Risk Factors Comparison 2024-03-08 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 described below, as well as the other information in this Annual Report on Form 10- K, including our financial statements and related notes appearing elsewhere in this Annual Report on Form 10- K and in the section entitled " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations **. Risks Related to Strategic Alternative Process and Potential Strategic Transaction We may not be successful in identifying and implementing any strategic business combination, stock or asset acquisition, or other transaction, and any strategic transactions that we may consummate in the future could have negative consequences. In addition to our efforts, if any, to pursue clinical development of GB1211, GB2064 or any other product candidate, we also continue to evaluate all potential strategic options for the company, including a merger, reverse merger, stock or asset acquisition, sale, liquidation and dissolution or other strategic transaction. However, there can be no assurance that we will be able to successfully consummate any particular strategic transaction. The process of continuing to evaluate these strategic options may be very costly, time- consuming and complex and we have incurred, and may divert us from pursuing clinical development of GB1211, GB2064 or any other product candidate. Additionally, we may incur significant costs related to this continued evaluation, such as financial advisor, legal and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business and may diminish or delay any future distributions to our stockholders. In addition, any strategic business combination or other transactions that we may consummate in the future could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affects our business and decreases the remaining cash available for use in our business or the execution of our strategic plan or we may incur substantial fees to fund the transaction and future operations. There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions, will decrease the remaining cash available for use in our business and may significantly diminish or delay any future distributions to our stockholders. We may not realize any additional value in a strategic transaction. The market capitalization of our company is below the value of our cash and cash equivalents. Potential counterparties in a strategic transaction involving our company may place minimal or no value on our other assets given the limited data relating to these assets. Further, the development and any potential commercialization of our product candidates will require substantial additional cash to fund the costs associated with conducting the necessary preclinical and clinical testing and obtaining regulatory approval. Consequently, any potential counterparty in a strategic transaction involving our company may choose not to spend additional resources and continue development of our product candidates and may attribute little or no value, in such a transaction, to those product candidates. If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks. Although there can be no assurance that a strategic transaction will result from the process we have undertaken to identify and evaluate strategic alternatives, the negotiation and consummation of any such transaction will require significant time on the part of our management, and the diversion of management' s attention may disrupt our business. The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including: • increased near- term and long- term expenditures; • exposure to unknown liabilities; • higher than expected acquisition or integration costs; • incurrence of substantial debt or dilutive issuances of equity securities to fund future operations; • write- downs of assets or goodwill or incurrence of non- recurring, impairment or other charges; • increased amortization expenses; • difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel; • impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership; • inability to retain key employees of our company or any acquired business; and • possibility of future litigation. Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects. If a strategic transaction is not consummated, our board of directors 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 a strategic transaction will be completed. If a strategic transaction is not completed, our board of directors 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 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. In addition, if our board**

of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, 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 liquidation. If a dissolution and liquidation were pursued, our board of directors, 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 dissolution and liquidation. Our ability to consummate a strategic transaction depends on our ability to retain our employees required to consummate such transaction. Our ability to consummate a strategic transaction depends upon our ability to retain our employees required to consummate such a transaction, the loss of whose services may adversely impact the ability to consummate such transaction. In September 2023, we undertook an organizational restructuring that significantly reduced our workforce in order to conserve our capital resources. Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment and may cause us to incur additional costs in order to retain our remaining employees. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain certain of our remaining personnel. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of a strategic alternative as well as business operations. Our corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business. In September 2023, we undertook an organizational restructuring that significantly reduced our workforce, including the departure of our chief medical officer and our chief operating officer. While we have realized certain operational efficiencies and cost savings as a result of the restructuring to date, we may not realize in full the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize in full the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. Furthermore, our restructuring plan may in the future prove to be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences, such as increased difficulties in implementing our business strategy, including retention of our remaining employees. Any future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, and loss of employees and reduced productivity among remaining employees. For example, the workforce reduction may negatively impact our clinical, regulatory, technical operations, and commercial functions, should we choose to continue to pursue them, which would have a negative impact on our ability to successfully develop, and ultimately, commercialize our product candidates. Our future financial performance and our ability to develop our product candidates or additional assets will depend, in part, on our ability to effectively manage any future growth or restructuring, as the case may be. We may become involved in securities class action litigation that could divert management' s attention and harm the company' s business, and insurance coverage may not be sufficient to cover all costs and damages. In the past, securities class action litigation has often followed certain significant business transactions, such as the sale of a company, an acquisition of stock or assets, or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in investigations by the Securities and Exchange Commission. We may be exposed to such 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 and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction . Risks Related to Our Financial Position and Need for Additional Capital We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future. We have incurred significant net losses since our inception and have financed our operations principally through equity and debt financing. We continue to incur significant research and development and other expenses related to our ongoing operations. For the years ended December 31, **2023 and** 2022 ~~and 2021~~ , we reported a net loss of $ **38. 3 million and $** 61. 6 million ~~and $ 51. 8 million~~ , respectively. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~217~~ **256** . ~~7~~ **1** million. We have devoted substantially all of our resources and efforts to research and development, and we expect that it will be several years, if ever, before we generate revenue from product sales. Even if we receive marketing approval for and commercialize one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to develop and market additional potential product candidates. We expect to continue to incur significant losses for the foreseeable future, and we anticipate that our expenses will increase substantially if, and as, we: • **negotiate and consummate a strategic business transaction; •** advance our ~~most advanced product candidate, GB0139, our other current~~ fibrosis and oncology product candidates and any future product candidates through clinical development, and, if successful, later- stage clinical trials; • advance our preclinical development programs into clinical development; • experience delays or interruptions to preclinical studies, clinical trials, our receipt of services from our third- party service providers on whom we rely, or our supply chain, including delays and economic uncertainty in various global markets caused by geopolitical instability and conflict and economic challenges caused by **global health crises such as** the COVID- 19 pandemic; • seek regulatory approvals for any

product candidates that successfully complete clinical trials; • commercialize ~~GB0139,~~ our ~~other current~~ fibrosis and oncology product candidates and any future product candidates, if approved; • increase the amount of research and development activities to discover and develop product candidates; • hire additional clinical development, quality control, scientific and management personnel; • expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development and manufacturing efforts, general and administrative functions and our operations as a public company; • establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties; • maintain, expand and protect our intellectual property portfolio; and • invest in or in- license other technologies or product candidates. To become and remain profitable, we must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post- marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and / or eliminate one or more of our research and drug development programs, future commercialization efforts or other operations. Developing biotechnology and biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our planned and ongoing clinical trials of ~~GB0139~~ **GB1211** , GB2064 ~~and GB1211~~ and any future product candidates that we may develop, seek regulatory approvals for any of our product candidates and to launch and commercialize any products for which we receive regulatory approval. We also expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and drug development programs or future commercialization efforts. As of December 31, ~~2022~~ **2023** , we had $ ~~66~~ **33** . ~~1~~ **2** million in cash, cash equivalents and marketable securities. **Subject to the outcome of our exploration of strategic alternatives, which may materially change any estimates, and** ~~Based~~ **based** on ~~our~~ current ~~operating plan~~ **estimates of our expenses going forward** , we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements ~~into~~ **through at least** the ~~second half~~ **next 12 months from the filing date** of ~~2024~~ **this Annual Report on Form 10- K** . We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect **. Our estimates do not include any cash, cash equivalents and marketable securities that will be needed to fund a potential strategic transaction nor our financial needs following the consummation of any strategic transaction** . Our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and in any event, we will require additional capital in order to complete clinical development of any of our current programs. Changes in economic conditions, including rising inflation and interest rates, lower consumer confidence, volatile equity capital markets and lower market prices for our securities, ongoing supply chain disruptions and geopolitical instability may adversely affect our business, our future capital requirements and our ability to finance our future cash needs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development, marketing and commercialization activities. Our future funding requirements, both near and long- term, will depend on many factors, including, but not limited to: • the **timing and outcome of our exploration of potential strategic alternatives; • our financial requirements following any strategic transaction; • timing of and costs associated with our restructuring, and the savings benefits we expect to receive from the restructuring; • the** initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates, including ~~GB0139~~ **GB1211** , GB2064 ~~, GB1211~~ and any our other product candidates we develop in the future; • the clinical development plans we establish for these product candidates; • the **scope, progress, results and costs of discovery, research, preclinical development, laboratory testing and clinical trials for our current and future product candidates; • the impacts of rising inflation and interest rates, geopolitical instability, changes in international trade relationships and conflicts; • the** number of, and development requirements for, other product candidates that we develop; • the timelines of our clinical trials and the overall costs to finish ~~the~~ clinical trials due to geopolitical instability and conflict ~~and economic challenges caused by the COVID- 19 pandemic~~ ; • the outcome, timing and cost of meeting regulatory requirements established by the FDA, the European Medicines Agency, or EMA, and other comparable foreign regulatory authorities; • our ability to enter into contract manufacturing arrangements for supply of active pharmaceutical ingredient, or API, and manufacture of our product candidates, and the terms of such arrangements; • whether we are able to enter into and maintain collaboration agreements, including the terms of and timing of payments under any such agreements; • the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights; • the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates; • the extent to which we acquire or in- license other products, product candidates, or technologies; • the **ability to receive additional non- dilutive funding, including grants from organizations and foundations; • the** effect of competing clinical, technological and market developments; • the cost and timing of completion of commercial- scale outsourced manufacturing activities; • changes in economic conditions, ~~including rising inflation and interest rates,~~ lower

consumer confidence and volatile equity capital markets; and • the costs of continuing to operate as a public company. We do not have any committed external source of funds or other support for our development efforts, and we cannot be certain that additional funding will be available on acceptable terms, if at all. Until **such time, if ever, as** we can generate ~~sufficient~~ **substantial product** revenue **and subject to our pursuit of a potential strategic transaction and the consummation of such potential transaction, we expect** to finance our **future operations through our existing** cash **and** ~~requirements, which we may never do, we expect to finance our future~~ cash ~~needs~~ **equivalents and marketable securities and** through a combination of ~~public or private~~ equity offerings, **including sales under our Open Market Sale AgreementSM with Jefferies LLC, as sales agent, to provide for the issuance and sale of up to $ 50. 0 million of our common stock from time to time in " at- the- market " offerings under the Registration Statement and related prospectus, or the ATM Program,** debt financings, collaborations, strategic alliances, **marketing and distribution arrangements, and / or** licensing ~~arrangements and other marketing or distribution~~ arrangements. Volatility in equity capital markets may adversely affect the market price of our equity securities, which may materially and adversely affect our ability to fund our business through public or private sales of equity securities **, including sales under our ATM Program** . If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also may be required to seek collaborators for any of our product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Market volatility and economic uncertainty in various global markets resulting from geopolitical instability and conflict ~~and economic challenges caused by the COVID- 19 pandemic~~ or other factors could also adversely impact our ability to access capital as and when needed. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline **. SEC regulations limit the funds we can raise during 12 months under our shelf registration statement on Form S- 3. As of March 1, 2024, our public float was approximately $ 19. 3 million, based on 27, 112, 697 shares of outstanding common stock held by non- affiliates and at $ 0. 82 per share, which was the last reported sale price of our common stock on the Nasdaq Global Select Market on March 1, 2024. SEC regulations limit the amount companies with a public float of less than $ 75 million may raise during 12 months under a shelf registration statement on Form S- 3. We are subject to General Instruction I. B. 6, Form S- 3, or the Baby Shelf Rule. As of the filing of this Annual Report on Form 10- K, we are subject to the Baby Shelf Rule. Under the Baby Shelf Rule, the amount of funds we can raise through primary public securities offerings in any 12 months using a registration statement on Form S- 3 is limited to one- third of the aggregate market value of the shares of our common stock held by non- affiliates of the Company. Therefore, we will be limited in the proceeds we can raise by selling shares of our common stock using our Form S- 3 until our public float exceeds $ 75 million. Before our public float exceeds $ 75 million, if our public float decreases, the number of securities we may sell under our Form S- 3 shelf registration statement will also decrease. Even if sufficient funding is available, there can be no assurance that it will be available on terms acceptable to our stockholders or us. Furthermore, if we are required or choose to file a new registration statement on a form other than Form S- 3, we may incur additional costs and be subject to delays due to review by the SEC staff** . The amount of our future losses is uncertain and our 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. Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following: • the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners; • our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts; • our ability to obtain marketing approval for our product candidates, and the timing and scope of any such approvals we may receive; • the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time; • the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers; • our ability to attract, hire and retain qualified personnel; • expenditures that we will or may incur to develop additional product candidates; • the level of demand for our product candidates should they receive approval, which may vary significantly; • the risk / benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates; • general market conditions or extraordinary external events, such as increased economic uncertainty in the United States and abroad ~~or the economic challenges caused by the COVID- 19 pandemic~~ ; • the changing and volatile U. S. and global economic environments; and • future accounting pronouncements or changes in our accounting policies. The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet

