prospects . Internationally** ~~our intellectual property rights in major markets for our products where such patent rights exist~~ , **virtually every jurisdiction in which** we ~~cannot ensure~~ **operate has established its own data security and privacy legal framework** that ~~we will be able to initiate or maintain similar efforts in all jurisdictions in which we~~ may ~~wish~~ **also apply** to **health** ~~market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement if a government is the infringer, which could materially diminish the value of the patent. If we fail to comply with our obligations under the license agreement with UNC, we could lose license rights that are necessary for developing and commercializing one or more of our product candidates. Our exclusive license with UNC for technology relating to our GB-~~ **related** ~~501 product candidate imposes various development, commercialization, royalty payment, diligence~~ and other **personal data** ~~obligations on us, and we currently do not anticipate being able to fulfill all of our obligations. Specifically, we are required to: • pay UNC potential milestone payments and annual license maintenance fees; • pay UNC low single- digit royalties on all net sales of products and a share of any sublicensing revenues; • meet specific clinical development milestones, one of which must occur by June 1, 2023; • use commercially reasonable efforts to bring products to market; • provide royalty reports to UNC; and • indemnify UNC against certain claims and maintain insurance coverage. If we breach any of these obligations, UNC may have the right to terminate the license, which would result in our being unable to develop, manufacture and sell products that are covered by the licensed technology, or in a competitor' s gaining access to the licensed technology. The rights we rely upon to protect our unpatented trade secrets may be inadequate. We rely on unpatented trade secrets, know- how and technology, which are difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be made public during the regulatory approval process. We seek to protect trade secrets, in part, by entering into confidentiality agreements with employees, consultants and others. These parties may breach or terminate these agreements or may refuse to enter into such agreements with us, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets or other proprietary information or result in the effective assignment to us of intellectual property and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other breaches of the agreements. Despite our efforts to protect our trade secrets, we or our collaboration partners, board members, employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors. If we fail to maintain trade secret protection, our competitive position may be adversely affected. Competitors may also independently discover our trade secrets. Enforcement of claims that~~

a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods and know- how, we would not be able to assert our trade secrets against them and our business could be harmed. Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property. We rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. To protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our current and potential corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case, we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Costly and time- consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or **For example** maintain trade secret protection could adversely affect our competitive business position. Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters Regulatory agencies , IRBs, or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they - **the EU** believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an **and** unacceptable safety risk to participants. Clinical trials must be conducted in accordance with GCPs and other applicable foreign regulatory authority guidelines. Clinical trials are subject to oversight by the FDA, foreign regulatory authorities and IRBs at the trial sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced in accordance with applicable current good manufacturing practices. Clinical trials may be placed on a full or partial clinical hold by the FDA, foreign regulatory authorities, or us for various reasons, including, but not limited to: deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols; deficiencies in the clinical trial operations or trial sites; deficiencies in the trial designs necessary to demonstrate efficacy; fatalities or other AEs arising during a clinical trial due to medical problems that may or may not be related to clinical trial treatments; the product candidates may not appear to be more effective than current therapies; or the quality or stability of the product candidates may fall below acceptable standards. Although we have never been asked by a regulatory agency, IRB or data safety monitoring board to temporarily or permanently discontinue a clinical trial, if we elect or are forced to suspend or terminate a future clinical trial of any of our current or future product candidates, the commercial prospects for that product may be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events could prevent us or our future partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these products either by us or by our collaboration partners. In our future clinical trials, any SAEs could result in the FDA delaying such clinical trials or denying or delaying clearance or approval of a product. Even though an AE may not be the result of the failure of one of our drug candidates, the FDA or an IRB could delay or halt a clinical trial for an indefinite period of time while an AE is reviewed, and likely would do so in the event of multiple such events. Any delay or termination of our future clinical trials as a result of the risks summarized above, including delays in obtaining or maintaining required approvals from IRBs, delays in patient enrollment, the failure of patients to continue to participate in a clinical trial, and delays or termination of clinical trials as a result of protocol modifications or AEs during the trials, may cause an increase in costs and delays in the submission of any New Drug Applications (" NDAs ") to the FDA, delay the approval and commercialization of our products or result in the failure of the clinical trial, which could adversely affect our business, operating results and prospects. Lengthy delays in the completion of clinical trials of our products would adversely affect our business and prospects and could cause us to cease operations. If preliminary data demonstrate that any of our product candidates has an unfavorable safety profile and is unlikely to receive regulatory approval or be successfully commercialized, we may voluntarily suspend or terminate future development of such product candidate. Any one or a combination of these events could prevent us from obtaining regulatory approval and achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product candidate, which in turn could delay or prevent us from generating significant revenues from the sale of the product. The activities associated with the development of our product candidates, including design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside the United States. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing a product candidate. We have not submitted for regulatory approval to market GB- 501 or any other product candidate. The process of obtaining regulatory approvals, both in the United States and abroad, is expensive and may take many years, especially if additional clinical trials are required, if approval is obtained at all. The FDA continually updates and refines its guidance to companies developing products that will require regulatory approval, which can also include material changes to established guidance that results in significant changes to the planned conduct, cost, and timing of clinical development programs. Securing regulatory 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 purity. The FDA' s and other regulatory agencies' decision to grant us regulatory approval will depend on our ability to demonstrate with substantial clinical evidence through adequate well- controlled clinical trials, that the product candidates are effective, as measured statistically by comparing the overall

improvement in actively- treated patients against improvement in the control group. However, there is a possibility that our data may fail to demonstrate statistically significant non- inferiority versus the active control. Alternatively, there is a possibility that our data may be statistically significant, but that the actual clinical benefit of the product candidates may not be considered to be clinically significant, clinically relevant or clinically meaningful. We cannot predict whether the regulatory agencies will find that our clinical trial results provide compelling data. Even if we believe that the data from our trials will support regulatory approval in the United States or in Europe, we cannot predict whether the agencies will agree with our analyses and approve our applications. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA, the EMA or other regulatory authorities may determine that our product candidates are not safe or effective, are only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining regulatory approval or prevent or limit commercial use. In addition, while we have had general discussions with the FDA concerning the design of some of our clinical trials, we have not discussed with the FDA the specifics of the regulatory pathways for our product candidates. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable. Approval of our product candidates may be delayed or refused for many reasons, including the following: • the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; • we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications; • the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; • we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks; • the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical programs or clinical trials; • the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere; • potential delays in enrollment, site visits, evaluations, dosing of patients participating in the clinical trial as hospitals prioritize the treatment of COVID- 19 patients or patients decide to not enroll in the trial as a result of the COVID- 19 pandemic; • government regulations that may be imposed in response to the COVID- 19 pandemic may restrict the movement of our global supply chain, divert hospital resources that are necessary to administer our product candidates; • the facilities or conduct of the third- party manufacturers with which we contract may not be adequate to support approval of our product candidates; and • the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Even if our product candidates meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non- approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process. The regulatory process can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. If we experience delays in obtaining approval, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired. Failure to obtain regulatory approval in international jurisdictions would prevent our product candidates from being marketed abroad. In order to market and sell our product candidates in the European Union and many other jurisdictions, we or our potential third- party collaborators, must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. 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 sold in that country. We or our 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 ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. Additionally, on June 23, 2016, the electorate in the United Kingdom **have** voted in favor of leaving the European Union, commonly referred to as Brexit. Following protracted negotiations, the United Kingdom left the European Union on January 31, 2020. The United Kingdom and European Union entered into the Trade and Cooperation Agreement, effective January 1, 2021, which sought to resolve some of the outstanding issues related to Brexit, including free trade and an overarching governance structure for business conducted between the jurisdictions. Under the Trade and Cooperation Agreement, there was a transition period in which the U. K. was not designated as a " third country " and, as a result, personal data could flow from the EU to the U. K. without any adequacy mechanisms (e. g., Standard Contractual Clauses, etc.). The Trade and Cooperation Agreement went into full force on May 1, 2021, and the transition period with regard to personal data automatically terminated on June 26, 2021. On June 28, 2021, the European Commission adopted two definitive adequacy decisions addressing the transfers of personal data to the United Kingdom under the General Data Protection Regulation (" **EU** GDPR " **and " UK GDPR, " respectively**) and the Law Enforcement Directive. Because this Trade and Cooperation Agreement is still new , **which imposes strict requirements** it is unclear how it may affect the regulatory framework for **processing** our products. Since the regulatory framework for pharmaceutical products in **personal data of individuals within the EEA and** the United Kingdom **. Companies** covering quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and

~~distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime~~ that ~~applies to products and the approval of product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business. The terms of approvals, ongoing regulations and post- marketing restrictions for our products may limit how we manufacture and market our products, which could materially impair our ability to generate revenue. Once regulatory approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any collaborators we may have in the future,~~ must ~~therefore~~ comply with **the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection** requirements ~~concerning advertising~~ and ~~promotion~~ **potential fines** for ~~any~~ **noncompliance** of **up to 20 million euros, 17. 5 million pounds sterling under the UK GDPR,** ~~our~~ **or** ~~products for which we or our collaborators obtain regulatory approval. Promotional communications with respect to drug products and medical devices are subject to a variety of legal and regulatory restrictions and must be consistent with the information~~ in **each case** ~~the product' s approved labeling. Thus~~, ~~if any~~ **up to 4 %** of ~~our product candidates receives regulatory approval, the accompanying approved labeling may limit the promotion of our product, which could limit sales of the product. In addition, manufacturers of approved products and those~~ -- **the** ~~manufacturers' facilities are required to~~ **annual global revenue of the noncompliant** ~~comply~~ **company** ~~with extensive FDA requirements~~, **whichever is greater** ~~including ensuring that quality control and manufacturing procedures conform to current good manufacturing practices applicable to drug manufacturers or quality assurance standards applicable to medical device manufacturers~~, ~~which include requirements relating to quality control and quality assurance~~ as well as **private litigation related to the processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent** ~~the~~ **their** ~~corresponding maintenance~~ **interests. Among other requirements, the GDPR regulates transfers** of ~~records~~ **personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data. Although there are currently various mechanisms that may be used to transfer personal data from the EEA** and ~~documentation~~ **UK to the United States in compliance with law, such as the EEA** and **UK' s standard contractual clauses, the United Kingdom' s International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto (which allows for transfers for relevant U. S.- based organizations who self- certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA or the United Kingdom to the United States, or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and United Kingdom to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR' s cross- border data transfer limitations. In addition, the new India Digital Personal Data Protection Act 2023 (" DPDP ") is likely to come into force in 2024. Like the GDPR, the DPDP has extra- territorial reach and failure to comply with the DPDP may lead to substantial fines. A significant portion of our ongoing CARPO trial is being conducted in India and we and certain third parties upon which we rely will be subject to the DPDP when it becomes effective. Failure by us or third parties upon which we rely to comply with U. S. and international data protection laws, regulations, and other obligations could result in significant consequences, including without limitation government enforcement actions (which could include investigations, civil or criminal penalties, audits inspections), private litigation or mass arbitration demands, additional** reporting requirements ~~. We, any CMOs we may engage in the future, our~~ - **or** ~~future~~ **oversight, bans on processing personal data, data breach reporting requirements and / or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential** collaborators ~~and their CMOs~~ **obtain information, as** ~~will~~ **well** ~~also be subject~~ **as the providers who share this information with us, may contractually limit our ability** to **use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business. Our information technology systems, or those of our CROs or** other ~~regulatory requirements~~ **contractors or consultants** , ~~including submissions~~ **may fail or suffer security breaches, loss or leakage** of ~~safety~~ **data,** and other ~~post- marketing information and reports, registration and listing requirements, requirements regarding the distribution~~ --- **disruptions** ~~of samples to physicians, recordkeeping and costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a risk evaluation and mitigation strategy. If any of our product candidates receives regulatory approval and we or others later identify undesirable side effects caused by the product, our ability to market and derive revenue from the products could be compromised. In the event any of our product candidates receive regulatory approval and we or others identify undesirable side effects, AEs or other problems caused by one of our products, any of the following adverse outcomes could occur~~ -, which could result in ~~the loss~~ **a material disruption** of ~~significant revenue~~ **our product candidates' development programs, compromise sensitive information related** to **our business or prevent** us ~~and materially and~~ **from accessing critical information, potentially exposing us to liability or otherwise** adversely ~~affect~~ **affecting** our ~~operating results and~~ business ~~: • regulatory authorities may withdraw~~ **. We are**