the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. Risks Related to Research and Development and the Biotechnology and Biopharmaceutical Industry We have a limited operating history, which may make it difficult to evaluate our prospects and likelihood of success. We are a clinical- stage biotechnology company with a limited operating history. We were founded as Galecto Biotech AB, a Swedish operating company, in 2011 and incorporated in Delaware as Galecto, Inc. in October 2019, have no products approved for commercial sale and have not generated any revenue. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and performing research and development of our product candidates. Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value. In addition, our product candidates, including ~~GB0139, for the treatment of IPF,~~ GB1211 ~~for the treatment of various oncology indications and liver cirrhosis,~~ and GB2064 ~~for the treatment of myelofibrosis~~ , are in the early stages of clinical development. These ~~three~~ programs will require substantial additional development and clinical research time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We have not yet demonstrated the ability to progress any product candidate through later- stage clinical trials leading to successful marketing authorization. We may be unable to obtain regulatory approval, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, achieve market access, and acceptance with insurers and health care providers, or conduct sales and marketing activities necessary for successful product commercialization. Investment in biotechnology and biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early- stage biotechnology and biopharmaceutical companies in rapidly evolving fields. Consequently, we have no meaningful history of operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drug products. Our business is highly dependent on the success of our product candidates, ~~GB0139,~~ GB1211 ~~,~~ **and** GB2064, as well as any other product candidates that we advance into the clinic. All of our product candidates may require significant additional preclinical and clinical development before we may be able to seek regulatory approval for and launch a product commercially. We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We are very early in our development efforts, and our product candidates, including ~~GB0139~~ **GB1211 and GB2064** , are in early clinical development. **If these** ~~Because GB0139 is our most advanced~~ product ~~candidate~~ **candidates** ~~, if GB0139 encounters~~ **encounter** safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and business would be significantly harmed ~~. We have completed a placebo- controlled Phase 2a multi- dose trial of GB0139 in 24 IPF patients. We are currently conducting a Phase 2b placebo- controlled clinical trial of GB0139 in IPF patients and we expect to release topline results in mid- 2023. The primary endpoint of the trial is to assess annual rate of decline in forced vital capacity, or FVC, after one year of dosing. Reduction in decline of FVC is the primary endpoint that was accepted by the FDA for the approval of both of the currently approved treatments for IPF. For future clinical trials of GB0139, including a Phase 3 clinical trial or trials, the design, duration, and scope of such clinical trials will be decided upon after further discussions with FDA or the EMA, as applicable. As a result, we are unable to predict with certainty the estimated timing or scope of future clinical trials of GB0139 we may conduct~~ . Before we can generate any revenue from sales of our ~~most advanced product candidate, GB0139, or any of our other~~ fibrosis or oncology product candidates, we must undergo additional preclinical and clinical development, regulatory review and approval in one or more jurisdictions. In addition, if one or more of our product candidates are approved, we must ensure access to sufficient commercial manufacturing capacity and conduct significant marketing efforts in connection with any commercial launch. These efforts will require substantial investment, and we may not have the financial resources to continue development of our product candidates. We may experience setbacks that could delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including: • negative or inconclusive results from our preclinical studies or clinical trials or positive results from the clinical trials of others for product candidates similar to ours leading to their approval, and evolving to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program; • product- related side effects experienced by patients or subjects in our clinical trials or by individuals using drugs or therapeutics that we, DSMBs, institutional review board, or IRBs, the FDA, other regulators or others view as relevant to the development of our product candidates; • delays in submitting INDs or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced; • conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials, including our clinical endpoints; • delays in enrolling subjects in clinical trials, including due to geopolitical instability and conflict in Eastern Europe and the economic challenges caused by **global pandemics such as** the COVID- 19 pandemic; • high drop- out rates of subjects from clinical trials; • inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials; • greater than anticipated clinical trial costs; • inability to compete with other therapies; • poor efficacy of our product candidates during clinical trials; • trial results taking longer than anticipated; • trials being subjected to fraud or data capture failure or other technical mishaps leading to the invalidation of our trials in whole or in part; • the results of our trials not supporting application for conditional approval in the EU; • unfavorable FDA or other regulatory agency inspection and review of a clinical trial site; • failure of our third- party contractors or investigators to comply with regulatory

requirements or otherwise meet their contractual obligations in a timely manner, or at all; • delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical development generally or with respect to our technology in particular; or • varying interpretations of data by the FDA and similar foreign regulatory agencies. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and our manufacturing, marketing, distribution and sales efforts or that of any future collaborator. Clinical development involves a lengthy, complex and expensive process, with an uncertain outcome, and the results of preclinical studies and early- stage clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, the general approach for FDA approval of a new drug is dispositive data from two well- controlled, Phase 3 clinical trials of the relevant drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. A product candidate can fail at any stage of testing, even after observing promising signals of activity in earlier preclinical studies or clinical trials. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials. ~~For example, in our earlier clinical trials, we did not identify any imbalance in the serious adverse events across study groups, in contrast to what was reported to us in March 2021 by the DSMB in our ongoing Phase 2b trial of GB0139. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed~~ . There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials **. For example, in August 2023, we announced that our Phase 2b trial evaluating GB0139 for the treatment of idiopathic pulmonary fibrosis, or IPF, did not meet its primary endpoint of change from baseline in rate of decline in forced vital capacity. As a result, we announced that we were discontinuing development of GB0139** . A number of companies in the biotechnology and biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as therapeutic products, and there can be no assurance that any of our future clinical trials will ultimately be successful or support further clinical development of ~~GB0139 or~~ any of our ~~other~~ fibrosis or oncology product candidates. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including: • preclinical studies or clinical trials may show the product candidates to be less effective than expected (e. g., a clinical trial could fail to meet its primary endpoint (s)) or to have unacceptable side effects or toxicities; • failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful; • failure to receive the necessary regulatory approvals; • manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make a product candidate uneconomical; and • the proprietary rights of others and their competing products and technologies that may prevent one of our product candidates from being commercialized. In addition, differences in trial design between early- stage clinical trials and later- stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. Additionally, several of our past, planned and ongoing clinical trials utilize an " open- label " trial design, where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open- label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open- label clinical trials are aware when they are receiving treatment. Open- label clinical trials may also be subject to a " patient bias " where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open- label clinical trials may be subject to an " investigator bias " where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open- label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open- label clinical trial when studied in a controlled environment with a placebo or active control. In addition, the standards that the FDA and comparable foreign regulatory authorities use when regulating our product candidates require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Although we are initially focusing our efforts on development of small molecule drug products, we may in the future pursue development of biological products, which could make us subject to additional regulatory requirements. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations. Examples of such regulations include future legislation or administrative action, or changes in FDA policy during the period of product development and FDA regulatory review. We cannot predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. The FDA may also require a panel of experts, referred to as an advisory committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the advisory committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop. We ~~are currently conducting~~ **have conducted our past** clinical trials in foreign countries ~~, as well as in the United States~~ . If we continue to seek to conduct clinical trials in foreign countries or pursue marketing approvals in foreign jurisdictions, we must comply with numerous foreign regulatory requirements governing, among other things, the

conduct of clinical trials, manufacturing and marketing authorization, pricing and third- party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval from foreign regulatory agencies may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa. Successful completion of clinical trials is a prerequisite to submitting a marketing application to the FDA and similar marketing applications to comparable foreign regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We may experience negative or inconclusive results, which may result in our deciding, or our being required by regulators, to conduct additional clinical studies or trials or abandon some or all of our product development programs, which could have a material adverse effect on our business. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of ~~GB0139 or~~ **our** ~~any of our other~~ fibrosis or oncology product candidates ~~in development~~. We may experience delays in initiating or completing clinical trials. We also may experience numerous unforeseen events during, or as a result of, any future clinical trials that could delay or prevent our ability to receive marketing approval for, or to commercialize, ~~GB0139 or~~ any of our ~~other~~ fibrosis or oncology product candidates in development, including: • regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; • the FDA or other comparable regulatory authorities may disagree with our clinical trial design, including with respect to dosing levels administered in our planned and ongoing clinical trials, which may delay or prevent us from initiating or continuing our clinical trials with our originally intended trial design; • we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, or subjects may drop out of these clinical trials or fail to return for post- treatment follow- up at a higher rate than we anticipate; • our third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators; • due to the impact of economic challenges caused by **global** ~~the COVID- 19 pandemic~~ **pandemics** and uncertainty in various global markets caused by geopolitical instability, we may experience delays or interruptions to our manufacturing supply chain, or we could suffer delays in reaching, or we may fail to reach, agreement on acceptable terms with third- party service providers on whom we rely; • additional delays and interruptions to our clinical trials could extend the duration of the trials and increase the overall costs to finish the trials as our fixed costs are not substantially reduced during delays; • we may elect to, or regulators, IRBs, DSMBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; • we may not have the financial resources available to complete our planned and ongoing clinical trials, or the cost of clinical trials of any product candidates may be greater than we anticipate; • the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate to initiate or complete a given clinical trial; and • the FDA or other comparable foreign regulatory authorities may require us to submit additional data such as long- term toxicology studies or impose other requirements before permitting us to initiate a clinical trial. Our product development costs will increase if we experience additional delays in clinical testing or in obtaining marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. In addition, we may voluntarily redesign or otherwise modify our plans with respect to an ongoing or planned clinical trial, and changing the design of a clinical trial can be expensive and time consuming. If we do not achieve our product development goals in the time frames we announce and expect, the approval and commercialization of our product candidates may be delayed or prevented entirely. Significant clinical trial modifications or delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any changes or delays in our clinical development programs may harm our business, financial condition and results of operations significantly. Our ongoing and future clinical trials may reveal significant adverse events or unexpected drug- drug interactions not seen in our preclinical studies and may result in a safety profile that could delay or prevent regulatory approval or market acceptance of any of our product candidates. ~~We have completed a placebo- controlled Phase 2a multi- dose trial of GB0139 in 24 IPF patients and, with the exception of a number of minor reported adverse events (fever, upper respiratory tract infection, abnormal taste in mouth, dry throat), GB0139 was observed to be generally well- tolerated in these patients with no serious drug- related adverse events. We are currently conducting a double- blind placebo- controlled Phase 2b trial of GB0139. In March 2021, the DSMB for this trial recommended that, based upon a safety analysis of the data, the company discontinue dosing and enrolling patients in the 10mg arm along with patients in the 3mg arm who are receiving combination treatment with the currently approved treatments of IPF, nintedanib and pirfenidone. The DSMB informed the company, based on unblinded safety and efficacy data, that there was an imbalance in the serious adverse events across the study groups, but not an imbalance between the groups in mortality.~~ Our product candidates are designed to inhibit galectin- 3 or LOXL2, and we believe such inhibition can play a key role in regulating fibrosis and cancer. However, our products are still in the testing phase. If significant adverse events or other side effects are observed in any of our ongoing or future clinical trials ~~, including of GB0139 for the treatment of IPF, GB02064 for the treatment of myelofibrosis or GB1211 for the treatment of liver cirrhosis and NSCLC~~, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to reduce the dosage amount of our intended product candidate or abandon the trials or our development efforts altogether. For instance, in the dose selection phase of our Phase 2a GALLANT- 1 trial

evaluating GB1211 in combination with atezolizumab for the first- line treatment of NSCLC, we observed two serious adverse events of autoimmune- type skin rashes (showing perivascular lymphocytic infiltrates), which were determined by the principal investigator to be related to the administration of atezolizumab. The reactions were similar to those observed with atezolizumab and described in the label, however, in accordance with the protocol, we reduced the GB1211 dose to 100mg twice daily for the second patient cohort. Some potential therapeutics developed in the biotechnology and biopharmaceutical industry that initially showed therapeutic promise in early- stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. If we ~~continue to~~ encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of completion of our clinical studies depends in part on the speed at which we can recruit patients to participate in testing our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. From 2020 to 2022, the COVID- 19 pandemic caused delays in certain of our studies, including (i) a delay in recruitment for our ~~ongoing~~ Phase 2b trial of GB0139 in IPF patients, which ~~has~~ resulted in certain trial protocol amendments and increased costs and (ii) a delay in the initiation and recruitment of our planned and ongoing clinical trials of GB1211 and GB2064. We may continue to experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including: • the patient eligibility and exclusion criteria defined in the protocol; • the size of the patient population required for analysis of the trial' s primary endpoints and the process for identifying patients; • the willingness or availability of patients to participate in our trials (including due to fears of contracting ~~COVID- 19 and other~~ highly infectious or contagious diseases) or known or perceived risks associated with our product candidates; • the proximity of patients to trial sites; • the design of the trial; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating; • the availability of competing commercially available therapies and other competing product candidates' clinical trials; • our ability to obtain and maintain patient informed consents; and • the risk that patients enrolled in clinical trials will drop out of the trials before completion. **Our** ~~For example, we are initially developing GB0139 for the treatment of IPF, which is an orphan indication. In the United States, IPF is estimated to affect approximately 100, 000 patients in the United States alone. As a result, we may encounter difficulties enrolling subjects in our clinical trials of GB0139 due, in part, to the small size of this patient population. In addition, our~~ clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Certain of our clinical trials may also involve invasive procedures, such as bone marrow biopsies in our **recently completed** MYLOX- 1 trial, which may lead some patients to drop out of trials to avoid these follow- up procedures. Further, timely enrollment in clinical trials is reliant on clinical trial sites which may be adversely affected by global health matters, including, among other things, pandemics and political and social conditions. For example, the COVID- 19 pandemic and military action and civil and political unrest in regions where we have operations have affected certain of our clinical trial sites as they have not been allowed to enroll or recruit patients and other sites have not been able to receive patient visits, which resulted in the need to amend our protocol for our GALACTIC- 1 trial in IPF ~~. In addition, after enrollment in these trials, if patients contract COVID- 19 during participation in our trials or are subject to isolation or shelter- in- place restrictions, they may drop out of our trials, miss scheduled doses or follow- up visits, or otherwise fail to follow trial protocols. If patients are unable to follow the trial protocols or if our trial results are otherwise disputed due to the effects of the COVID- 19 pandemic or actions taken to mitigate its spread and other restrictions resulting from political instability and conflict, the integrity of data from our trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program~~ . Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our future clinical trials, which could cause us to reprioritize our clinical trials and use of funds for such trials, prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. The design or execution of our ongoing and future clinical trials may not support marketing approval or commercialization. The design or execution of a clinical trial can determine whether its results will support marketing approval and successful commercialization, and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. Additionally, in some instances, there can be significant variability in safety or efficacy results between different trials with the same product candidate due to numerous factors, including differences in trial protocols, size and type of the patient populations, variable adherence to the dosing regimen or other protocol requirements and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we conduct will demonstrate consistent or adequate efficacy and safety to obtain marketing approval to market our product candidates, or commercial acceptance thereafter. For example, we have designed our product candidates to be selective, but they may not be selective enough to achieve the desired safety or efficacy to gain marketing approval. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether marketing approval will be obtained for any

of our product candidates. Our product candidates may not be approved even if they achieve their primary endpoints in future Phase 3 clinical trials or registrational trials. The FDA or comparable foreign regulatory authorities may disagree with our trial designs and our interpretation of data from preclinical studies or clinical trials. In addition, any of these regulatory authorities may change the requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 or registrational clinical trial. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post- marketing clinical trials. The FDA or comparable foreign regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates, if approved. We intend to develop certain of our product candidates and potentially other product candidates in combination with other therapies, which exposes us to additional risks. We intend to develop certain of our product candidates and likely other future product candidates in combination with one or more other approved or unapproved therapies to treat cancer or other diseases. For example, in the fourth quarter of 2021, we announced that we had entered into a clinical trial supply agreement with Roche for our planned Phase 2a trial of GB1211 in combination with atezolizumab, a PD- L1 checkpoint inhibitor, for the first- line treatment of NSCLC. **In** ~~For instance, in~~ the dose selection phase of our Phase 2a GALLANT- 1 trial for the first- line treatment of NSCLC, we observed two serious adverse events of autoimmune- type skin rashes (showing perivascular lymphocytic infiltrates), which were determined by the principal investigator to be related to the administration of atezolizumab. The reactions were similar to those observed with atezolizumab and described in the label. Both reactions responded to therapy with oral glucocorticosteroids and were clinically manageable. In accordance with the protocol, we reduced the GB1211 dose to 100mg twice daily for the second patient cohort. ~~Recruitment~~ **We did not observe such reaction** in ~~this~~ **the second patient** cohort ~~is currently ongoing. Interestingly~~ , ~~inflammatory and perivascular lymphocytic infiltrates were observed in both skin reactions, and could signal an exaggerated immune activation, something often observed with checkpoint inhibitor therapy and associated with improved clinical outcomes. Because a central aspect of the mechanism of action~~ for **which** ~~GB1211 in combination with a checkpoint inhibitor is to remove galectin- 3 from the lymphocytes and the tumor cells, and thereby increase lymphocyte based tumor killing,~~ we ~~believe this could be a positive signal~~ **reported topline results in the fourth quarter** of **2023** ~~enhanced lymphocyte activation~~ . Although we may be able to observe activity of our product candidates as a monotherapy, it may be difficult to observe activity of our product candidates when administered with approved agents or investigational products. ~~For example, based on an interim review of unblinded safety and efficacy data by a DSMB, the addition of GB0139 to nintedanib or pirfenidone was determined to potentially give rise to side effects that were not anticipated based on preclinical studies or early clinical studies in which GB0139 was given as a monotherapy, and, as a result, we modified our ongoing Phase 2b clinical for GB0139 to remove combination therapy.~~ Such discoveries may lead to discontinuations of certain dosing groups and the modification or termination of our clinical trials. We are unable to predict how the results of our combination therapy trial cohorts could affect the prospects for securing marketing approval of ~~GB0139~~ **our product candidates** or commercial acceptance thereafter. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially. We also may choose to evaluate our current product candidates or any other future product candidates in combination with one or more cancer therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell our current product candidates or any product candidate we develop in combination with an unapproved cancer therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved cancer therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval. If the FDA or comparable foreign regulatory authorities do not approve these other products or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the products we choose to evaluate in combination with our product candidate we develop, we may be unable to obtain approval of or market such combination therapy ~~. We have obtained orphan drug designation for GB0139; however, we may be unable to maintain this designation or obtain orphan drug designation for our other fibrosis or oncology product candidates, and we may not be able to realize the benefits of such designation, including potential marketing exclusivity of our product candidates, if approved. As part of our business strategy, we sought and have received orphan drug designation from the FDA and the EC for treatment of IPF for GB0139; however, we may not be able to maintain this status. We may also seek orphan drug designation for future product candidates, and we may be unsuccessful in obtaining this designation. Regulatory authorities in some jurisdictions, including the United States and other major markets, may designate drugs intended to treat conditions or diseases affecting relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, or the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having 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. 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 Europe, the EC grants orphan drug designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan drug designation application. Orphan drug~~

~~designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10, 000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, orphan drug designation 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. Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or EMA from approving another marketing application for a product that constitutes the same drug treating the same indication for that marketing exclusivity period, except in limited circumstances. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug or biologic no longer meets the criteria for orphan drug designation or if the drug or biologic is sufficiently profitable such that market exclusivity is no longer justified. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. Even though we have obtained orphan drug designation for GB0139, and even if we are able to obtain orphan drug exclusivity for a future product candidate, that exclusivity may not effectively protect the relevant product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off- label for the orphan disease. Even after an orphan drug is approved, the FDA may subsequently approve another product for the same condition if the FDA concludes that the latter product is not the same product or is clinically superior to the protected orphan drug because it is shown to be safer or more effective or makes a major contribution to patient care. The FDA may reevaluate its regulations and policies under the Orphan Drug Act. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the orphan indication for which it was designated. 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 have obtained orphan drug designation for GB0139, we may not be able to maintain such designations; and while we may seek orphan drug designation for applicable indications for any future product candidates, we may never receive such designations. Even though we have received such designations for GB0139, and may receive further such designations in the future, there is no guarantee that we will enjoy the benefits of those designations~~ . Breakthrough Therapy designation and Fast Track designation by the FDA, neither of which has been obtained, even if granted for any of our current or future product candidates, may not lead to a faster development or regulatory review process, and such designations do not increase the likelihood that any of our product candidates will receive marketing approval in the United States. We intend to evaluate regulatory strategies that could enable us to take advantage of expedited development pathways for certain of our product candidates, although we cannot be certain that our product candidates will qualify for any expedited development pathways or that regulatory authorities will grant, or allow us to maintain, the relevant designations. Potential expedited development pathways that we could pursue include breakthrough therapy and Fast Track designation. Breakthrough Therapy designation is intended to expedite the development and review of product candidates that are designed to treat serious or life- threatening diseases when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation of a product candidate as a breakthrough therapy provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and ensure collection of appropriate data needed to support approval; more frequent written correspondence from FDA about such things as the design of the proposed clinical trials and use of biomarkers; intensive guidance on an efficient drug development program, beginning as early as Phase 1; organizational commitment involving senior managers; and eligibility for rolling review and priority review. Fast Track designation is designed for product candidates intended for the treatment of a serious or life- threatening disease or condition, where nonclinical or clinical data demonstrate the potential to address an unmet medical need for this disease or condition. The designation of a product candidate as Fast Track provides potential benefits that include more opportunities for frequent interaction and communication with FDA during product development and eligibility for rolling review and priority review. Even if we believe a particular product candidate is eligible for Breakthrough Therapy or Fast Track designation, we cannot assure you that the FDA would decide to grant such a designation in response to our written requests. Breakthrough Therapy designation and Fast Track designation do not change the standards for product approval, and there is no assurance that such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the Breakthrough Therapy designation or Fast Track designation. Thus, even if we do receive Breakthrough Therapy or Fast Track designation for any of our product candidates, we may not experience a faster development process, review or marketing approval compared to conventional FDA procedures. The FDA may withdraw Breakthrough Therapy or Fast Track designation if it believes that the product no longer meets the qualifying criteria. Our business may be harmed if we are unable to avail ourselves of these or any other expedited development and regulatory pathways. We ~~currently~~ **have** ~~conduct~~ **conducted** and may in the future conduct clinical trials for