increasingly dependent upon information technology systems, infrastructure and data to operate ~~or~~ **our** ~~modify~~ **business. In** ~~their --~~ **the ordinary course** ~~approval of the product and require us to take the product off -~~ **of business,** ~~the market or seize the product; •~~ we **collect, store** ~~may need to recall the product or change the way the product is administered to patients; • we may need to conduct additional preclinical studies or clinical trials or change the labeling of the product; • additional restrictions may be imposed on the marketing~~ and **transmit confidential information** ~~promotion of the particular product or the manufacturing processes for the product or any component thereof; • we may not be able to secure or maintain adequate coverage and reimbursement for our products from government~~ (including ~~U. S. federal~~ **but not limited to intellectual property, proprietary business information and personal data, including** health ~~care programs~~ **- related information**) **. As use of digital technologies has increased, cyber incidents, including deliberate attacks** and ~~private payors; • regulatory authorities may require~~ **attempts to gain unauthorized access to computer systems and networks, which could result in material adverse impacts to our business, including the theft of our intellectual property, have increased in frequency and sophistication. Despite our implementation of security measures, given their size and complexity and the increasing amounts of confidential information that** ~~the~~ **they maintain, our information technology systems and those of our third-party CROs and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, sophisticated nation- state and nation- state supported actors, and / or other third parties, or from cyber- attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering attacks, malicious code, credential stuffing attacks, credential harvesting, supply- chain attacks, software bugs, and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our or our third party partners' system infrastructure or lead to data leakage. For example, we have experienced phishing attacks in the past and we may be a target of phishing attacks or other cyber- attacks in the future. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications (or those of our third- party partners), or inappropriate disclosure of confidential information, we could incur liability and reputational damage and the further development and commercialization of our product candidates could be delayed. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third- party contractors who have access to our confidential information. We rely on these third- party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud- based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third- party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In** addition ~~of labeling statements~~ , **supply** ~~such as a boxed warning, or equivalent, or contraindications or limitations on the indications for use; • regulatory authorities may require us to implement a Risk Evaluation and Mitigation Strategy (" REMS ") plan, or to conduct post - marketing studies or clinical trials~~ **chain attacks have increased in frequency** and **severity, and** ~~surveillance to monitor the safety or efficacy of the product; •~~ we **cannot guarantee that third** ~~may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients --~~ **parties ' infrastructure in our supply chain** ~~; • we may be exposed to potential lawsuits and associated legal expenses, including costs of resolving claims; • the product may become less competitive and sales may decrease; and • our -~~ **or** ~~reputation may suffer both among clinicians and patients~~ **our third- party partners' supply chains have not been compromised** . ~~Any of these~~ **While we invest in our information security systems, we cannot assure you that our data protection efforts and our investment in information technology will** ~~events -~~ **prevent breakdowns, data leakages, breaches in our systems or other cyber incidents that** could have **an adverse effect upon our reputation, business, financial condition, results or operations and prospects. We may not be successful in preventing or detecting cyber- attacks or mitigating their effects, or we may be perceived as having failed to do so. We take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after** a **security incident has occurred. Unremediated high risk or critical vulnerabilities pose** material **risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. For example, if a cyber- attack were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and / or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property,**

proprietary business information, and personal data), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal data, including personal data regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and / or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal data, which could result in significant legal and financial exposure and reputational damages that could potentially have ~~and~~ **an** adverse effect on our **business. We or the third parties upon whom we depend may be adversely affected by earthquakes, fires or other natural disasters, terrorism or similar unforeseen events and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Our headquarters and main research facility are located in California near major earthquake faults and fire zones. If earthquakes, fires, other natural disasters, terrorism or similar unforeseen events beyond our control prevent us from using all or a significant portion of our headquarters or research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third- party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe AEs. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business. Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. As of December 31, 2023, we had federal and state net operating loss (" NOL ") carryforwards of approximately $ 278. 7 million and $ 103. 5 million, respectively. $ 74. 6 million of our federal NOLs were generated prior to 2018 and will begin to expire in 2026, unless previously utilized, but may be used to offset up to 100 % of future taxable income before expiration. Under current law, our federal NOLs generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80 % of taxable income. It is uncertain if and to what extent various states will conform to federal tax law. We also have federal and state research and development credit carryforwards totaling $ 12. 4 million and $ 2. 4 million, respectively. The federal research and development credit carryforwards will begin to expire in 2027, unless previously utilized. The state research and development credits do not expire. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the " Code "), and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a rolling three- year period, the corporation' s ability to use its pre- change NOL carryforwards and certain other tax attributes to offset its post- change income or taxes may be limited. This could limit the amount of NOLs or other applicable tax attributes that we can utilize annually to offset future taxable income or tax liabilities. We have not undertaken a Section 382 study, and it is possible that we have previously undergone one or more ownership changes so that our use of net operating losses is subject to limitation. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre- change NOLs to offset U. S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows. Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of** operations ~~and~~ **. New income, sales, use, or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our** business **operations and financial performance** . ~~The commercial prospects~~ **Further, existing tax laws, statutes, rules, regulations,** ~~for~~ **or ordinances could be interpreted, changed, modified,** ~~our~~ **or applied adversely to us. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act (the " Tax Act "), the Coronavirus Aid, Relief, and Economic Security Act and the Inflation Reduction Act (" IRA ") enacted many significant changes to the U. S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one- time charges, and could increase our future U. S. tax expense. Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations. In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of** product candidates **, restrict** ~~may be harmed and our~~ **or** ~~ability to generate revenues will be materially impaired. If our product candidates receive regulatory~~ **regulate** ~~approval, we will also be subject to ongoing FDA obligations and continued regulatory review, such as continued safety reporting requirements, and we may also be subject to additional FDA post- marketing obligations or new regulations, all of which may result in significant expense and limit our ability to commercialize our drugs. Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate and may require us to conduct~~ post- approval ~~clinical studies. The FDA has significant post- market authority, including the authority to require labeling changes based on new safety information and to require post- market studies or clinical trials to evaluate safety risks~~

related to the use of a product or to require withdrawal of the product from the market. The manufacturing facilities -- **activities** used to manufacture our product candidates will also be subject to periodic review and inspection by the FDA and other regulatory agencies -, **and affect** including for continued compliance with current good manufacturing practices requirements. The discovery of any new or **our** previously unknown problems with our third- party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility -- **ability** , including withdrawal of the product from the market. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. If we promote our product candidates in a manner inconsistent with FDA- approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. In addition, if the FDA or a foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with current good manufacturing practices and GCPs, for any clinical trials that we conduct post- approval. Moreover, if we obtain regulatory approval for our product candidates, we will only be permitted to market our products for the indication approved by the FDA or foreign regulatory authority, and such approval may involve limitations on the indicated uses or promotional claims we may make for our products, or otherwise not permit labeling that sufficiently differentiates our product candidates from competitive products with comparable therapeutic profiles. For example, we will not be able to claim that our products have fewer side effects, or improve compliance or efficacy as compared to other drugs unless we can demonstrate those attributes to the FDA or foreign regulatory authority in comparative clinical trials. If we or our CMOs or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things, fines, warning or untitled letters, holds on clinical trials, delay of approval or refusal by the FDA or similar foreign regulatory bodies to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution. The FDA' s and foreign regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, and we may not achieve or sustain profitability --- **profitably** . We may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products. Violations of the FDCA relating to the promotion or manufacturing of drug products may lead to investigations by the FDA, the Department of Justice and state Attorneys General alleging violations of federal and state healthcare fraud and abuse laws, as well **sell** as state consumer protection laws. In addition, later discovery of previously unknown AEs or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including: • restrictions on such products, manufacturers or manufacturing processes; • restrictions on the labeling or marketing of a product; • restrictions on product distribution or use; • requirements to conduct post- marketing studies or clinical trials; • warning or untitled letters; • withdrawal of the products from the market; • refusal to approve pending applications or supplements to approved applications that we submit; • recall of products; • fines, restitution or disgorgement of profits or revenues; • suspension or withdrawal of regulatory approvals; • refusal to permit the import or export of our products; • product seizure or detention; or • injunctions or the imposition of civil or criminal penalties. Non- compliance with European Union requirements regarding safety monitoring or pharmacovigilance, or with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. If the FDA does not conclude that the product candidates for which we may use the Section 505 (b) (2) regulatory approval pathway satisfy the requirements for the use of such pathway, or if the requirements for such product candidates under Section 505 (b) (2) are not as we expect, the approval pathway for any such product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful. We may seek FDA approval through the Section 505 (b) (2) regulatory pathway for future product candidates. The Hatch- Waxman Amendments added Section 505 (b) (2) to the FDCA. Section 505 (b) (2) permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505 (b) (2), if applicable to us under the FDCA, would allow an NDA to rely in part on data in the public domain or the FDA' s prior conclusions regarding the safety and effectiveness of approved drug products, which could expedite the development program for our product candidates by potentially decreasing the amount of preclinical or clinical data that we would need to generate in order to obtain FDA approval. If we cannot pursue the Section 505 (b) (2) regulatory pathway for future product candidates, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. In addition, notwithstanding the approval of products by the FDA under Section 505 (b) (2), certain pharmaceutical companies and others have objected to the FDA' s interpretation of Section 505 (b) (2). If the FDA' s current interpretation of Section 505 (b) (2) is successfully challenged, the FDA may change its 505 (b) (2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505 (b) (2). In addition, the pharmaceutical industry is highly competitive, and Section 505 (b) (2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced

~~in a Section 505 (b) (2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for the owner of the NDA of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions could significantly delay, or even prevent, the approval of a new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505 (b) (2) regulatory pathway, there is no guarantee this would ultimately lead to earlier approval. Moreover, even if our product candidates are approved under Section 505 (b) (2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post- marketing testing and surveillance to monitor the safety or efficacy of the products. Our relationships with customers and third- party payors may be subject, directly or indirectly, to applicable anti- kickback, fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings. Healthcare providers, physicians and third- party payors will play a primary role in the recommendation, affordability, and use of~~ any product candidates for which we obtain ~~regulatory~~ **marketing** approval. ~~Our future arrangements~~ **Among policy makers and payors in the United States and elsewhere, including in the EU, there is significant interest in promoting changes in healthcare systems** with ~~third- party payors and customers may expose us to broadly applicable fraud and abuse and other~~ -- **the stated goals of containing** healthcare **costs** ~~laws and regulations that may constrain the business or financial arrangements and relationships through which we market~~, ~~sell~~ **improving quality** and ~~/ distribute any products for~~ -- **or expanding access** ~~which we obtain regulatory approval~~. In ~~addition~~ **the United States**, ~~we may be subject to transparency laws~~ **the pharmaceutical industry has been a particular focus of these efforts** and ~~patient privacy regulation~~ **has been significantly affected** by ~~U~~ **major legislative initiatives**. ~~S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include: • the federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or~~ **For example** ~~providing remuneration~~, ~~directly or indirectly, in cash or in kind, to induce or reward, or in return for, either~~ the ~~referral of~~ **Patient Protection** ~~an~~ **and Affordable Care** ~~individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid; • federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims~~ Act ~~, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; • HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; • HIPAA~~, as amended by ~~HITECH, and their~~ -- **the** ~~respective implementing regulations~~ **Health Care and Education Reconciliation Act (collectively**, ~~which imposes obligations~~ **the " Affordable Care Act ")**, **substantially changed the way** ~~including mandatory contractual terms, on covered~~ healthcare **is financed** ~~providers, health plans and healthcare clearinghouses, as well as their business associates, with respect to safeguarding the privacy, security and transmission of protected health information; and • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed~~ by ~~non-~~ **both the** ~~governmental~~ -- **government and** ~~third- party payors, including~~ private insurers **,** ~~; state~~ and **continues** ~~foreign laws that require pharmaceutical companies~~ to ~~comply with~~ **significantly impact** the **U. S.** pharmaceutical industry **. As another example, the 2021 Consolidated Appropriations Act signed into law on December 27, 2020 incorporated extensive healthcare provisions and amendments to existing laws, including a requirement that all manufacturers of drugs and biological products covered under Medicare Part B report the product** ' s ~~voluntary compliance guidelines~~ **average sales price, or ASP, to Department of Health** and **Human Services (" HHS ") beginning on January 1, 2022, subject to enforcement via civil money penalties. Since its enactment,** ~~the~~ **there** ~~relevant compliance guidance promulgated by~~ **have been judicial, executive and Congressional challenges to certain aspects of the Affordable Care Act. By way of example, the Tax Act repealed penalties for not complying with the Affordable Care Act' s individual mandate to carry health insurance, commonly referred to as the " individual mandate. " Following several years of litigation in** the federal ~~government or otherwise restrict payments~~ **courts, in June 2021 the U. S. Supreme Court upheld the Affordable Care Act when it dismissed a legal challenge to the Affordable Care Act' s constitutionality on procedural grounds following** that **legislative repeal of** ~~may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other~~ -- **the individual mandate** ~~transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs~~. It is possible that ~~governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other~~ -- **the** ~~healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, it may be subject to criminal, civil or~~

~~administrative sanctions, including exclusions from participation in government funded healthcare programs. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management' s attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources. Recently enacted and future legislation, including healthcare legislative reform measures, may adversely affect or limit our ability to commercialize our products, including the prices that we can obtain for any products that are approved in the United States or foreign jurisdictions, and may negatively impact our business and results of operations. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could affect our ability to profitably sell or commercialize any product candidate for which we obtain regulatory approval. The pharmaceutical industry and medical device industry have been a particular focus of these efforts and have been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted, may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any FDA approved product. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (" MMA ") changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could limit coverage of and reduce the price that we receive for any FDA approved products. While the MMA applies only to product benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA or other healthcare reform measures may result in a similar reduction in payments from private payors. In March 2010, President Obama signed into law the Patient Protection and~~ Affordable Care Act **will be subject** ~~, as amended by the Health Care and Education Reconciliation Act, or collectively, the " ACA ". Among the provisions of the ACA of importance~~ to **additional challenges in the future. Prior to the Supreme** ~~our~~ **Court ' s decision** ~~business, including, without limitation, our ability to commercialize and the prices we may obtain for any of our product candidates and that are approved for sale, are increased manufacturer rebate liability under the Medicaid Drug Rebate Program, imposition of a significant annual fee on companies that manufacture or import branded prescription drug products and the requirement for manufacturers to provide a discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the " donut hole, " which is now 70 % of the negotiated price. There have been executive, legislative and judicial efforts to modify, repeal, or otherwise invalidate all, or certain aspects of, the ACA. On January 28, 2021~~ , President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ~~ACA~~ **Affordable Care Act** marketplace ~~, which began on February 15, 2021 and closed on August 15, 2021~~ . The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ~~ACA~~ **Affordable Care Act** . **Further, on August 16, 2022, President** ~~It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is uncertain how any such challenges and the healthcare measures of the~~ Biden ~~administration will impact the ACA and our business. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. These changes include aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year, which went into effect in April 2013 and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID- 19 pandemic, unless additional Congressional action is taken. The Medicare reductions phased back in starting with a 1 % reduction in effect from April 1, 2022 to June 30, 2022 before increasing to the full 2 % reduction. In January 2013, President Obama~~ signed **the IRA** into law ~~the American Taxpayer Relief Act of 2012~~ , which ~~,~~ among other things, ~~reduced Medicare payments to several types of providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations. Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. By way of example, in December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer- sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value- based purchasing arrangements. On September 9, 2021, the Biden Administration published a wide- ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The HHS plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These initiatives recently culminated in the enactment of the Inflation Reduction Act (" IRA ") in August 2022, which will, among other things, allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although this will only apply to high- expenditure single- source drugs that have been approved for at least 7 years (11 years for biologics). The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to~~

~~regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also~~ extends enhanced subsidies for individuals purchasing health insurance coverage in ~~ACA~~ **Affordable Care Act** marketplaces through plan year 2025. **The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost through a newly established manufacturer discount program. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act, our business, or financial condition. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted that affect healthcare expenditures. These changes include aggregate reductions to Medicare payments to providers of 2 % per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to legislative amendments to the statute, will remain in effect until 2032, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. In addition, new laws may result in additional reductions in Medicare and other healthcare funding, which may adversely affect customer demand and affordability for our product candidates and, accordingly, the results of our financial operations. Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries, presidential executive orders, and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. Moreover, in July 2021, President Biden issued a sweeping executive order on promoting competition in the American economy that includes several mandates pertaining to the pharmaceutical and healthcare insurance industries. Among other things, the executive order includes several directives regarding the Federal Trade Commission' s oversight of potentially anticompetitive practices within the pharmaceutical industry. The executive order also directs the FDA to work towards implementing a system for importing drugs from Canada (following on a Trump administration notice- and- comment rulemaking on Canadian drug importation that was finalized in October 2020). On January 5, 2024, the FDA approved Florida' s Section 804 Importation Program (" SIP ") proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. In response to President Biden' s executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single- source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation.** These provisions ~~will~~ take effect progressively starting in **fiscal year** 2023 **. On August 29, 2023 HHS announced the list of the first ten drugs that will be subject to price negotiations** , although ~~they~~ **the ~~may be~~ Medicare drug price negotiation program is currently** subject to legal challenges **. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs as implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration' s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care** . It is unclear **whether the models ~~to what extent new statutory, regulatory, and administrative initiatives~~** will be **utilized in ~~enacted and implemented and to what extent these or~~** any **health reform measures in the** future **~~legislation or regulations by~~ . Further, on December 7, 2023,** the Biden administration **announced an initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that** will **continue under the new framework ~~have on our business, including our ability to generate revenue and achieve profitability~~** . At the state level, legislatures **~~are~~ have** increasingly **~~passing~~ passed** legislation and **~~implementing~~ implemented** regulations designed to control pharmaceutical **~~and biological~~** product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures **. For example** , **California requires pharmaceutical manufacturers to notify certain purchasers, including health insurers and government health plans at least 60 days before any scheduled increase in the wholesale acquisition cost (" WAC "), of their product if the increase exceeds 16 %, and further requires pharmaceutical manufacturers to explain whether a change or improvement in the product necessitates such ~~and~~ an increase. Similarly** , **Vermont requires pharmaceutical manufacturers ~~in some cases, designed~~** to **~~encourage importation from~~ disclose price information on certain prescription drugs, and to provide notification to the state if introducing a new drug with a WAC in excess of the Medicare Part D specialty drug threshold. In December 2020, the U. S. Supreme Court**

also held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers, or PBMs, and other **members** ~~countries and bulk purchasing. The pricing~~ of ~~prescription~~ **the healthcare and** ~~pharmaceuticals~~ **pharmaceutical supply chain** ~~is also subject to governmental control outside the United States. In these countries~~, ~~pricing negotiations with governmental authorities can~~ **an important decision** ~~take considerable time after the receipt of regulatory approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial~~ that **may lead** ~~compares the cost- effectiveness of our product candidates~~ to **further** ~~other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues~~ and ~~become profitable could be impaired~~ **more aggressive efforts by states in this area** . We expect that **these** ~~additional state~~ and ~~federal~~ **other** healthcare reform measures ~~will~~ **that may** be adopted in the future ~~, particularly in light of the new presidential administration. Such reform measures~~ may result in more rigorous coverage criteria **and lower reimbursement** and in additional downward pressure on the price that we receive for any approved product. **Any reduction in reimbursement from Medicare or other government- funded programs may result in a similar reduction in payments from private payors.** The implementation of cost **-** containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability ~~,~~ or commercialize our ~~therapeutics~~ **drugs, once marketing approval is obtained** . **In the European Union, coverage and reimbursement status of any product candidates for which we obtain regulatory approval are provided for by the national** ~~Laws~~ **laws of member states. The requirements may differ across the EU member states. Also, at national level, actions have been taken to enact transparency and anti- gift laws (similar to the US Physician Payments Sunshine Act) regarding payments between pharmaceutical companies and health care professionals. We are subject to applicable fraud and abuse, transparency, government price reporting, and other healthcare laws** and regulations ~~governing~~ **. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Healthcare providers and third- party payors will play a primary role in the recommendation and prescription of** any ~~international operations~~ **future product candidates** we may **develop and any product candidates for which we obtain marketing approval. Our current and future arrangements with clinical investigators, third- party payors, healthcare provider and customers expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which we research, market, sell and distribute our product candidates. The laws that may affect our ability to operate include, but are not limited to: • the federal Anti- Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term " remuneration " has been broadly interpreted to include anything of value. The federal Anti- Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, and purchasers, on the other the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but these exceptions and safe harbors are narrowly drawn. Practices that are alleged to be intended to induce prescribing, purchases or recommendations, or include any payments of more than fair market value, may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a person or entity does not need to** have **actual knowledge** ~~in the future may preclude us from developing, manufacturing or selling certain products outside~~ of the ~~United States~~ **statute or specific intent to violate it in order to have committed a violation; • federal civil** and **criminal false claims laws,** such **as** ~~foreign operations would require us to develop and implement costly compliance programs. If we expand our operations outside of~~ the **civil False Claims** ~~United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices~~ Act (" ~~FCPA~~ **FCA** ") **, which can be enforced by private citizens through civil qui tam actions, and civil monetary penalty laws** ~~prohibits~~ **prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. For example, pharmaceutical companies have been prosecuted under the FCA in connection with, among other things their alleged off- label promotion of drugs, engaging in improper consulting arrangements with physicians, concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and providing free product to customers with the expectation that the customers would bill federal health care programs for the product. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "** any **request or demand " for money or property presented to the** U. S. **government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to " cause " the submission of false or fraudulent claims. Moreover, a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA; • HIPAA which, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third- party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the**