our product candidates outside the United States. The FDA, EMA or comparable foreign regulatory authorities may not accept data from such trials, and doing so subjects us to the risk that clinical development of our product candidates may be adversely affected by changes in local and regional political and economic conditions. ~~All of~~ **Historically,** our ~~ongoing~~ clinical trials ~~are enrolling or will seek to enroll~~ **enrolled** some or all patients outside of the United States. The acceptance of trial data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from clinical trials conducted outside the United States are intended to serve as the sole basis for approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; (ii) the trials were performed by clinical investigators of recognized competence and (iii) the data may be considered valid without the need for an on- site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. Additionally, the FDA' s clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA, EMA or any comparable regulatory authority does not accept 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 our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction. In particular, we ~~are seeking~~ **may seek** to enroll ~~and have enrolled~~ patients in our clinical trials in Ukraine, Russia and other Eastern European countries. Any escalation of political tensions, economic instability, military activity or civil hostilities in this region could disrupt or delay such trials, or adversely affect the timeliness of such trials. ~~In connection with this geopolitical instability, the United States and other countries have imposed sanctions against Russia.~~ Our ability to conduct these trials ~~is~~ **may be** dependent upon whether or not our involvement in such projects is restricted under U. S. or EU sanctions laws and the extent to which any of our current or prospective operations may become subject to those laws ~~. Those laws may change from time to time, and any expansion of sanctions against Russia could hinder our ability to conduct such trials, which would result in the need for alternative trial sites, which would be costly and time- consuming and delay the clinical development of our product candidates~~ . Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay. As product candidates progress through preclinical to late- stage clinical trials to marketing approval and commercialization, various aspects of the development program, such as manufacturing methods and the product' s formulation, may be altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. These changes carry the risk that they will not achieve their intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of our current clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue. In addition, there are risks associated with process development and large- scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale- up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our product candidates, there is no assurance that our third- party manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. Additionally, if we advance a biological candidate into IND- enabling studies, the manufacturing processes for biological products are more complex and expensive than with small molecule products and additional manufacturing suppliers may be needed to manufacture clinical supplies for these programs. If our contract manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. We may not be successful in our efforts to identify or discover additional product candidates in the future. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including: • our inability to design such product candidates with the pharmacological properties that we desire or attractive pharmacokinetics; • our inability to design and develop a suitable manufacturing process; or • potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance. Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable compounds for preclinical and clinical development, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price. Due to our limited resources and access to capital, we must make decisions on the allocation of resources to certain programs and product candidates; these decisions may prove to be wrong and may adversely affect our business. We have limited financial and human resources and intend to ~~initially~~ focus on research programs and product candidates for a limited set of indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. In addition, we may seek to accelerate our development timelines, including by modifying the designs of ongoing or planned clinical trials or initiating certain clinical trials of our product candidates before earlier- stage studies have been completed. This approach may cause us to commit significant resources to prepare for and conduct later- stage trials for one or more product candidates that subsequently fail earlier- stage clinical testing. Therefore, our resource allocation

decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities or expend resources on product candidates that are not viable. There can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful. If product liability lawsuits are brought against us, we may incur substantial financial or other liabilities and may be required to limit commercialization of our product candidates. We face an inherent risk of product liability as a result of testing ~~GB0139 and any of~~ our ~~other~~ fibrosis or oncology product candidates in clinical trials and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense of these claims would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • inability to bring a product candidate to the market; • decreased demand for our products; • injury to our reputation; • withdrawal of clinical trial participants and inability to continue clinical trials; • initiation of investigations by regulators; • fines, injunctions or criminal penalties; • costs to defend the related litigation; • diversion of management' s time and our resources; • substantial monetary awards to trial participants; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • loss of revenue; • exhaustion of any available insurance and our capital resources; • the inability to commercialize any product candidate, if approved; and • decline in our share price. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We will need to obtain additional insurance for clinical trials ~~as GB0139, and any~~ **if we continue clinical development** of our ~~other~~ fibrosis ~~or~~ **and** oncology product candidates **,** ~~continue clinical development~~ and as additional product candidates enter the clinic. However, we may be unable to obtain, or may obtain on unfavorable terms, clinical trial insurance in amounts adequate to cover any liabilities from any of our clinical trials. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. 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 products is highly competitive. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major biotechnology and biopharmaceutical companies, specialty biotechnology and biopharmaceutical companies, and other biotechnology and biopharmaceutical companies worldwide. 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. There are a number of large biotechnology and biopharmaceutical companies that are currently pursuing the development of products for the treatment of the biological processes that drive fibrosis and certain cancers. Companies that we are aware of that are targeting the treatment of various fibrosis indications include large companies with significant financial resources such as ~~Pharmaxis Ltd, Biogen, Inc.,~~ AbbVie Inc., ~~Gilead Sciences~~ **Akero Therapeutics** , Inc., **Biogen** ~~Pliant Therapeutics~~ , Inc., **Boehringer Ingelheim** ~~Galectin Therapeutics, Inc., FibroGen, Inc., Liminal BioSciences, Inc., Galapagos NV~~ , Bristol Myers Squibb Co., **Galectin Therapeutics, Inc., Gilead Sciences, Inc.,** Madrigal Pharmaceuticals, Inc., ~~Inventiva~~ **Novartis AG** , ~~Akero~~ **Pharmaxis Ltd, Pliant** Therapeutics, Inc. **and** ~~, Boehringer Ingelheim,~~ Roche / Genentech ~~and Novartis AG~~ . However, we know of no other companies currently in clinical development with an inhaled or orally available small molecule inhibitor of galectin- 3 or an orally available small molecule inhibitor of LOXL2 ~~for myelofibrosis~~ . ~~For additional information regarding our competition, see " Business — Competition. "~~ Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, more convenient, or less expensive than any products that we may develop. Furthermore, products currently approved for other indications could be discovered to be effective treatments of the biological processes that drive fibrosis as well, which could give such products significant regulatory and market timing advantages over **any** ~~GB0139 or other~~ fibrosis product candidates that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we do, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete and we may not be successful in marketing any product candidates we may develop against competitors. The availability of competitive products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize. Risks Related to Marketing,

Reimbursement, Healthcare Regulations and Ongoing Regulatory Compliance Even if a product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. Even if ~~GB0139 or~~ any **of** ~~other~~ -- **the** fibrosis or oncology product ~~candidate~~ **candidates that** we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors, such as Medicare and Medicaid programs and managed care organizations, and others in the medical community. In addition, the availability of coverage by third- party payors may be affected by existing and future health care reform measures designed to reduce the cost of health care. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including: • the efficacy and potential advantages of our current or future product candidates compared to alternative treatments; • limitations or warnings contained in the labeling approved for our current or future product candidates by the FDA or other applicable regulatory authorities; • the clinical indications for which our current or future product candidates are approved; • availability of alternative treatments already approved or commercially launched in the future; • the ability to offer our products, if approved, for sale at competitive prices; • convenience and ease of administration compared to alternative treatments; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • the recommendations with respect to our product candidates in guidelines published by various scientific organizations applicable to us and our product candidates; • the strength of marketing and distribution support; • the ability to obtain sufficient third- party coverage and adequate reimbursement; and • the prevalence and severity of any side effects. Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our products are safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable. If government and other third-party payors do not provide coverage and adequate reimbursement levels for any products we commercialize, market acceptance and commercial success would be reduced. Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably. In the United States and in other countries, patients who are prescribed treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any products for which we may receive regulatory marketing approval will depend, in part, on the availability of coverage and reimbursement from third- party payors. Third- party payors include government authorities such as Medicare, Medicaid, TRICARE, and the Veterans Administration, managed care providers, private health insurers, and other organizations. Patients who are provided medical treatment for their conditions generally rely on third- party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use our product candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop. See the section entitled, " Business – Government Regulation – Coverage and Reimbursement. " Government authorities and other third- party payors decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third- party payor may depend upon a number of factors, including the third- party payor' s determination that use of a product is: • a covered benefit under its health plan; • safe, effective and medically necessary; • appropriate for the specific patient; • cost- effective; and • neither experimental nor investigational. Our ability to commercialize any products successfully will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third- party payors, including government health care programs and private health insurers. Moreover, a payor' s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors. Therefore, coverage and reimbursement for our products can differ significantly from payor to payor. As a result, obtaining coverage and reimbursement approval of a product from a government or other third- party payor is a time- consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost- effectiveness data for the use of our products on a payor- by- payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co- payments that patients find unacceptably high. Additionally, third- party payors may not cover, or provide adequate reimbursement for, long- term follow- up evaluations required following the use of product candidates, once approved. It is difficult to predict at this time what third- party payors will decide with respect to the coverage and reimbursement for our product candidates, if approved. The MMA established the Medicare Part D program to provide a voluntary prescription drug and biologic benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in

prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs and biologics. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs and biologics, and each drug plan can develop its own formulary that identifies which drugs and biologics it will cover, and at what tier or level. However, Part D prescription drug formularies must include products within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs and biologics in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs and biologics may increase demand for products for which we obtain marketing approval. Any negotiated prices for any of our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors. Changes to these current laws and state and federal healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential. In order to market any products 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 products 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 products will be harmed. We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell any products for which we obtain regulatory approval, we may not be able to generate product revenue. We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receives regulatory approval, we expect to establish a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming. We have no prior experience as a company in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may also choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop and for which we receive regulatory approval ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses. Our relationships with healthcare providers, physicians, prescribers, purchasers, third- party payors, charitable organizations and patients will be subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. Healthcare providers, physicians and third- party payors in the United States and elsewhere play a primary role in the recommendation and prescription of biotechnology and biopharmaceutical products. Arrangements with third- party payors and customers can expose biotechnology and biopharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti- Kickback Statute, or AKS, and the federal False Claims Act, or FCA, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute biotechnology and biopharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission (s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient

recruitment for clinical trials. See the section entitled, " Business — Government Regulation — Other Healthcare Laws ". The distribution of biotechnology and biopharmaceutical products is subject to additional requirements and regulations, including extensive record- keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of biotechnology and biopharmaceutical products. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource- consuming and can divert a company' s attention from other aspects of its business. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws. Further, if any of the physicians or other 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 significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Any action for violation of these laws, even if successfully defended, could cause a biotechnology and biopharmaceutical manufacturer to incur significant legal expenses and divert management' s attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way. Even if we receive regulatory approval of any product candidates, we will be subject to ongoing post- marketing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates. If any of our product candidates are approved, they will be subject to ongoing post- marketing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, conduct of post- marketing studies and submission of safety, efficacy and other post- market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with current good manufacturing practice, or cGMP, for any drug products we distribute and with good clinical practice, or GCP, requirements for any clinical trials that we conduct post- approval. Manufacturers and their facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable tracking and tracing requirements. 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 marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Any regulatory approvals that we receive for our 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 trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval of our product candidates, which could entail requirements for 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. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post- marketing information and reports and registration. For example, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product' s ability to be marketed. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post- market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things: • restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or product recalls; • fines, warning letters or holds on clinical trials; • refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or withdrawal of approvals; • product seizure or detention or refusal to permit the import or export of our product candidates; and • consent decrees or injunctions or the imposition of civil or criminal penalties. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is not inconsistent with the labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses and a company that is found to have improperly promoted off- label uses may be subject to significant liability. The policies of the FDA and of other regulatory authorities 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 marketing approval that we may have obtained and we

may not achieve or sustain profitability. Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, changes to our manufacturing arrangements; additions or modifications to product labeling; the recall or discontinuation of our products; or additional record- keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability. See the section entitled, " Business — Government Regulation — Current and Future Healthcare Reform Legislation ". Moreover, increasing efforts by governmental and third- party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects. These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Additionally, we expect to experience pricing pressures in connection with the sale of any future approved product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes. Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U. S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC, and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to review and process our regulatory submissions timely, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. ~~Separately, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume pre- pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre- approval inspections Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the FDA has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID- 19 public health emergency, several companies announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications. Regulatory authorities outside the U. S. may adopt similar restrictions or other policy measures in response to the COVID- 19 pandemic and may experience delays in their regulatory activities.~~ EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European member states. We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, the recent U. K. referendum on its membership in the EU resulted in a majority of U. K. voters voting to exit the European Union, often referred to as Brexit. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations, including those related to the pricing of prescription pharmaceuticals, as the U. K. determines which EU laws to replicate or replace. If the U. K. were to significantly alter its

regulations affecting the pricing of prescription pharmaceuticals, we could face significant new costs. As a result, Brexit could impair our ability to transact business in the European Union and the U. K. Market acceptance and sales of our product candidates will also depend significantly on the availability of adequate coverage and reimbursement from third- party payors for our product candidates and may be affected by existing and future health care reform measures. Much like the AKS prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to reward improper performance generally is governed by the national anti- bribery laws of the EU Member States, and in respect of the U. K. (which is no longer a member of the EU), the Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001 / 83 / EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the U. K. despite its departure from the EU. Payments made to physicians in certain EU member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician' s employer, his or her competent professional organization and / or the regulatory authorities of the individual EU member states. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. In addition, in most foreign countries, including the EEA, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low- priced and high- priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost- effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for biotechnology and biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States, and generally, prices tend to be significantly lower. Publication of discounts by third- party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected. We may incur substantial costs in our efforts to comply with evolving global data protection laws and regulations, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations. The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about participants and healthcare providers in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may create uncertainty in our business, affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. California passed the California Data Privacy Protection Act of 2018, or the CCPA, which went into effect in January 2020, and was recently amended by the California Privacy Rights Act, which became effective on January 1, 2023, provides new data privacy rights for consumers and new operational requirements for companies, which may increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. The CCPA may lead to similar laws in other U. S. states or at a national level, which could increase our potential liability and adversely affect our business. Additionally, a California ballot initiative, the California Privacy Rights Act, or the CPRA, was passed in November 2020 and became effective January 1, 2023. The CPRA imposes additional obligations on companies covered by the legislation and significantly modifies the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. Certain other state laws impose similar privacy obligations and we also expect that more states may enact legislation similar to the CCPA, which provides consumers with new privacy rights and increases the privacy and security obligations of entities handling certain personal information of such consumers. The CCPA has prompted a number of proposals for new federal and state- level privacy legislation. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and / or changes in business practices and policies. In addition, on March 2, 2021, Virginia enacted the

Consumer Data Protection Act, or the CDPA, which became effective on January 1, 2023. The CDPA regulates how businesses (which the CDPA refers to as " controllers ") collect and share personal information. While the CDPA incorporates many similar concepts of the CCPA and CPRA, there are also several key differences in the scope, application, and enforcement of the law that will change the operational practices of controllers. The law impacts how controllers collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests. Also, on July 8, 2021, Colorado' s governor signed the Colorado Privacy Act, or the CPA, into law. The CPA will become effective on July 1, 2023. The CPA is rather similar to Virginia' s CPDA but also contains additional requirements. The new measure applies to companies conducting business in Colorado or who produce or deliver commercial products or services intentionally targeted to its residents of the state that either: (1) control or process the personal data of at least 100, 000 consumers during a calendar year; or (2) derive revenue or receive a discount on the price of goods or services from the sale of personal data and process or control the personal data of at least 25, 000 consumers. With the CPA, Colorado became the third state to enact a comprehensive privacy law but it is quite possible that other states will follow suit. The existence of comprehensive privacy laws in different states in the country will make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. In addition to our operations in the United States, which may be subject to healthcare and other laws relating to the privacy and security of health information and other personal information, we have operations in Europe and are subject to European data privacy laws, regulations and guidelines. The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EEA, including personal health data, is subject to the EU GDPR and similar processing of personal data regarding individuals in the U. K. is subject to the U. K. GDPR and the U. K. Data Protection Act 2018. The GDPR is wide-ranging and imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record- keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non- compliance, including fines of up to € 20 million (£ 17. 5 million) or up to 4 % of our total worldwide annual turnover, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross- border data transfers. Further, national laws of member states of the EU are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EEA. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty. In addition, further to the U. K.' s exit from the EU on January 31, 2020, the GDPR ceased to apply in the U. K. at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the U. K.' s European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain U. K. specific amendments) into U. K. law, referred to as the U. K. GDPR. The U. K. GDPR and the U. K. Data Protection Act 2018 set out the U. K.' s data protection regime, which is independent from but aligned to the EU' s data protection regime. The U. K. Government has announced plans to reform its data protection legal framework in the Data Reform Bill, but those have been put on hold. Non- compliance with the U. K. GDPR may result in monetary penalties of up to £ 17. 5 million or 4 % of worldwide revenue, whichever is higher. Although the U. K. is regarded as a third country under the EU' s GDPR, the EC has now issued a decision recognizing the U. K. as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the U. K. remain unrestricted. Like the EU GDPR, the U. K. GDPR restricts personal data transfers outside the U. K. to countries not regarded by the U. K. as providing adequate protection. To enable the transfer of personal data outside of the EEA or the U. K., adequate safeguards must be implemented in compliance with European and U. K. data protection laws. On June 4, 2021, the EC issued new forms of standard contractual clauses for data transfers from controllers or processors in the EEA (or otherwise subject to the EU GDPR) to controllers or processors established outside the EEA (and not subject to the EU GDPR). The new standard contractual clauses replace the standard contractual clauses that were adopted previously under the EU Data Protection Directive. The U. K. is not subject to the EC' s new standard contractual clauses but has published its own version of standard clauses, referred to as " International Data Transfer Agreement " which entered into force on March 21, 2022 and enables transfers originating from the U. K. Transfers made pursuant to these new mechanisms need to be assessed on a case-by- case basis to ensure the law in the recipient country provides " essentially equivalent " protections to safeguard the transferred personal data as the EEA, and businesses are required to adopt supplementary measures if such standard is not met. We will be required to implement these new safeguards when conducting restricted data transfers under the EU and U. K. GDPR and doing so will require significant effort and cost. In addition to the GDPR, the European Union is also in the process of replacing the e- Privacy Directive (2002 / 58 / EC) with a new set of rules taking the form of a regulation, which will be directly implemented in the laws of each European member state, without the need for further enactment. Originally planned to be adopted and implemented at the same time as the GDPR, the ePrivacy Regulation is still going through the European legislative process. Draft regulations were rejected by the Permanent Representatives Committee of the Council of EU on November 22, 2019; it is not clear when new regulations will be adopted. Preparing for and complying with the GDPR and the

ePrivacy Regulation (if and when it becomes effective) has required and will continue to require us to incur substantial operational costs and may require us to change our business practices. Despite our efforts to bring practices into compliance with the GDPR and before the effective date of the ePrivacy Regulation, we may not be successful either due to internal or external factors such as resource allocation limitations. Non- compliance could result in proceedings against us by governmental entities, customers, data subjects, consumer associations or others. We are conducting clinical trials in the EEA, and the GDPR increases our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we are required to have in place additional mechanisms and safeguards to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR is a rigorous and time- intensive process that increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. We expect that we will continue to face uncertainty as to whether our efforts to comply with any obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or biotechnology and biopharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi- national vendors or biotechnology and biopharmaceutical partners to continue to use our products due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such vendors or biotechnology and biopharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the forgoing could materially harm our business, prospects, financial condition and results of operations. Legal, political and economic uncertainty surrounding the exit of the U. K. from the EU may be a source of instability in international markets, create significant currency fluctuations, adversely affect our operations in the U. K. and pose additional risks to our business, revenue, financial condition, and results of operations. The U. K. formally left the EU on January 31, 2020, and the EU and the U. K. have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA provides details on how some aspects of the U. K. and EU' s relationship will operate going forward however there are still many uncertainties and how the TCA will take effect in practice is still largely unknown. This lack of clarity on future U. K. laws and regulations and their interaction with the EU laws and regulations may negatively impact foreign direct investment in the U. K., increase costs, depress economic activity and restrict access to capital. The uncertainty concerning the U. K.' s legal, political and economic relationship with the EU after Brexit may be a source of instability in the international markets, create significant currency fluctuations, and / or otherwise adversely affect trading agreements or similar cross- border co- operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise) beyond the date of Brexit. These developments may have a significant adverse effect on global economic conditions and the stability of global financial markets and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the U. K. financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility. In addition, if other EU Member States pursue withdrawal, barrier- free access among the EEA overall could be diminished or eliminated. The long- term effects of Brexit will depend on how the terms of the TCA take effect in practice and any further agreements (or lack thereof) between the U. K. and the EU. Such a withdrawal from the EU is unprecedented, and it is unclear how the restrictions on the U. K.' s access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our current and future operations (including business activities conducted by third parties and contract manufacturers on our behalf) and clinical activities in the U. K. In addition to the foregoing, our U. K. operations support our current and future operations and clinical activities in the EU and EEA, and these operations and clinical activities could be disrupted by Brexit. We may also face new regulatory costs and challenges that could have an adverse effect on our operations. The U. K. will lose the benefits of global trade agreements negotiated by the EU on behalf of its members, which may result in increased trade barriers that could make our doing business in the EU and the EEA more difficult. Since the regulatory framework in the U. K. covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime with respect to the approval of our product candidates in the U. K. now that the U. K. legislation can diverge from EU legislation. For instance, Great Britain will now no longer be covered by the centralized procedures for obtaining EEA- wide marketing and manufacturing authorizations from the EMA (under the Northern Irish Protocol, centralized marketing authorizations will continue to be recognized in Northern Ireland) and a separate process for authorization of drug products will be required in Great Britain, resulting in an authorization covering the U. K. or Great Britain only. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the U. K. and / or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the U. K. and / or EU for our product candidates, which could significantly and materially harm our business. Even prior to any change to the U. K.' s relationship with the EU, the announcement of Brexit has created economic uncertainty surrounding the terms of Brexit, and its consequences could adversely impact customer confidence resulting in customers reducing their spending budgets on our product candidates, if approved, which could adversely affect our business, financial condition, results of operations and could adversely affect the market price of our common stock. Additional laws and regulations governing international operations, and the complexity associated with maintaining geographically diverse operations, could negatively impact or restrict our operations and ability to grow. We have offices and operations in six cities