statute or specific intent to violate it in order to have committed a violation; • HIPAA, as amended by HITECH and their implementing regulations, which imposes privacy, security and breach reporting obligations with respect to ~~individual~~ **individually** ~~or~~ **identifiable health information upon covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective** business ~~from paying~~ **associates and covered subcontractors. HITECH also created new tiers of civil monetary penalties** , ~~offering~~ **amended HIPAA to make civil and criminal penalties directly applicable to business associates** , ~~authorizing~~ **and gave state attorneys general new authority to file civil actions for damages or injunctions in U. S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions; • the federal transparency requirements under the Physician Payments Sunshine Act, created under the Affordable Care Act, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children' s Health Insurance Program to report to CMS information related to** ~~payment~~ **payments and other transfers** ~~or offering of anything~~ of value **provided** ~~, directly or indirectly,~~ to **physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician' s immediate family members; • federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; • state and foreign law equivalents of each of the above federal laws, such as anti- kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by** any **non- governmental third- party payors, including private insurers; and • state and** foreign **laws that require pharmaceutical** ~~official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates~~ companies ~~whose securities are listed in the United States~~ to **implement compliance programs,** 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. Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in~~ the pharmaceutical industry **' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government** , ~~because~~ **or to track and report gifts** , ~~in~~ **compensation and other remuneration provided to physicians and other health care providers; state and local laws that require the registration of pharmaceutical sales representatives; and state health information privacy laws,** many ~~countries, hospitals~~ **of which differ from each other in significant ways and often** are ~~operated~~ **not pre- empted** by **HIPAA, thus requiring additional compliance efforts. We have entered into consulting and scientific advisory board arrangements with physicians and** ~~the~~ **other healthcare providers, including some who could influence the use of our product candidates, if approved, and have received equity awards as compensation for services provided to us. Because of the complex and far- reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who may influence the ordering of and use our product candidates, if approved, to be in violation of applicable laws. Federal and state enforcement bodies have continued their scrutiny of interactions between healthcare companies and healthcare providers, which has led to significant investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource- consuming and can divert management' s attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. If our operations are found to be in violation of any of these laws or any other current or future governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from** government **funded healthcare programs** , **such as Medicare** and ~~doctors~~ **Medicaid, contractual damages, reputational harm, diminished profits** and **future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or** other ~~hospital~~ **agreement to resolve allegations of non- compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Our current or future** employees **, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements and insider trading. We** are **exposed** ~~considered foreign officials. Certain payments~~ to ~~hospitals in connection~~ **the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply** with ~~clinical trials and other~~ -- **the** ~~work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Various laws,~~ regulations ~~and executive orders also restrict the use and dissemination outside~~ of the **FDA and applicable** ~~United States, or the sharing with certain~~ non- U. S. ~~nationals~~ **regulators** , ~~of~~ **provide accurate** information ~~classified for national security purposes, as well as certain products and technical data relating~~ to ~~those~~ -- **the** ~~products~~ **FDA and applicable non- U** . ~~If we expand our presence outside of~~ **S. regulators, comply with healthcare fraud and abuse laws and regulations in** the United States **and abroad** , ~~it will require~~ **report financial information or data accurately or disclose unauthorized activities to** us **. In particular, sales, marketing and business arrangements in the healthcare industry are subject** to ~~dedicate additional resources~~ **extensive laws and regulations**

intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws **or regulations. If any such actions are instituted against us , those actions could have a significant impact on our business, including the imposition of significant civil, criminal** and **administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with** these laws **, and the curtailment or restructuring of our operations. Risks Related to Our Intellectual Property If we are unable to obtain and maintain sufficient intellectual property protection for Auxora, any future product candidates, and other proprietary technologies we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize Auxora, any future product candidates, and other proprietary technologies if approved, may be adversely affected. Our commercial success will depend in part on our ability to obtain and maintain a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to Auxora, any future product candidates, and other proprietary technologies we develop. If we are unable to obtain or maintain patent protection with respect to Auxora, any future product candidates, and other proprietary technologies we may develop, our business, financial condition, results of operations, and prospects could be materially harmed. The patent position of biotechnology and pharmaceutical companies is highly uncertain and involves complex legal, scientific, and factual questions and has been the subject of frequent litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our patent applications may not result in patents being issued which protect Auxora, any future product candidates, and other proprietary technologies we may develop or which effectively prevent others from commercializing competitive technologies and products. Further, no consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in ~~may~~ many ~~preclude~~ jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our actual or potential future collaborators will be successful in protecting Auxora, any future product candidates, and other proprietary technologies and their uses by obtaining, defending and enforcing patents. These risks and uncertainties include the following: • the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction; • patent applications may not result in any patents being issued; • patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or may otherwise not provide any competitive advantage; • our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, or eliminate our ability to make, use and sell our potential product candidates; • other parties may have designed around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same composition of matter, methods or formulations or by claiming subject matter that could dominate our patent position; • any successful opposition to any patents owned by or licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any products or product candidates that we may develop; • because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to Auxora, any future product candidates, and other proprietary technologies and their uses; • an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications for any application with an effective filing date before March 16, 2013; • there may be significant pressure on the U. S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and • countries other than the United States may have patent laws less favorable to patentees than those upheld by U. S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing product candidates in those countries. The patent prosecution process is expensive, time- consuming, and complex, and we may not be able to file, prosecute, or maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-**

disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection for such output. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, 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 that we were the first to make the inventions claimed in any of our owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use Auxora, any future product candidates, and other proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations. For example: • others may be able to make compounds that are similar to Auxora and any future product candidates but that are not covered by the claims of our patents; • we might not have been the first to make the inventions covered by our pending patent applications; • we might not have been the first to file patent applications for these inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies; • any patents that we obtain may not provide us with any competitive advantages; • we may not develop additional proprietary technologies that are patentable; • our competitors might conduct research and development activities in countries where we do not have patent rights or where patent protection is weak and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we cannot ensure that any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products; • we cannot ensure that we will be able to successfully commercialize our products on a substantial scale, if approved, before the relevant patents that we own expire; or • the patents of others may have an adverse effect on our business. Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed by us, or that we will not be involved in interference, opposition or invalidity proceedings before U. S. or non- U. S. patent offices. We cannot be certain that the claims in our issued patents and pending patent applications covering Auxora or any future product candidates will be considered patentable by the USPTO, courts in the United States, or by patent offices and courts in foreign countries. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property internationally. The strength of patents in the biotechnology and pharmaceutical fields involves complex legal and scientific questions and can be uncertain. The patent applications that we own may fail to result in issued patents with claims that cover Auxora and any future product candidates in the United States or in foreign countries. Even if such patents do successfully issue, third parties may challenge the ownership, validity, enforceability, or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to our patents could deprive us of exclusive rights necessary for the successful commercialization of Auxora and any future product candidates. Furthermore, even if they are unchallenged, our patents may not adequately protect our intellectual property, provide exclusivity for Auxora or any future product candidates or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold with respect to Auxora or any future product candidates is threatened, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, Auxora or any future product candidates. For U. S. patent applications in which claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our participation in an interference proceeding may fail and, even if successful, may result in substantial costs and distract our management and other employees. For U. S. patent applications containing a claim not entitled to priority before March 16, 2013, there is greater level of uncertainty in the patent law. In September 2011, the Leahy- Smith America Invents Act, or America Invents Act, was signed into law. The America Invents Act includes a number of significant changes to U. S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is developing regulations and procedures to govern the administration of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and in particular, the " first to file " provisions, were enacted on March 16, 2013. This will require us to be cognizant going forward of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from ~~developing, manufacturing,~~ **promptly filing patent applications on ~~or~~ our ~~selling certain products~~ inventions. It remains unclear what impact the America Invents Act will have on the operation of our business. As such, the America Invents Act** and **its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on**

our business and financial condition. Patent terms may be inadequate to protect our competitive position on our product candidates ~~outside~~ **for an adequate amount** of **time. The term of any individual patent depends on applicable law in the country where the patent is granted. In** the United States, **and we** employ an outside firm and rely on our outside counsel to pay these fees due to ~~foreign~~ **non- U.S.** patent agencies. ~~While~~ **We employ reputable law firms and other professionals to help us comply,and in many cases,** an inadvertent lapse **can** ~~may sometimes~~ be cured by payment of a late fee or by other means in accordance with the applicable rules **.However** ,there are situations in which **non-** ~~noncompliance~~ --- **compliance** 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.In such an event,our competitors might be able to enter the market **and this circumstance** ~~with similar or identical products or technology earlier than should otherwise have been the case,which~~ would have a material adverse effect on our business ~~,financial condition,results of operations,and prospects~~ . **We rely on** ~~Changes in U.S.patent law could diminish the value of patents in general,thereby impairing~~ our ability to **stop others from competing by enforcing our patents;however,some jurisdictions** which could **materially diminish the value of those patents. This could** limit our ~~growth~~ potential **revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. 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 or pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. In Europe, beginning June 1, 2023, European applications and patent may be subjected to the jurisdiction of the Unified Patent Court (" UPC "). Also, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty. As a single court system can invalidate a European patent, we, where applicable may opt out of the UPC and as such, each European patent would need to be challenged in each individual country. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Geopolitical actions in the United States and in foreign countries could** increase ~~our development~~ **the uncertainties and** costs **surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia' s invasion of Ukraine and the conflict in the Middle East may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. We currently maintain one granted patent in Russia. We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents rights, trade secrets, or other intellectual property as an inventor or co- inventor** . The failure to ~~comply~~ **name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. For example, we may have inventorship disputes arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing Auxora or as a result of questions regarding co- ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and / or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in- licenses. Our program may require the use of intellectual property rights held by third parties. The growth of our business may depend in part on our ability to acquire, in- license or use these proprietary rights. In addition, Auxora may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in- license, on reasonable terms, proprietary rights related to any compositions, formulations, methods of use, processes or other intellectual property rights from third parties that we identify as being necessary for Auxora. Even if we are able to obtain a license to such proprietary rights, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Where we obtain licenses from or collaborate** with **third parties, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. Therefore, these patents and applications may not be prosecuted and enforced in**