and in five countries. If we are unable to manage the risks of our global operations, including the potential for fluctuations in foreign exchange and inflation rates, international hostilities, the need for our executives to travel internationally, natural disasters, security breaches, failure to maintain compliance with internal control requirements and multiple legal and regulatory systems, our results of operations and ability to grow could be materially adversely affected. We must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The U. S. Foreign Corrupt Practices Act, or the FCPA, prohibits any U. S. individual or business entity from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the biotechnology and biopharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals and healthcare providers in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non- U. S. nationals, of information products classified for national security purposes, as well as certain products, technology and technical data relating to those products. As we expand our operations throughout the world, we will be required to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC may also suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA' s accounting provisions. We are subject to certain U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations. Among other matters, U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We plan to engage third parties for clinical trials and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals, and we could 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. Risks Related to Our Intellectual Property Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection. Our business will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates, their respective components, synthetic intermediates, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third- party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities and whether a court would issue an injunctive remedy. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected. The patenting process is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The patenting process is subject to numerous risks and there can be no assurance that we will be successful in obtaining patents for which we have applied. In addition, we may not pursue, obtain, or maintain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees. The strength of patents in the biotechnology and biopharmaceutical fields involves complex legal and scientific questions and can be uncertain. The patent applications that we own, or in- license, may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our technology, including our product candidates, or prevent others from designing around the claims in our patents. If the breadth or strength of protection provided by the patent applications, we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. We cannot be certain that we were the first to file any patent application related to our technology, including our product candidates, and, if we were not, we may be precluded from obtaining patent protection for our technology, including our product candidates. We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to

priority disputes. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third- party or instituted by the United States Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Similarly, for U. S. applications in which at least one claim is not entitled to a priority date before March 16, 2013, derivation proceedings can be instituted to determine whether the subject matter of a patent claim was derived from a prior inventor' s disclosure. We may be required to disclaim part or all of the term of certain patents. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent or patent application claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, would adequately protect our product candidates, or would be found by a court to be infringed by a competitor' s technology or product. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products that have the same effect as our products on an independent basis and that do not infringe our patents or other intellectual property rights or will design around the claims of patents that may issue that cover our products. Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Under the enacted Leahy- Smith America Invents Act, or the America Invents Act, after March 2013, the United States moved from a " first- to- invent " to a " first- inventor- to- file " system. Under a " first- inventor- to- file " system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U. S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post- grant review system. The effects of these changes are currently unclear, as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the " first- inventor- to- file " provisions. In addition, the courts have yet to address many of these provisions and the applicability of the America Invents Act and new regulations on specific patents discussed herein, for which issues have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example: • others may be able to make or use compounds that are similar to the compositions of our product candidates but that are not covered by the claims of our patents or those of our licensors; • we or our licensors, as the case may be, may fail to meet our obligations to the U. S. government in regards to any in- licensed patents and patent applications invented or developed using U. S. government funding, leading to the loss of patent rights; • we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies; • it is possible that our pending patent applications will not result in issued patents; • it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents; • it is possible that others may circumvent our owned or in- licensed patents; • it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours; • the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States; • the claims of our owned or in- licensed issued patents or patent applications, if and when issued, may not cover our product candidates; • our owned or in- licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties; • the inventors of our owned or in- licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors; • it is possible that our owned or in- licensed patents or patent applications omit individual (s) that should be listed as inventor (s) or include individual (s) that should not be listed as inventor (s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable; • we have engaged in scientific collaborations in the past and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents; • we may not develop additional proprietary technologies for which we can obtain patent protection; • it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; or • the patents of others may have an adverse effect on our business. We may enter into license or other collaboration agreements in the future that may impose certain obligations on us. If we fail to comply with our obligations under such future agreements with third parties, we could lose license rights that may be important to our future business. In connection with our efforts to expand our pipeline of product candidates **and our exploration of strategic alternatives** , we may enter into certain licenses or other collaboration agreements in the future pertaining to the in- license of rights to additional product candidates. Such agreements may impose various diligence, milestone payment, royalty, insurance or other obligations on us. If we fail to comply with these obligations, our licensor or collaboration partners may have the right to terminate the relevant agreement, in which event we would not be able to develop or market the products covered by such licenses or agreements. Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • the extent to which our product

candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • the sublicensing of patent and other rights under our collaborative development relationships; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and • the priority of invention of patented technology. In addition, the agreements under which we may license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. In addition, we may have limited control over the maintenance and prosecution of these in- licensed patents and patent applications, or any other intellectual property that may be related to our in- licensed intellectual property. For example, we cannot be certain that such activities by any future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors initiate an infringement proceeding against a third- party infringer of the intellectual property rights or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding, or defense activities may be less vigorous than had we conducted them ourselves. If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be negatively impacted, and our business and competitive position would be harmed. In addition to patent protection, we rely heavily upon know- how and trade secret protection, as well as non- disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time- consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed. In addition, courts may be unwilling to protect trade secrets. If we choose to go to court to stop a third- party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party' s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We also plan to adopt policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets. Third- party claims of intellectual property infringement may be costly and time consuming to defend, and could prevent or delay our product discovery, development and commercialization efforts. Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and biopharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and / or proprietary technologies infringe their intellectual property rights. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and biopharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods. If a third- party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

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

adversely affect our ability to compete in the marketplace. Others may claim an ownership interest in our intellectual property, which could expose us to litigation and have a significant adverse effect on our prospects. A third party may claim an ownership interest in one or more of our or our licensors' patents or other proprietary or intellectual property rights. A third party could bring legal actions against us and seek monetary damages and / or enjoin clinical testing, manufacturing and marketing of the affected product or products. While we are presently unaware of any claims or assertions by third parties with respect to our patents or other intellectual property, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. If we become involved in any litigation, it could consume a substantial portion of our resources and cause a significant diversion of effort by our technical and management personnel. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross- licenses to our patents. We cannot, however, assure you that any such license will be available on commercially acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product candidate or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. We may not be successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms. Because our programs may involve additional product candidates that may require the use of proprietary 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. Our product candidates may also require specific formulations to work effectively and efficiently, and these rights may be held by others. We may develop products containing our compounds and pre- existing biotechnology and biopharmaceutical compounds. We may be unable to acquire or in- license any compositions, methods of use, processes or other third- party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third- party intellectual property rights and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. The licensing and acquisition of third- party intellectual property rights is a competitive area, and companies that may be more established, or that have greater resources than we do, may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, or challenging the patent rights of others, which could be expensive, time- consuming and unsuccessful. Competitors or other third parties such as chemical and reagent suppliers may infringe our patents or the patents of our current or future licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question or for other reasons. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We may choose to challenge the patentability of claims in a third party' s U. S. patent by requesting that the USPTO review the patent claims in an ex- parte re- examination, inter partes review or post- grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party' s patent in patent opposition proceedings in the European Patent Office, or EPO, or other foreign patent offices. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent offices then we may be exposed to litigation by a third- party alleging that the patent may be infringed by our product candidates or proprietary technologies. In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in- licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent or first to file a patent application covering the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our owned and in- licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U. S. patent application on inventions similar to those owned by or in- licensed to us, we or, in the case of in- licensed technology, the licensor may have to participate in an interference or derivation proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference or derivation proceeding involving a U. S. patent application on inventions owned by or in- licensed to us, we may incur substantial costs, divert management' s time and expend other resources, even if we are successful. Interference or derivation

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

provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in- licensed patent applications and the enforcement or defense of our owned or in- licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, the patent positions of companies in the development and commercialization of biotechnology and biopharmaceuticals are particularly uncertain. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future **. Further, a European Unified Patent Court (UPC) came into force during 2023. The UPC is a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of any of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce our European patents or defend the validity thereof. We may decide to opt out our European patents and patent applications from the UPC. If certain formalities and requirements are not met, however, our European patents and patent applications could be challenged for non- compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC** . We have limited intellectual property rights outside of the United States and Europe and may not be able to protect and enforce our intellectual property rights throughout the world. We have limited intellectual property rights outside the United States and Europe. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States and Europe can be less extensive than those in the United States and Europe. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States or laws in Europe. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or Europe, or from selling or importing products made using our inventions in and into the United States, Europe or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of, and may require a compulsory license to, patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology and biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest claimed U. S. non- provisional filing date. Various extensions such as patent term adjustments and / or extensions, may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we do not obtain patent term extension and data exclusivity or similar non- U. S. legislation extending the term of protection covering any product candidates we may develop, our business may be materially harmed. Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, also known as the Hatch-Waxman Amendments. The Hatch- Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended, and only those claims

covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failure to exercise due diligence during the testing phase or regulatory review process, failure to apply within applicable deadlines, failure to apply prior to expiration of relevant patents, or otherwise failure to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. Risks Related to Our Reliance on Third Parties We rely and expect to continue to rely on third parties to conduct certain aspects of our ongoing and future preclinical studies and clinical trials, including investigator-sponsored clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates. We rely and expect to continue to rely on third parties to conduct certain aspects of our ongoing and future preclinical studies and clinical trials, under agreements with universities, medical institutions, clinical investigators, CROs, strategic collaborators and others. We expect to have to negotiate budgets and contracts with such third parties, which may result in delays to our development timelines and increased costs. We will rely especially heavily on third parties over the course of our clinical trials, and, as a result, will have limited control over the clinical investigators and limited visibility into their day- to- day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We may also rely on academic and private non- academic institutions and clinical investigators to conduct and sponsor clinical trials relating to our product candidates, such as the planned Phase 2 clinical trial of GB1211 in metastatic melanoma and HNSCC patients that will be sponsored by Providence Cancer Institute. We will not control the design or conduct of the investigator- sponsored trials, and it is possible that the FDA or foreign regulatory authorities will not view these investigator- sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including due to elements of the design or execution of the trials or safety concerns or other trial results. Such arrangements will likely provide us certain information rights, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator- sponsored trials. However, we would not have control over the timing and reporting of the data from investigator- sponsored trials, nor 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 of our product candidates. 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 first- hand 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 ourselves may be adversely affected. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials conducted by third parties comply with the GCP requirements. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. Any third parties conducting aspects of our preclinical studies or clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons or if, due to federal or state orders, they are unable to meet their contractual and regulatory obligations, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. If any of our relationships with these third- party CROs or other third parties terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time

and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. We rely on third parties for materials, including tissue samples, required for our research and development activities, and if we are unable to reach agreements with these third parties, our research and development activities would be delayed. We rely on third parties, primarily hospitals, health clinics and academic institutions, for the provision of tissue samples and other materials required in our research and development activities. Obtaining these materials requires various approvals as well as reaching a commercial agreement on acceptable terms with the hospital or other provider of the materials. While we currently have agreements in place with the institutions from which we receive our tissue samples, we do not have any exclusive arrangements with such sources, and there is no guarantee that we will be able to maintain or renew such agreements on commercially reasonable terms, if at all. If we were unable to maintain or renew such agreements, we would be forced to seek new arrangements with new hospitals, clinics or health institutions. If so, we may not be able to reach agreements with alternative partners or do so on terms acceptable to us. If we are unable to enter into such agreements, our research and development activities will be delayed and our ability to implement a key part of our development strategy will be compromised. We contract with third parties for the manufacture of our product candidates for preclinical development, clinical testing, and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. We rely on third- party contract manufacturers to manufacture our product candidates for preclinical studies and clinical trials. We do not own manufacturing facilities for producing any clinical trial product supplies. There can be no assurance that our preclinical and clinical development product supplies will not be limited or interrupted, or that they will be of satisfactory quality or continue to be available at acceptable prices. For example, the extent to which instability in geographies where we have operations or **global** ~~the COVID- 19 pandemic~~ **pandemics** ~~impacts~~ **impact** our ability to procure sufficient supplies for the development of our product candidates will depend on whether broad- based sanctions continue for long term or escalate or if the economic challenges caused by **global pandemics** ~~the COVID- 19~~ continue to impact supply chain, among many other factors. Any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, 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 party, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills or technology to a back- up or alternative supplier, or we may not be able to transfer such skills or technology at all. Furthermore, a manufacturer may possess technology related to the manufacture of our product candidate that such manufacturer owns independently. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturer or manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. 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. We expect to continue to rely on third- party manufacturers if we receive regulatory approval for ~~GB0139 or~~ any ~~other~~ **of our** fibrosis or oncology product ~~candidate~~ **candidates** . To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party' s failure to execute on our manufacturing requirements and comply with cGMP could adversely affect our business in a number of ways, including: • an inability to initiate or continue clinical trials of product candidates under development; • delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates; • loss of the cooperation of an existing or future collaborator; • subjecting third- party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities; • requirements to cease distribution or to recall batches of our product candidates; and • in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products. We rely on a sole supplier or, in some cases, a limited number of suppliers for the manufacture of components of ~~GB0139 and~~ our ~~other current~~ fibrosis and oncology product candidates. If these suppliers are unable to supply necessary materials to us in the quantities we require, or at all, or otherwise default on their supply obligations to us, we may not be able to obtain alternative supplies from other suppliers on acceptable terms, in a timely manner, or at all. We also do not have long- term supply agreements with any of our suppliers. Our current contracts with certain suppliers may be canceled or not extended by such

suppliers and, therefore, do not afford us with protection against a reduction or interruption in supplies. Moreover, in the event any of these suppliers breach their contracts with us, our legal remedies associated with such a breach may be insufficient to compensate us for any damages we may suffer. In addition, we contract with fill and finishing providers with the appropriate expertise, facilities and scale to meet our needs. Failure to maintain cGMP can result in a contractor receiving FDA sanctions, which can impact our ability to operate or lead to delays in any clinical development programs. We believe that our current fill and finish contractor is operating in accordance with cGMP, but we can give no assurance that FDA or other regulatory agencies will not conclude that a lack of compliance exists. In addition, any delay in contracting for fill and finish services, or failure of the contract manufacturer to perform the services as needed, may delay any clinical trials, registration and launches, which could negatively affect our business. In the future, if we were to advance a biological product candidate into IND- enabling studies, we would need to identify and contract with suppliers who are able to produce biological product candidates and adhere to additional cGMP compliance obligations required for biologicals. We may in the future seek to enter into collaborations with third parties for the development and commercialization of our product candidates, and our future collaborations will be important to our business. If we are unable to enter into collaborations, or if these collaborations are not successful, our business could be adversely affected. A part of our strategy is to consider partnerships in indications and geographies where we believe partners can add significant commercial and / or development capabilities. Further, we have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we have entered and may in the future enter into collaborations with other companies to provide us with important technologies and funding for our programs and technology. Any future collaborations we enter into may pose a number of risks, including the following: • collaborators have significant discretion in determining the efforts and resources that they will apply; • collaborators may not perform their obligations as expected; • collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates; • collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product; • collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products; • collaborators may not provide us with timely and accurate information regarding development progress and activity under any future license agreement, which could adversely impact our ability to report progress to our investors and otherwise plan development of our product candidates; • disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time- consuming and expensive; • collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; • collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; • if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and • collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. If any future collaborations we enter into do not result in the successful discovery, development and commercialization of product candidates, if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10- K also apply to the activities of our collaborators. Additionally, if one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected. We face significant competition in seeking appropriate collaborators for our product candidates, and the negotiation process is time- consuming and complex. In order for us to successfully establish a collaboration for one or more of our product candidates, potential collaborators must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies. Collaborations are complex and time- consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large biotechnology and biopharmaceutical companies that have resulted in a reduced number of potential future collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization

activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into future collaborations or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate revenue from sales of drugs or continue to develop our technology, and our business may be materially and adversely affected. Even if we are successful in our efforts to establish new strategic collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into new strategic collaboration agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. Risks Related to Managing Our Business and Operations We may encounter difficulties in managing our ~~growth~~ **organization** , which could adversely affect our operations. As of December 31, ~~2022~~ **2023** , we had ~~45~~ **13** full- time employees. As our clinical development and commercialization plans and strategies develop, and as we ~~transition into~~ **continue to** ~~operating~~ **operate** as a public company, **or if** we ~~will~~ **consummate a strategic transaction, we may** need to expand our managerial, clinical, regulatory, sales, marketing, financial, development, manufacturing and legal capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future growth would impose significant added responsibilities on members of management, including: • identifying, recruiting, integrating, maintaining and motivating additional employees; • managing our development and commercialization efforts effectively, including the clinical and FDA review process for **our** ~~GB0139 and any other~~ fibrosis ~~or~~ **and** oncology product candidates, while complying with our contractual obligations to contractors and other third parties; and • improving our operational, financial and management controls, reporting systems and procedures. Our ability to continue to develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day- to- day activities in order to devote a substantial amount of time to managing these growth activities. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including contract manufacturers and companies focused on research and development and discovery activities. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality, accuracy or quantity of the services provided is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain, or may be substantially delayed in obtaining, regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. ~~If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize GB0139 or any other fibrosis or oncology product candidates and, accordingly, may not achieve our research, development and commercialization goals.~~ In December 2019, we acquired PharmAkea Inc., or PharmAkea, and may acquire additional technology and complementary businesses in the future **as part of our strategic review process or otherwise** . Acquisitions involve many risks, any of which could materially harm our business, including the diversion of management' s attention from core business concerns, failure to effectively exploit acquired technologies, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either our business or the acquired businesses. ~~We have previously identified a material weakness in our internal control over financial reporting, which has since been remediated. If we experience future material weaknesses or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations. In connection with our preparation and the audits of our financial statements as of and for the years ended December 31, 2020 and 2019, we and our independent registered public accounting firm identified a material weakness as defined under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and by the Public Company Accounting Oversight Board (United States) in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. Our previous material weakness related to our financial statement closing process, primarily related to the lack of sufficient skilled personnel with U. S. generally accepted accounting principles, or U. S. GAAP, and Securities and Exchange Commission, or SEC, reporting knowledge and expertise for purposes of timely and reliable financial reporting and our dependence on third- party service providers for the preparation and closing of our financial records. Specifically, the material weakness identified related to the lack of appropriate internal controls over the work performed by the third- party service providers and that, as a result thereof, management failed to timely identify material misstatements in accounting for our debt and equity instruments, research and development, and taxation. We have remediated the material weakness and have taken steps to strengthen our internal control over financial reporting, such as the hiring of Jonathan Freve as Chief Financial Officer in the second quarter of 2020 and a Corporate Controller in the fourth quarter of 2020. Additionally, we have designed and implemented a cross functional risk assessment process to identify and assess changes in the business that could significantly impact internal control over financial reporting. If, in the future, we identify further material weaknesses in our internal controls over financial reporting, we may not detect errors on a timely basis, and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our~~

~~reported financial information and cause the trading price of our stock to fall. In addition, as a public company, we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Select Market or other adverse consequences that would materially harm our business. In addition, we could become subject to investigations by Nasdaq, the SEC, and other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and our financial condition, or divert financial and management resources from our core business. An independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting in accordance with the provision of the Sarbanes- Oxley Act of 2002, as amended, or the Sarbanes- Oxley Act, because no such evaluation has been required. Had an independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes- Oxley Act, material weaknesses may have been identified.~~ If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to develop current product candidates or identify and develop new product candidates will be impaired, could result in loss of markets or market share and could make us less competitive. Our ability to compete in the highly competitive biotechnology and biopharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including Hans T. Schambye, M. D., Ph. D., our Chief Executive Officer and President, **and** ~~Anders Pedersen, our Chief Operating Officer, Bertil Lindmark, M. D., Ph. D., our Chief Medical Officer,~~ Jonathan Freve, our Chief Financial ~~Officer, and Stephanie Oestreich, our Chief Business~~ Officer. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business. We conduct our operations globally from several locations including Denmark, the United States, ~~Sweden,~~ the U. K. and Canada. Competition for skilled personnel in our industry is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. To induce valuable employees to remain with us, in addition to salary and cash incentives, we have provided stock options **and restricted stock units** that vest over time. The value to employees of stock options **and restricted stock units** 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. Our key employees are at- will employees, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain " key person " insurance policies, but we may enter into such policies, on the lives of these individuals or the lives of certain of our employees. There is no guarantee that any " key person " insurance policy we may enter into would adequately compensate us for the loss of any key employee. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid- level and senior scientific and medical personnel. We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure. Our internal computer systems and those of any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, phishing or other unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, financial loss, a loss of our trade secrets or other proprietary information and damage to our reputation and otherwise negatively impact us. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. We rely on information technology systems that we or our third- party providers operate to process, transmit and store electronic information in our day- to- day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as names, mailing addresses, email addresses, phone numbers and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial of service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e. g., state breach notification laws), federal (e. g., HIPAA, as amended by HITECH), and international (e. g., the GDPR) law and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business. We rely on our third- party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. If we or our third- party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third- party providers could have

difficulty preventing, detecting and controlling such cyberattacks, and any such attacks could result in the losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business. By way of example, the CCPA, which went into effect on January 1, 2020, creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. By way of example regarding foreign laws and regulations with respect to data privacy and security, the GDPR imposes strict requirements for processing the personal data of individuals in the EEA and U. K. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to € 20 million (£ 17. 5 million) or 4 % of the annual global revenues of the noncompliant company, whichever is greater. 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 any such serious disaster. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics **and pandemics** , power shortage, telecommunication failure or other natural or man- made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third- party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of 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, results of operations and prospects. If a natural disaster, power outage or other event were to occur that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third- party contract manufacturers, 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. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third- party contract manufacturers, 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. Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Portions of our future clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the U. S. dollar would make those clinical trials more costly to operate. Furthermore, the most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. **Changes in economic conditions, including rising inflation and interest rates, volatile equity capital markets and lower market prices for our securities may adversely affect our business, our future capital requirements and our ability to finance our future cash needs.** A severe or prolonged economic downturn ~~, including due to the economic challenges caused by the COVID- 19 pandemic,~~ could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or international trade disputes could also strain our suppliers, some of which are located outside of the United States, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. The increasing use of social media platforms presents new risks and challenges. Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates, if any. Social media practices in the biotechnology and biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off- label marketing or other prohibited activities and heightened scrutiny by the FDA, the SEC and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public' s legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. In addition, we may encounter attacks on social media regarding our company, management, product candidates or products. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business. The estimates of

market opportunity and forecasts of market growth included in this Annual Report on Form 10- K or that we may otherwise provide may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all. Market opportunity estimates and growth forecasts included in this Annual Report on Form 10- K or that we may otherwise provide are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. The estimates and forecasts included in this Annual Report on Form 10- K relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet the size estimates and growth forecasts included in this Annual Report on Form 10- K, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties. Our employees, independent contractors, consultants, commercial partners, collaborators and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, collaborators and vendors. Misconduct by these parties could include intentional, reckless and / or negligent conduct that fails to comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws will also increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. We have a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by our employees, independent contractors, consultants, commercial partners and vendors, 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 actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations. We use and generate materials that may expose us to material liability. Our research programs involve the use of hazardous materials and chemicals, which are currently only handled by third parties. We are subject to foreign, federal, state and local environmental and health and safety laws and regulations governing, among other matters, the use, manufacture, handling, storage and disposal of hazardous materials and waste products such as human tissue samples that may have the potential to transmit diseases. We may incur significant costs to comply with these current or future environmental and health and safety laws and regulations. In addition, we cannot completely eliminate the risk of contamination or injury from hazardous materials and may incur material liability as a result of such contamination or injury. In the event of an accident, an injured party may seek to hold us liable for any damages that result. Any liability could exceed the limits or fall outside the coverage of our workers' compensation, property and business interruption insurance and we may not be able to maintain insurance on acceptable terms, if at all. We currently carry no insurance specifically covering environmental claims. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We or our CROs generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean- up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third- party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and / or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials or other work- related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers' compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our products. The Animal Welfare Act, or AWA, is the federal law that covers the treatment of certain animals used in research.