a manner consistent with the best interests of our business, or in compliance with applicable laws ~~governing international~~ **and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such application. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, including making royalty and milestone payments, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, could have a material adverse impact on our** business **. Our business would suffer if any such licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third** ~~practices~~ **parties , if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties** may **gain the freedom to seek regulatory approval of, and to market, products identical or similar to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a** result **, we** ~~in substantial civil and criminal penalties and suspension or debarment from government contracting. The Securities and Exchange Commission (" SEC ") also~~ may ~~suspend or bar issuers from trading securities on U. S. exchanges~~ **be subject to claims, regardless of their merit, that we are infringing** ~~for~~ **or otherwise** ~~violations~~ **violating** ~~of~~ the ~~FCPA~~ **licensor** ' s ~~accounting provisions~~ **rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability. The licensing and acquisition of third- party proprietary rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third- party proprietary rights that we may consider necessary or attractive in order to commercialize Auxora. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. For example, we may collaborate with U. S. and foreign academic institutions to accelerate our research development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate an exclusive license to any of the institution' s proprietary rights in technology resulting from the collaboration. Regardless of such option to negotiate a license, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer, on an exclusive basis, their proprietary rights to other parties, potentially blocking our ability to pursue our program. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us, either on reasonable terms, or at all** . We **also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we** are ~~subject~~ **unable** to ~~stringent and changing privacy laws~~ **successfully obtain rights to required third- party intellectual property rights on commercially reasonable terms** , ~~regulations~~ **our ability to commercialize our products,** and ~~standards~~ **our business, financial condition, and prospects for growth, could suffer. Third- party claims alleging intellectual property infringement may prevent or delay our drug discovery and development efforts. Our success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries,** as well as ~~contractual obligations~~ **administrative proceedings for challenging patents, including inter partes review, interference and reexamination proceedings before the USPTO, or oppositions and other comparable proceedings in foreign jurisdictions. The America Invents Act introduced new procedures including inter partes review and post grant review. The implementation of these procedures brings uncertainty to the possibility of challenges to our patents in the future and the outcome of such challenges. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing Auxora. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our activities** related to ~~data privacy~~ **Auxora may give rise to claims of infringement of the patent rights of others. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. We cannot assure you that any of our current or future product candidates will not infringe existing or future patents. We may not be aware of patents that have already issued that a third party might assert are infringed by one of our current or future product candidates. Nevertheless, we are not aware of any issued patents that will prevent us from marketing Auxora. Third parties may assert that we are employing their proprietary technology without authorization. There may be third- party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of Auxora. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be currently pending third- party patent applications which may later result in issued patents that Auxora, any future product candidates, and other proprietary technologies may infringe, or which such third parties claim are infringed by the use of our technologies. Parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize Auxora or future product candidates. Defense of these claims, regardless of their merit, could involve substantial expenses and could be a substantial diversion of management and other employee resources from our business. If we collaborate with third parties in the development of technology in the future, our 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 litigation or potential liability. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties. Any claims of patent infringement asserted by third parties would be time- consuming and could: • result in costly litigation; • divert the time and attention of our technical personnel and management; • cause development delays; • prevent us from commercializing Auxora or any future product candidates until the asserted patent expires or is finally held invalid, unenforceable, or not infringed in a court of law; • require us to develop non-infringing technology, which may not be possible on a cost- effective basis; • require us to pay damages to the party whose intellectual property rights we may be found to be infringing, which may include treble damages if we are found to have been willfully infringing such intellectual property; • require us to pay the attorney' s fees and costs of litigation to the party whose intellectual property rights we may be found to be willfully infringing; and / or • require us to enter into royalty or license agreements, which may not be available on commercially reasonable terms, or at all. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do either. Proving invalidity or unenforceability is difficult. For example, in the United States, proving invalidity before federal courts requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management' s time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend ~~and~~ **- an** ~~seeurity~~ **infringement action or challenge the validity or enforceability of the patents in court. Patent litigation is costly and time- consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non- infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid or unenforceable, we may incur substantial monetary damages, encounter significant delays in bringing Auxora or any future product candidates to market and be precluded from developing, manufacturing or selling Auxora or any future product candidates. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. We cannot be certain that any of our patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the United States, Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction, because: • some patent applications in the United States may be maintained in secrecy until the patents are issued; • patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived; • pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, Auxora, and any future product candidates or the use of Auxora and any future product candidates; • identification of third- party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims; • patent applications in the United States are typically not published until 18 months after the priority date; and • publications in the scientific literature often lag behind actual discoveries. Furthermore, the scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history and can involve other factors such as expert opinion** . Our ~~actual~~ **interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact** ~~or~~ **our ability** ~~perceived failure~~ to ~~comply~~ **market our products. Further, we may incorrectly determine that our technologies, products, or product candidates are not covered by a third- party patent or may incorrectly predict whether a third party' s pending patent application will issue** with **claims of relevant scope. Our determination of the expiration date of any patent in the United States or internationally that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products or product candidates. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours, and others may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import Auxora and future approved products or impair our competitive position. Numerous third-party U. S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third- party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of Auxora. Any** such ~~obligations~~ **patent application may have priority over our patent applications, which** could **further require** ~~harm our reputation, subject~~ us to ~~significant fines and liability, or otherwise adversely affect~~ **obtain rights to issued patents covering such technologies. If another party has filed a U. S. patent application on inventions similar to** ~~our~~ **ours** ~~business or prospects. We are~~ , **we may have to participate in** ~~and~~ - **an interference proceeding declared by** ~~may increasingly become, subject to various laws and regulations, as well as contractual obligations, relating to data privacy and security in~~ the ~~jurisdictions~~ **USPTO to determine priority of invention** in ~~which we operate~~ **the United States** . The **costs of** ~~regulatory environment related to data privacy and security is increasingly rigorous, with new and constantly changing requirements applicable to our business, and enforcement practices are likely to remain uncertain for the foreseeable future. These~~ **these proceedings could** ~~laws and regulations may~~ be **substantial** ~~interpreted and applied differently over time and from jurisdiction to jurisdiction~~ , and it is possible that **such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the**

same or similar invention prior to our own invention, resulting in a loss of our U. S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications and may be entitled to priority over our applications in such jurisdictions. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they ~~will be interpreted~~ **have substantially greater resources. In addition, any uncertainties resulting from the initiation** and ~~applied in ways that may~~ **continuation of any litigation could** have a material adverse effect on our **ability to raise the funds necessary to continue our operations. If a third party prevails in a patent infringement lawsuit against us, we may have to stop making and selling the infringing product, pay substantial damages, including treble damages and attorneys' fees if we are found to be willfully infringing a third party' s patents, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of Auxora. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize Auxora, which could harm our** business **significantly. Even if we were able to obtain a license** , ~~financial condition~~ **the rights may be nonexclusive** , **which may give our competitors access to the same intellectual property. We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers. As is common in the biotechnology and pharmaceutical industries, in addition to our employees, we engage the services of consultants to assist us in the development of Auxora, any future product candidates, and other proprietary technologies. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could** ~~results~~ **result** ~~of operations~~ **in substantial costs** and **be a distraction to our management team and other employees. We may be involved in lawsuits to** ~~prospects~~ **protect or enforce our patents which could be expensive, time- consuming, and unsuccessful** . ~~In~~ **Further, our issued patents could be found invalid or unenforceable if challenged in court, and we may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights. Third parties including competitors may infringe, misappropriate or otherwise violate our patents or patents that may issue to us in the future. To counter infringement or unauthorized use, we may need to or choose to file infringement claims, which can be expensive and time- consuming. We may not be able to prevent, infringement, misappropriation, or other violation of our intellectual property, particularly in countries where the laws may not protect those rights as fully as in** the United States ~~, in addition~~ **. If we choose** to ~~HIPAA~~ **go to court to stop another party from using the inventions claimed in our patents** , ~~various federal~~ **that individual or company has the right to ask the court to rule that such patents are invalid, unenforceable, or should not be enforced against that third party for any number of reasons. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. Grounds for a validity challenge include** ~~and~~ **an** ~~state regulators~~ **alleged failure to meet any of several statutory requirements for patentability, including lack of novelty, obviousness, lack of written description, indefiniteness, or non- enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution, i. e., committed inequitable conduct. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in foreign patent offices and courts and may result in the revocation, cancellation, or amendment of any foreign patents we hold now or in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents invalid. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would** have ~~adopted,~~ **a material adverse impact on** ~~or~~ **our business** ~~are considering adopting, laws and regulations concerning personal information and data security~~ . **Interference** ~~Certain state laws may be more stringent~~ or ~~broader in scope,~~ **derivation proceedings provoked by third parties** or ~~offer greater individual rights,~~ **brought by us or declared by the USPTO may be necessary to determine the priority of inventions** with respect to ~~personal information than federal, international or~~ **our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all if a non- exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and** other ~~state laws~~ **employees. In addition** , ~~and such laws may differ from each other~~ -- **the uncertainties** ~~, all of which may complicate compliance efforts. For example, the California Consumer Privacy Act (" CCPA ") which increases privacy rights for California residents and imposes obligations on companies that process their personal information, came into effect on January 1, 2020, and became enforceable by the California Attorney General on July 1, 2020, along with related regulations which came into force on August 14, 2020. Additionally, although not effective until January 1, 2023, the California Privacy Rights Act (the " CPRA ") which expands upon the CCPA, was passed in the recent~~

~~election on November 3, 2020. Among other things, the CCPA requires covered companies to provide new disclosures to California consumers about their data collection, use and sharing practices and provide such consumers new data protection and privacy rights, including the ability to opt out of certain sales of personal information, right to request correction, access, and deletion of their personal information, the right to opt out of certain personal information sharing, and the right to receive detailed information about how their personal information is processed. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks~~ associated with ~~, data breach~~ litigation ~~. The CPRA significantly modifies the CCPA, including by expanding consumers' rights with respect to certain personal information and creating a new state agency to oversee implementation and enforcement efforts. The CCPA and CPRA may increase our compliance costs and potential liability, particularly in the event of a data breach, and~~ could have a material adverse effect on our ~~business~~ **ability to raise the funds necessary to continue our clinical trials** , ~~including how we~~ **continue our research programs, license necessary technology from third parties, or enter into development or manufacturing partnerships that would help** ~~use~~ **us bring Auxora and any future product candidates to market. Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management** ~~personal~~ **personnel** ~~information~~ **from their normal responsibilities. In addition** , **there could be public announcements of the results of hearings, motions,** ~~our~~ **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 ~~condition, the results of our~~ **or** ~~operations~~ **other resources to conduct such litigation or proceedings adequately. Some of** ~~or~~ **our** ~~prospects~~ **competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources** . ~~State laws are changing rapidly~~ **Uncertainties resulting from the initiation** and **continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation,** there is ~~discussion~~ **a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used** in **connection with** ~~the~~ **their** ~~U~~ **products and services** . ~~S.~~ **Moreover, it may be difficult or impossible to obtain evidence** of **infringement in** a ~~new comprehensive federal data privacy law~~ **competitor' s or potential competitor' s product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties. Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk- adjusted cost of bringing and enforcing such a claim or action may be** ~~to~~ **too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non- litigious action or solution. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. Our reliance on third parties requires us to share our trade secrets,** which **increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. We may rely on trade secrets to protect our proprietary technologies, especially where** we ~~would become subject if~~ **do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors, and inventions agreements with employees, consultants, and advisors, to protect our trade secrets and other proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and** it is **not clear at** ~~enacted. Additionally, the CCPA has prompted a number of proposals for new federal and state- level privacy legislation, such as in Nevada, Virginia, New Hampshire, Illinois and Nebraska. Such new privacy laws add additional complexity, requirements, restrictions and potential legal risk, require additional investment in resources for compliance programs, and could impact business strategies and the availability of previously useful data. Internationally, laws, regulations and standards in many jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other -- **the present time how** ~~processing of personal information. For example,~~ the **FDA** ~~General Data Protection Regulation (" GDPR ") of the European Union (" EU ") which became effective in May 2018, greatly increased the European Commission~~ ' s ~~jurisdictional reach of its laws~~ **disclosure policies may change in the future, if at all. Costly** and ~~adds a broad array~~ **time- consuming litigation could be necessary to enforce and determine the scope** of ~~requirements~~ **our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. In addition, such security measures may not provide adequate protection** for ~~handling personal~~ **our proprietary** information ~~, including~~ , for example, ~~requirements to establish~~ **in the case of misappropriation of** a ~~legal basis~~ **trade secret by an employee, consultant, customer, or third party with authorized**

access. Our security measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time- consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for ~~processing, higher standards~~ **protection of trade secrets can vary among different jurisdictions. Enforcing a claim that a party illegally disclosed** ~~for -~~ **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. Moreover, third parties may still** ~~obtaining --- obtain consent~~ **this information or may come upon this or similar information independently, and we would have no right to prevent them** from **using that technology or** ~~individuals to process their personal~~ information ~~, more robust disclosures~~ to **compete with us. Trade secrets will over time be disseminated within** ~~individuals and a strengthened individual data rights regime, requirements to implement safeguards to protect~~ the ~~security and confidentiality~~ **industry through independent development, the publication** of **journal articles, and the movement of** ~~personal~~ **personnel skilled in** ~~information that requires~~ the **art from company to company** ~~adoption of administrative, physical and technical safeguards, shortened timelines for -~~ **or academic** ~~data breach notifications~~ to ~~appropriate data protection authorities~~ **industry scientific positions. Though** ~~or~~ **our agreements with third parties typically restrict the ability** ~~data subjects, limitations on retention and secondary use~~ of ~~information~~ **our advisors** , **employees, collaborators, licensors, suppliers,** ~~increased requirements pertaining to health data and additional requirements that we impose certain contractual obligations on~~ third- party ~~processors in connection~~ **contractors, and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete** with **us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our products and provision of our services, we must, at times, share trade secrets with** ~~the~~ **them** ~~processing of~~ **. Despite employing the contractual and** ~~the~~ **other** ~~personal~~ **security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this** information **may be greatly reduced and our competitive position would be harmed** . ~~EU member states~~ **If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized. If our trademarks and trade names** are ~~tasked under~~ **not adequately protected,** ~~the~~ **then** ~~GDPR~~ **we may not be able** to ~~enact~~ **build name recognition in our markets of interest and our business may be adversely affected. Our future trademarks or trade names may be unable to be obtained** , **challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build** ~~and~~ **brand** ~~have enacted~~ **identity and possibly leading to market confusion. In addition** , ~~certain implementing legislation~~ **there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks** that **incorporate variations of** ~~adds to and / or~~ **our** ~~further interprets~~ **registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names,** ~~the~~ **then we may not be able** ~~GDPR requirements and potentially extends our obligations and potential liability for failing~~ to ~~meet~~ **compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties,** such ~~obligations~~ **as distributors** . **Though these license agreements may provide** ~~The GDPR, together with national legislation, regulations and~~ guidelines ~~of the EU member states governing the processing of personal information, impose strict obligations and restrictions on the ability to collect, use, retain, protect, disclose, transfer and otherwise process personal information. In particular, the GDPR includes obligations and restrictions concerning the consent and rights of individuals to whom the personal information relates, the transfer of personal information out of the European Economic Area, security breach notifications and the security and confidentiality of personal information. The GDPR authorizes fines for certain violations of up to 4 % of global annual revenue or € 20 million, whichever is greater, and other administrative penalties. Additionally, the United Kingdom (" UK ") implemented the Data Protection Act effective in May 2018 and statutorily amended in 2019, that substantially implements the GDPR and contains provisions, including UK- specific derogations,~~ for how **our trademarks and** ~~GDPR is applied in the UK. On May 1, 2021, the transition period of the Trade~~ **trade** ~~and Cooperation~~ **names may be used, a breach of these** ~~Agreement~~ **agreements or misuse** ~~between the EU and the UK ended. Subsequently, the European Commission adopted a definitive adequacy decision addressing the transfers~~ of ~~personal data from~~ **our trademarks and tradenames by our licensees may jeopardize our rights in or diminish** the **goodwill associated** ~~European Economic Area to the United Kingdom under the GDPR on June 28, 2021. As a result, we will have to continue to comply~~ with ~~the GDPR and also the Data Protection Act in the UK as well as the EU, with each regime having the ability to fine up to the greater of € 20 million (£ 17 million) or~~ **our trademarks** ~~4 % of global turnover. The costs of compliance with,~~ and **trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights, or** other **intellectual property** ~~burdens imposed by, such laws and regulations that are applicable to our business operations~~ may **be ineffective** ~~limit~~

~~the use and adoption of our services, reduce overall demand for them. Changes in these legislations may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment in resources for compliance programs, could impact strategies and availability of previously useful data,~~ and could result in **substantial** ~~increased compliance~~ costs and ~~/ or changes in business practices and policies. Additionally, on July 16, 2020, the Court of Justice of the European Union (the " Court of Justice ") invalidated the European Union- United States (" EU- U. S. ") Privacy Shield on the grounds that the EU- U. S. Privacy Shield failed to offer adequate protections to EU personal information transferred to the United States. While the Court of Justice upheld the use of other data transfer mechanisms, such as the Standard Contractual Clauses, the decision has led to some uncertainty regarding the use of such mechanisms for data transfers to the United States, and the court made clear that reliance on Standard Contractual Clauses alone may not necessarily be sufficient in all circumstances. The use of Standard Contractual Clauses for the transfer of personal information specifically to the United States also remains under review by a number of European data protection supervisory authorities. For example, German and Irish supervisory authorities have indicated that the Standard Contractual Clauses alone provide inadequate protection for EU- U. S. data transfers. Use of the data transfer mechanisms must now be assessed on a case- by- case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals. The European Data Protection Board (the " EDPB ") issued additional guidance regarding the Court of Justice' s decision on November 11, 2020 which imposes higher burdens on the use of data transfer mechanisms, such as the Standard Contractual Clauses, for cross- border data transfers. To comply with this guidance, we may need to implement additional safeguards to further enhance the security of data transferred out of the EU, which could increase our compliance costs, expose us to further regulatory scrutiny and liability, and adversely affect our business. Further, in November 2020, the European Commission published new versions~~ - **diversion** of **resources** ~~the Standard Contractual Clauses. Other countries (e. g., Australia and Japan) have also adopted certain legal requirements for cross- border transfers of personal information. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. While the Court of Justice of the European Union has upheld the adequacy of the Standard Contractual Clauses, it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Some countries also are considering or have passed legislation requiring local storage and processing of data, or similar requirements, which could increase the cost and complexity of delivering our products and services. If we are required to implement additional measures to transfer data from the European Economic Area, this could increase our compliance costs,~~ and could adversely affect our ~~business,~~ financial condition ~~and~~ **or** results of operations. ~~All of~~ **Moreover, any trade name we have proposed to use for products in** ~~these~~ -- **the United States** ~~evolving compliance and operational requirements impose significant costs~~ , such as ~~costs related to organizational changes~~ **Auxora must be approved by the FDA** , ~~implementing~~ **regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, we may be required to expend significant** additional **resources in** ~~protection technologies, training employees and~~ - **an effort** ~~engaging consultants, which are likely~~ to ~~increase over~~ **identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. Similar requirements exist in Europe. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At** ~~time~~ **times , competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion** . In addition, **there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of** such ~~requirements~~ **trademarks. Any collaboration arrangements that we** may ~~require~~ **enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products. Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that: • collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations; • collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with Auxora and any future product candidates; • a collaborator with marketing, manufacturing, and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities; • we could grant exclusive rights to our collaborators that would prevent** us ~~to modify~~ **from collaborating with others; • collaborators may not properly maintain** ~~our~~ - **or** ~~data~~ **defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; • disputes may arise between us and a collaborator that causes the delay or termination of the research, development, or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources; • collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue**

further development or commercialization of the applicable current or future products; • collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and • a collaborator' s sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal ~~processing~~ **proceedings . General Risk Factors Our business operations may subject us to disputes, claims and lawsuits, which may be costly and time- consuming and could materially and adversely impact our financial position and results of operations. From time to time, we may become involved in disputes, claims and lawsuits relating to our business operations. In particular, we may face claims related to the safety of our products, intellectual property matters, employment matters, tax matters, commercial disputes, competition, sales and marketing** practices ~~and policies~~ , ~~distract~~ **environmental matters, personal injury, insurance coverage and acquisition or divestiture- related matters. Any dispute, claim or lawsuit may divert** management ~~or divert resources~~ **' s attention away** from **our business, we may incur significant expenses in addressing or defending any dispute, claim or lawsuit, and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our operations and financial results. Litigation related to these disputes may be costly and time- consuming and could materially and adversely impact our financial position and results of operations if resolved against us. In addition,** ~~other~~ -- **the** ~~initiatives and projects~~ **uncertainty associated with litigation could lead to increased volatility in our stock price. If we fail to comply with environmental** , ~~all of which~~ **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 ~~, financial condition, results of operations and prospects~~ . **We** ~~Any failure or perceived failure by us to comply with any applicable federal~~ , ~~state or similar foreign laws~~ and ~~regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other~~ -- **the** third parties ~~, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties or judgments. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects. If we or any CMOs we engage fail to comply~~ with **whom** ~~environmental, health and safety laws and regulations,~~ we **share** ~~could become subject to fines or~~ **our facilities,** ~~penalties or incur significant costs. We and any CMOs we may engage in the future~~ are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. **Each of** ~~From time to time and in the future,~~ our operations ~~may~~ involve the use of hazardous **and flammable** materials, including chemicals and biological **and radioactive** materials ~~, and~~ **. Each of our operations also** produce hazardous waste products. We generally contract with third parties for the disposal of these materials and ~~wastes~~ **waste** . We cannot eliminate the risk of contamination or injury from these materials. **We** ~~In the event of contamination or injury resulting from our use of hazardous materials, we~~ could be held liable for any resulting damages **in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities** , and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties ~~for failure to comply with such laws and regulations~~ . Although we maintain ~~general liability insurance as well as~~ 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 maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research ~~,~~ **and** development ~~or production efforts~~ . ~~Our failure~~ **Failure** to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. ~~Further,~~ **Our business involves the use of hazardous materials and we and our third- party manufacturers and suppliers must comply** with ~~respect~~ **environmental laws and regulations, which can be expensive and restrict how we do business. Our research and development activities and our or any third- party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us. We and our manufacturers and suppliers are subject** to **laws and regulations governing the use, manufacture, storage, handling and disposal of** ~~the~~ **these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our research and development efforts and business** operations ~~of any CMOs~~ , ~~it is possible~~ **environmental damage resulting in costly clean- up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe** that ~~if they~~ **the** ~~fail to operate in compliance~~ **safety procedures utilized by our third- party manufacturers and suppliers for handling and disposing of these materials generally comply** with **the standards prescribed by these** ~~applicable environmental, health and safety~~ laws and regulations ~~or properly dispose of wastes associated with~~ **, this may not be the case** ~~our~~ **or and** ~~products,~~ we ~~could~~ **may not eliminate the risk of accidental contamination or injury from these materials. In such an event, we may** be held liable for any resulting damages **and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and / or interrupt our business operations. Furthermore** , ~~suffer~~ **environmental laws and regulations are complex, change frequently and have tended to become more stringent over time. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage. Any contamination by such hazardous materials could therefore adversely affect our business, financial condition, results of operations and prospects. Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations. Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and**

affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. We are subject to certain U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations. U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations, including the U. S. Foreign Corrupt Practices Act (collectively, " Trade Laws "), prohibit, among other things, companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm **, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We also expect** ~~or~~ **our** ~~experience a disruption in~~ **non- U. S. activities to increase over time. We expect to rely on third parties for research, preclinical studies, and clinical trials and / or to obtain necessary permits, licenses, patent registrations, and** ~~the~~ **other** ~~manufacture and supply~~ **marketing approvals. We can be held liable for the corrupt or other illegal activities** of **our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. The market price of our stock has been and may continue to be volatile, and you could lose all or part of** ~~our~~ **your investment. The trading price of our common stock has been in the past, and may continue to be, highly volatile and subject to wide fluctuations in response to various factors, many of which we cannot control. Market prices for securities of early- stage pharmaceutical, biotechnology, and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include: • our ability to obtain regulatory approvals for** product candidates **,** ~~or products. Risks Related to Employee Matters~~ and **delays** ~~Managing Growth Our future success will depend on our~~ **or** ~~ability~~ **failures** to **obtain such approvals; •** ~~retain key executives and to attract, retain and motivate qualified personnel. We are highly dependent on the research and development, clinical and business development expertise of Frederic Guerard, our chief executive officer, as well as other principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them~~ **the failure of** ~~may terminate their employment with us at~~ any ~~time. If our planned merger fails to close, recruiting and retaining qualified scientific, clinical, manufacturing 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 have relied 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 may need 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. If our planned merger fails to close, we may require significant growth in the number of our employees and the scope of our operations, particularly in the areas of product development, clinical, regulatory affairs, manufacturing, sales, marketing, finance and distribution, which growth would need to begin before we receive regulatory approval from the FDA or other regulatory authorities, and we may never receive such regulatory approval for any of our future product approvals. To manage such future growth, we would need to continue to implement and improve our managerial, operational, and financial systems, reestablish our facilities and recruit and train additional qualified personnel. Due to our limited financial resources and our limited experience in managing such growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. Risks Related to Ownership of Our Common Stock Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. If our planned merger fails to close, our operating plan, which currently comprises the development of our two preclinical programs, we would expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results would then be affected by numerous factors, including: • variations in the level of expense related to the development** of our product candidates **, if approved** ~~or~~ **for marketing** ~~future development programs; • results of clinical trials, or the addition or termination of clinical trials or funding support by us, or existing or future collaborators or licensing partners; • our execution of any additional collaboration, licensing or similar arrangements,~~ and **commercialization, to achieve**

commercial success ~~the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements~~ ; • any **inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices; • the entry into, or termination of, key agreements, including key licensing, supply or collaboration agreements; • the initiation of material developments in, or conclusion of, disputes or litigation to enforce or defend any of our** intellectual property **rights** ~~infringement lawsuit~~ or **defend against the intellectual property rights of others** ~~opposition, interference or cancellation proceeding in which we may become involved~~ ; • ~~additions and departures of key personnel; • strategic decisions by us or our competitors, such as acquisitions, divestitures, spin- offs, joint ventures, strategic investments or~~ changes in **laws** ~~business strategy; • if any of our~~ **or** ~~product candidates receives regulatory~~ **regulations applicable to our** ~~approval, the terms of such approval and market acceptance and demand for such~~ product candidates; • ~~regulatory developments affecting our product candidates or those~~ -- **the** ~~of our competitors; and • changes in general market and economic conditions. If our quarterly operating~~ results ~~fall below the expectations~~ of **current** ~~investors or securities analysts~~ , **and** ~~the price of our common stock could decline substantially. Furthermore,~~ any ~~quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our~~ future **, nonclinical** ~~performance. The trading price of our~~ - **or** ~~common stock has been in the past, and may continue to be, highly volatile and subject to wide fluctuations in response to various factors, many of which we cannot control. The market price for our common stock may be influenced by many factors, including the other risks described in this section and elsewhere in this filing, and the following: • market perception of the value of our proposed merger partner, CalciMedica, or the likelihood of the merger being completed in a timely fashion, if at all; • results of future preclinical studies and~~ clinical trials of ~~our product candidates, or those of our competitors or our existing or future collaborators; • the impact of the COVID- 19 pandemic on our employees, future preclinical studies or clinical trials, collaboration partners, suppliers, our results of operations, liquidity and financial condition; • regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to~~ our product candidates; • ~~the success of competitive products or technologies; • introductions and announcements of new product candidates by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements; • actions taken by regulatory agencies with respect to our product candidates, future preclinical studies or clinical trials, manufacturing process or sales and marketing terms; • actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us; • the success of our future efforts to acquire or in- license additional technologies, products or product candidates; • developments concerning any future collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners; • market conditions in the pharmaceutical and biotechnology sectors; •~~ announcements by ~~us or~~ **commercial partners** ~~our~~ - **or** competitors of **new commercial products, clinical progress (or the lack thereof),** significant ~~acquisitions~~ **contracts** , ~~strategic collaborations~~ **commercial relationships** , ~~joint ventures~~ or capital commitments; • **failure to meet or exceed financial and development projections we may provide to the public; • failure to meet or exceed the financial and development projections of the investment community; • the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community; • adverse publicity relating to our markets, including with respect to other products and potential products in such markets; • the introduction of technological innovations or new therapies competing with our potential products; • announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors; • disputes or other** developments **relating to** ~~or disputes concerning patents or other~~ proprietary rights, including patents, litigation matters **,** and our ability to obtain patent protection for our **technologies** ~~product candidates and products~~ ; • ~~our ability or inability to raise additional capital and~~ the **loss of key employees** ~~terms on which we raise it~~ ; • **significant lawsuits, including patent or stockholder litigation; • if securities or industry analysts do not publish research or reports about our business, or if** ~~the~~ **they** ~~recruitment~~ **issue an adverse or misleading opinion regarding** ~~or~~ **our business and stock** ~~departure of key personnel~~ ; • changes in the **market valuations** ~~structure or policies~~ of **similar companies** ~~healthcare payment systems~~ ; • ~~actual~~ **general and industry- specific economic conditions potentially affecting** ~~or~~ **our research and development expenditures; • sales of its** ~~anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our~~ common stock ~~, other comparable companies or our industry generally; • our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market; • fluctuations in the valuation of companies perceived~~ by ~~investors to be comparable to~~ us **or** ~~; • announcement and expectation of additional financing efforts; • speculation in the press or~~ **our** ~~investment community~~ **stockholders in the future** ; • trading volume ~~of our common stock; • delisting, or the expectation of delisting of our common stock from the Nasdaq Global Market stock exchange; • sales of our common stock by us or our stockholders; • the concentrated ownership~~ of our common stock; • changes in ~~accounting principles~~ **the structure of health care payment systems** ; • **adverse regulatory decisions** ~~terrorist acts, acts of war or periods of widespread civil unrest~~ ; • **trading volume of our common stock** ~~natural disasters, pandemics and other calamities~~ ; and • **period- to- period fluctuations in our financial results. Moreover, the stock markets in** general ~~economic, industry and market conditions including increased interest rates and the effects of inflation. In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular,~~ have experienced **substantial volatility** ~~extreme price and volume fluctuations~~ that ~~have~~ **has often** been ~~often~~ unrelated ~~or disproportionate~~ to the operating performance of **individual companies or** the ~~issuer~~ **biotechnology and pharmaceutical sectors, including as a result of disruptions to and volatility in the credit and financial markets in the United States and worldwide from geopolitical and macroeconomic events, including the ongoing Russia- Ukraine and Middle East conflicts and related sanctions, and bank failures** . These broad market **fluctuations** ~~and industry factors~~ may ~~seriously harm~~ **also adversely affect the trading price of our common stock. In the past, following periods of volatility in** the market price of **a company' s securities, stockholders have often instituted class action securities litigation against those companies.**

Regardless of the merits or the ultimate results of such litigation, if instituted, such litigation could result in substantial costs and diversion of management' s attention and resources, which could significantly harm our profitability and reputation. Financial reporting obligations of being a public company in the United States are expensive and time-consuming, and our management needs to devote substantial time to compliance matters. As a publicly traded company, we incur significant additional legal, accounting and other expenses that CalciMedica did not incur as a privately held company, including costs associated with public company reporting requirements. The obligations of being a public company in the United States require significant expenditures and will place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended (the " Exchange Act ") and the rules and regulations regarding corporate governance practices, including those under the Sarbanes- Oxley Act of 2002 (the " Sarbanes- Oxley Act "), the Dodd- Frank Wall Street Reform and Consumer Protection Act (the " Dodd- Frank Act ") and the listing requirements of the stock exchange on which our securities are listed. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain such insurance. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules and regulations will make some activities more time- consuming and costly, particularly after we are no longer an " emerging growth company " or a " small reporting company ". Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation, among other potential problems. The relative lack of public company experience of our management team may put us at a competitive disadvantage. Our management team lacks significant public company experience, which could impair our ability to comply with legal and regulatory requirements such as, but not limited to, those imposed by the Sarbanes- Oxley Act. Our senior management does not have significant experience managing a publicly traded company. Such responsibilities include complying with federal securities laws and making required disclosures on a timely basis. Our senior management may be unable to implement programs and policies in an effective and timely manner or that adequately respond to the increased legal, regulatory and reporting requirements associated with being a publicly traded company. Our failure to comply with all applicable requirements could lead to the imposition of fines and penalties, distract our management from attending to the management and growth of our business, result in a loss of investor confidence in our financial reports and have an adverse effect on our business and stock price. Substantial future sales of shares of our common stock ~~, regardless of our actual operating performance. Finally, recent market volatility in certain stocks has at times been driven by factors unrelated to the underlying businesses, or macro or industry fundamentals, of public companies, and it is impossible to predict how long these dynamics will last. The realization of any of the above risks or any of a broad range of other risks, including those described in this " Risk Factors " section,~~ could ~~have a dramatic and adverse~~ **adversely affect** ~~impact on~~ the market price of **such shares. If existing stockholders sell, or indicate an intention to sell, substantial amounts of** our common stock **in the public market, or there is the perception that these sales could occur, this could adversely affect the market price of such shares and could materially impair our ability to raise capital through equity offerings in the future. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale would have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options or warrants, or the perception that such sales may occur, could adversely affect the market price of our common stock. Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. Based on the beneficial ownership of our common stock as of March 21, 2024, our executive officers, directors and holders of 5 % or more of our capital stock and their respective affiliates beneficially owned a significant percentage of our voting stock. As a result, these stockholders, if continuing to act together, will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise. We are a smaller reporting company. We cannot be certain whether the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors or otherwise limit our ability to raise additional funds. We are a " smaller reporting company " under applicable securities regulations. A smaller reporting company is a company that, as of the last business day of its most recently completed fiscal quarter, has an aggregate market value of the company' s voting stock held by non- affiliates, or public float, of less than $ 250 million, or has annual revenues less than $ 100 million and either no public float or public float less than $ 750 million. SEC rules provide that companies with a non- affiliate public float of less than $ 75 million may only sell shares under a Form S- 3 shelf registration statement, during any 12- month period, in an amount less than or equal to one- third of the public float. If we do not meet this public float requirement, any offering by us under a Form S- 3 will be limited to raising an aggregate**

of one- third of our public float in any 12- month period. In addition, a smaller reporting company is able to provide simplified executive compensation disclosures in its filings, is exempt from the provisions of Section 404 (b) of the Sarbanes- Oxley Act requiring that an independent registered public accounting firm provide an attestation report on the effectiveness of internal control over financial reporting if its public float is less than $ 75 million, and has certain other reduced disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. Reduced disclosure in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze its results of operations and financial prospects. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock will be influenced by the research and reports that industry or equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock after the completion of the merger, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause its stock price or trading volume to decline. Anti- takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management. Provisions in our amended and restated certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders, and the ability of the board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the " DGCL "), which prohibits stockholders owning in excess of 15 % of our voting stock from merging or combining with us in certain circumstances. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our Board of Directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of our Board of Directors, which is responsible for appointing the members of management. Our bylaws provide 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 other employees. Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for any state law claims for (a) any derivative action or proceeding brought on behalf of us; (b) any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any of our directors, officers, stockholders, employees or agents to us or our stockholders; (c) any action asserting a claim against us or any of our directors, officers, stockholders, employees or agents arising pursuant to any provision of the DGCL, the certificate of incorporation or the bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; (d) any action to interpret, apply, enforce or determine the validity of the certificate of incorporation or the bylaws; or (e) any action asserting a claim against us or any of our directors, officers, stockholders, employees or agents governed by the internal affairs doctrine; provided, that these choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. The amended and restated bylaws will provide that the federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The choice of forum provision may make it more expensive for stockholders to bring a claim than if the stockholders were permitted to select another jurisdiction and 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. If a court were to find the choice of forum provision contained in the bylaws 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. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our bylaws described above . Unfavorable global economic conditions could adversely affect our business, financial condition **or** ~~, stock price and~~ results of operations. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. ~~For example, the global financial crisis of 2007- 2008 caused extreme volatility and disruptions in the capital and credit markets. Similarly, the volatility associated with the COVID- 19 pandemic has caused significant instability and disruptions in the capital and credit markets and, in recent months, the global economy has been impacted by increasing interest rates and inflation. Likewise, the capital and credit markets may be adversely affected by the 2022 invasion of Ukraine by Russia, and the~~

possibility of a wider European or global conflict, and global sanctions imposed in response thereto. A severe or prolonged economic downturn , such as a global financial crisis, could result in a variety of risks to our business, including **, weakened** a decrease in the demand for our drug **product** candidates and in our ability to raise additional capital when needed on acceptable terms, if at all. A downturn may also make it more difficult for us to consummate a sale of the company, merger or other strategic transaction. A weak or declining economy **could** also could strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our **products or** services. We **Any of the foregoing could harm our business and we** cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business or our ability to consummate a strategic transaction . Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn. Our common stock may be delisted from The Nasdaq Global Market if we do not maintain compliance with Nasdaq' s continued listing requirements. Nasdaq maintains several requirements for continued listing of our common stock (" Nasdaq Listing Rules ") one of which is the maintenance of a minimum closing bid price of one dollar (" Minimum Bid Price Requirement "). As a result of our stock having closing bid price of less than a dollar for thirty consecutive trading days, Nasdaq issued a notice of delisting to us on December 27, 2022. Pursuant to the Nasdaq Listing Rules, we were provided an initial compliance period of 180 calendar days to regain compliance with the Minimum Bid Price Requirement. To regain compliance, Nasdaq Listing Rules required that the closing bid price of our common stock must be at least $ 1. 00 per share for a minimum of 10 consecutive business days prior to June 26, 2023, and that we must otherwise satisfy Nasdaq' s requirements for continued listing. Our plan to regain compliance includes a reverse stock split, which may result in the liquidity of our common stock being adversely impacted, which may further reduce our stock price. If our stockholders do not approve our proposed reverse split, and we do not achieve compliance during the initial 180 calendar day period, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would need to transfer the listing of our common stock to the Nasdaq Capital Market, provided that we then meet the continued listing requirement for market value of publicly held shares and all other initial listing standards of the Nasdaq Capital Market, with the exception of the minimum bid price. In the event that we become noncompliant, and are unable to regain compliance, our common stock could be delisted from Nasdaq and the ability to buy or sell our common stock could be impaired. We intend to take all commercially reasonable actions to maintain our Nasdaq listing, including an evaluation of all reasonable strategic alternatives. A perception among investors that we are at heightened risk of a deficiency under the Minimum Bid Price Requirement and of subsequent delisting could negatively affect the market price of our securities and trading volume of our common stock. Additionally, any delisting determination, if made following the notification of a deficiency and expiration of any applicable cure period, would have an adverse effect on the market liquidity of our common stock and, as a result, the market price for our common stock could become more volatile. Further, a delisting also could make it more difficult for us to raise additional capital. If our common stock is delisted in the future, it is unlikely that we will be able to list our common stock on another national securities exchange and, as a result, we expect our securities would be quoted on an over- the- counter market; however, if this were to occur, our stockholders could face significant material adverse consequences, including limited availability of market quotations for our common stock and reduced liquidity for the trading of our securities. In addition, in the event of such delisting, we could experience a decreased ability to issue additional securities and obtain additional financing in the future. The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as " covered securities. " Because our common stock is listed on the Nasdaq Global Market, shares of our common stock qualify as covered securities under the statute. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. Further, if we were no longer listed on the Nasdaq Global Market, our securities would not qualify as covered securities under the statute, and we would be subject to regulation in each state in which we offer our securities. Further, there can be no assurance that an active trading market for our common stock will be sustained despite our listing on the Nasdaq Global Market. We may become involved in securities class action litigation that could divert management' s attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages. In the past, securities class action litigation has often followed the announcement or consummation of certain significant business transactions, such as the merger or sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as discontinuations of clinical programs. These events may also result in investigations by the SEC or FINRA. We have received three notices of complaints filed against us for our planned merger with CalciMedica, which we believe are without merit, but we may be exposed to litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management' s attention and resources, which could adversely affect our business and cash resources, our ability to consummate our planned merger with CalciMedica, or the ultimate value our stockholders receive as a result. The future sale and issuance of equity or of debt securities that are convertible into equity will dilute our share capital. If our planned merger fails to close, we may choose to raise additional capital in the future, depending on market conditions, strategic considerations and operational requirements. To the extent that additional capital is raised through the sale and issuance of shares or other securities convertible into shares, our stockholders will be diluted. Future issuances of our common stock or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of our common stock and impair our ability to raise capital through future offerings of shares or equity securities. No prediction can be made as to the effect, if any, that future sales of common stock or the availability of common stock for future sales will have on the trading price of our common stock. Sales of a substantial number of shares of our common stock may cause the price of our common stock to decline. Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common

stock could decline significantly. We had a total of 21, 696, 433 shares of our common stock outstanding as of December 31, 2022. All shares of our common stock are freely tradable, generally without restrictions or further registration under the Securities Act of 1933, as amended (the " Securities Act ") subject to certain exceptions for shares held by our " affiliates " as defined in Rule 144 under the Securities Act. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale would have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options or warrants, or the perception that such sales may occur, could adversely affect the market price of our common stock. If our planned merger fails to close, we would also expect that significant additional capital may be needed in the future to continue our operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline. The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the analysts or the content and opinions included in their reports. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our future preclinical studies and clinical trials and results of operations fail to meet the expectations of analysts, our stock price would likely decline. Three of our five covering analysts have formally suspended coverage of us, and the remaining two have not published reports on us since May of 2022. If our remaining analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume. Based on the beneficial ownership of our common stock as of December 31, 2022, our executive officers, directors, holders of 5 % or more of our capital stock and their respective affiliates beneficially owned a significant percentage of our voting stock. In connection with our planned merger with CalciMedica, all of our officers and directors, along with our two largest investors, signed voting agreements requiring them to each vote for the planned merger, subject to very limited exceptions. As a result, these stockholders, if continuing to act together, will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise. We are an " emerging growth company " and a " smaller reporting company " and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors. We are an " emerging growth company, " or EGC, as defined in the Jumpstart Our Business Startups Act of 2012 (" JOBS Act "). For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (1) not being required to comply with the independent auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002, as amended, or Sarbanes- Oxley Act, (2) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (3) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements and two years of selected financial data in our periodic reports. We will remain an EGC until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenue of at least $ 1. 235 billion or (c) in which we are deemed to be a " large accelerated filer, " which requires the market value of our common stock that is held by non- affiliates to exceed $ 700. 0 million as of June 30, and (ii) the date on which we have issued more than $ 1. 0 billion in non- convertible debt during the prior three- year period. Even after we no longer qualify as an EGC, we may still qualify as a " smaller reporting company, " or SRC, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the independent auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile. Under the JOBS Act, EGCs can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an EGC, or we affirmatively and irrevocably opt out of the exemption provided by Section 7 (a) (2) (B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non- EGCs and the date on which we will adopt the recently issued accounting standard. We are also currently an SRC, in part because the market value of our stock held by non- affiliates is less than $ 700. 0 million and our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year. We are also currently considered an SRC because the market value of our stock held by non- affiliates is less than $ 250. 0 million as of June 30. We may continue to be a SRC if either (i) the market value of our stock held by non- affiliates is less than $ 250. 0

million as of June 30 or (ii) our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year and the market value of our stock held by non- affiliates is less than $ 700. 0 million as of June 30. If we are an SRC at the time we cease to be an EGC, we may continue to rely on exemptions from certain disclosure requirements that are available to SRCs. Specifically, as an SRC we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10- K and, similar to EGCs, SRCs have reduced disclosure obligations regarding executive compensation. Anti- takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Our restated certificate of incorporation and our restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions: • establish a classified board of directors so that not all members of our board are elected at one time; • permit only the board of directors to establish the number of directors and fill vacancies on the board; • provide that directors may only be removed " for cause " and only with the approval of two- thirds of our stockholders; • require super- majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws; • authorize the issuance of " blank- check " preferred stock that our board could use to implement a stockholder rights plan; • eliminate the ability of our stockholders to call special meetings of stockholders; • prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders; • prohibit cumulative voting; and • establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings. In addition, our restated certificate of incorporation provides that 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 Delaware General Corporation Law (" DGCL ") our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our restated bylaws provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, referred to as a Federal Forum Provision. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal courts or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court. While neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act of 1934, as amended (" Exchange Act "), Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder also must be brought in federal court. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder. Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit a stockholder' s ability to bring a claim in a judicial forum of their choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. In addition, Section 203 of the DGCL may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15 % or more of our common stock. We have incurred 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, and particularly if we are no longer deemed an emerging growth company or smaller reporting company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market 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. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have substantially increased our legal and financial compliance costs and have made some activities more time- consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. 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. Moreover, 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. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.