Currently, the AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size, and feeding, watering and shipping conditions. Third parties with whom we contract are subject to registration, inspections and reporting requirements under the AWA and comparable rules, regulations, and or obligations that may exist in many foreign jurisdictions. Furthermore, some states have their own regulations, including general anti- cruelty legislation, which establish certain standards in handling animals. Comparable rules, regulations, and / or obligations exist in many foreign jurisdictions. If we or our contractors fail to comply with regulations concerning the treatment of animals used in research, we may be subject to fines and penalties and adverse publicity, and our operations could be adversely affected. Changes in U. S. tax law could adversely affect our financial condition and results of operations. The rules dealing with U. S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, or IRS, and the U. S. Treasury Department. Changes to **applicable** tax laws **, rules, regulations, or their interpretation and application** (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, ~~on March 27~~ **many provisions of the Tax Cuts and Jobs Act of 2017** , **or TCJA, the Inflation Reduction Act of** ~~2020~~ **2022** , **or IRA** ~~President Trump signed into law the Coronavirus Aid~~ , **and the Tax** Relief ~~,~~ **for American Families** and **Workers** ~~Economic Security~~ Act ~~or~~ **of 2024 still require guidance through** the **issuance or finalization of regulations by** ~~CARES Act, which included certain changes in tax law intended to stimulate~~ the U. S. ~~economy~~ **Treasury Department** in ~~light of~~ **order to fully assess** ~~the~~ **their** ~~COVID- 19 coronavirus outbreak, including temporary beneficial changes to~~ **effects. There may be substantial delays before such regulations are promulgated or finalized as well as proposed technical corrections or** ~~the~~ **other legislation** ~~treatment of net operating losses~~ , ~~interest deductibility limitations and payroll tax matters~~ **resulting in uncertainty as to their ultimate effects** . Future changes in U. S. tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisors regarding the implications of potential changes in U. S. tax laws on an investment in our common stock. Unanticipated changes in effective tax rates or adverse outcomes resulting from examination of our income or other tax returns could expose us to greater than anticipated tax liabilities. The tax laws applicable to our business, including the laws of Denmark, Sweden, the United States, and other jurisdictions, are subject to interpretation ~~and certain jurisdictions may aggressively interpret their laws in an effort to raise additional tax revenue~~ . The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for valuing intercompany arrangements or our revenue recognition policies, which could increase our worldwide effective tax rate and harm our financial position and results of operations. It is possible that tax authorities may disagree with certain positions we have taken and any adverse outcome of such a review or audit could have a negative effect on our financial position and results of operations. Further, the determination of our worldwide provision for income taxes and other tax liabilities requires significant judgment by management, and there are transactions where the ultimate tax determination is uncertain. Although we believe that our estimates are reasonable, the ultimate tax outcome may differ from the amounts recorded in our consolidated financial statements and may materially affect our financial results in the period or periods for which such determination is made. Our corporate structure and intercompany arrangements are subject to the tax laws of various jurisdictions, and we could be obligated to pay additional taxes, which would harm our results of operations. Based on our current corporate structure, we are subject to taxation in several jurisdictions around the world with increasingly complex tax laws, the application of which can be uncertain. The amount of taxes we pay in these jurisdictions could increase substantially as a result of changes in the applicable tax principles, including increased tax rates, new tax laws or revised interpretations of existing tax laws and precedents. The authorities in these jurisdictions could review our tax returns or require us to file tax returns in jurisdictions in which we are not currently filing, and could impose additional tax, interest, and penalties. These authorities could also claim that various withholding requirements apply to us or our subsidiaries and assert that benefits of tax treaties are not available to us or our subsidiaries. The relevant taxing authorities may determine that the manner in which we operate our business does not achieve the intended tax consequences. If such a disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest, and penalties. ~~Such authorities could claim that various withholding requirements apply to us or our subsidiaries or assert that benefits of tax treaties are not available to us or our subsidiaries.~~ Any increase in the amount of taxes we pay or that are imposed on us could increase our worldwide effective tax rate. Several countries in which we are located allow for tax incentives to attract and retain business. We have obtained incentives where available and practicable. Our taxes could increase if certain tax incentives are retracted, which could occur if we are unable to satisfy the conditions on which such incentives are based, if they are not renewed upon expiration ~~,~~ or if tax rates applicable to us in such jurisdictions otherwise increase. It is not anticipated that any material tax incentives will expire within the next year. However, due to the possibility of changes in existing tax law and our operations, we are unable to predict how any expirations will impact us in the future. In addition, acquisitions may cause our **worldwide** effective tax rate to increase, depending on the jurisdictions in which the acquired operations are located. Certain of our subsidiaries may provide financing, products and services to, and may undertake certain significant transactions with, us or other of our subsidiaries in different jurisdictions. Several jurisdictions in which we operate have tax laws with detailed transfer pricing rules that require all transactions with non- resident related parties be priced using arm' s length pricing principles, and that contemporaneous documentation must exist to support such pricing. There is a risk that the **relevant** taxing authorities may not deem our transfer pricing documentation acceptable. In addition, the Organization for Economic Cooperation and Development **, or OECD,** continues to issue guidelines and proposals related to ~~Base Erosion~~ **enacting a 15 % global minimum corporate tax rate** and ~~Profit Shifting~~ **participating OECD member countries continue to work towards the enactment of a global minimum tax rate. We will continue to monitor these developments and evaluate the impact of the global minimum tax,** which ~~may result in legislative changes that~~ could ~~reshape international tax rules in numerous countries and~~ negatively impact our

worldwide effective tax rate. Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation. We have net operating loss carryforwards and tax credit carryforwards for U. S. federal and state income tax purposes which **will** begin to expire in future years. Additionally, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, changes in our ownership may limit the amount of our net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset our future taxable income, if any. **Under Section 382 of the Code and applicable U. S. Treasury Department regulations,** ~~This~~ **this** limitation would generally apply in the event of **an" ownership change," generally defined as** a cumulative change in **equity** ownership of our company of more than 50 ~~percentage~~ **percent** ~~points~~ **, by value,** within a **rolling** three- year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. Public offerings, private placements and other transactions that have occurred since our inception, may **have** ~~trigger~~ **triggered** such an ownership change pursuant to Section 382 **of the Code** . Any such limitation, whether as the result of a prior public offering, prior private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us, could have a material adverse effect on our results of operations in future years. ~~The reduction of~~ **We may experience ownership changes in** the **future as a result** ~~corporate tax rate under the Tax Cuts and Jobs Act~~ of ~~2017,~~ **subsequent shifts in** ~~or~~ **our** ~~the Tax Cuts~~ **stock ownership, some of which may be outside of our control. If we determine that** ~~and~~ **an** ~~Jobs Act, may~~ **ownership change has occurred and our ability to** ~~cause~~ **use** ~~a reduction in the economic benefit of~~ our **historic** net operating ~~loss~~ **losses and tax credit** carryforwards **is materially** ~~and other deferred tax assets available to us. Our ability to utilize those net operating loss carryforwards could be~~ limited ~~by an " ownership change " as described above~~ , ~~which could~~ **it may** result in increased **future** tax liability to us **and could adversely affect our operating results and financial condition** . Risks Related to Our Common Stock The price of our stock may be volatile, and you could lose all or part of your investment. The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this " Risk Factors " section and elsewhere in this Annual Report on Form 10- K, these factors include: • the ~~commencement~~ **initiation** , ~~enrollment or~~ **progress, timing, costs and** results of **preclinical studies** ~~our current fibrosis-~~ and ~~oncology- focused Phase 2~~ clinical trials ~~of GB0139~~ **for our product candidates, including GB2064** , GB1211 and ~~GB2064~~ **any our other product candidates we develop in the future** ; • any delay in ~~identifying and advancing a clinical candidate for our other development programs; • any delay in~~ our regulatory filings for ~~GB0139 or~~ **our** ~~our other~~ fibrosis or oncology product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such filings, including, without limitation, the FDA' s issuance of a " refusal to file " letter or a request for additional information; • adverse results or delays in future clinical trials; • our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial; • adverse regulatory decisions, including failure to receive regulatory approval ~~of GB0139 or~~ **for our** ~~any other~~ fibrosis ~~or~~ **and** oncology product ~~candidate~~ **candidates** ; • changes in laws or regulations applicable to ~~GB0139 or~~ **our** ~~any other~~ fibrosis or oncology product ~~candidate~~ **candidates** , including, but not limited to, clinical trial requirements for approvals; • adverse developments concerning our manufacturers; • our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices; • our inability to establish collaborations, if needed; • our failure to commercialize our product candidates, if approved; • additions or departures of key scientific or management personnel; • unanticipated serious safety concerns related to the use of ~~GB0139~~ **GB1211, GB2064** or any other fibrosis or oncology product candidate; • introduction of new products or services offered by us or our competitors; • announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors; • our ability to effectively manage our growth; • actual or anticipated variations in quarterly operating results; • our cash position; • our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; • publication of research reports about us or our industry, or product candidates in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts; • changes in the market valuations of similar companies; • changes in the structure of the healthcare payment systems; • overall performance of the equity markets; • sales of our common stock by us or our stockholders in the future; • trading volume of our common stock; • changes in accounting practices; • ineffectiveness of our internal controls; • disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; • significant lawsuits, including patent or stockholder litigation; • general political and economic conditions **, including conflict, hostilities or war, inflationary pressures and rising interest rates** ; and • other events or factors, many of which are beyond our control. In addition, the stock market in general, and the market for biotechnology and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies ~~, including as a result of the COVID- 19 pandemic~~ . Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. You may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company' s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management' s attention and resources. **Our failure to meet Nasdaq' s continued listing requirements could result in a delisting of our common stock.** If **we fail to satisfy the continued listing requirements of the Nasdaq Stock Market, or Nasdaq, such as the corporate governance requirements or the requirement to maintain a minimum bid price of $ 1. 00 per share of our common stock pursuant to Nasdaq Listing Rule 5450 (a) (1), or the Minimum Bid Price Requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. Any such delisting could also adversely impact our ability to raise additional capital or enter into strategic transactions. On September 27, 2023, we received a written notice from the staff, or the Staff, of Nasdaq' s Listing**

Qualifications Department, notifying us that, for the prior 30 consecutive business days, our common stock had not complied with the Minimum Bid Price Requirement. Nasdaq' s written notice does not result in the immediate delisting of our common stock from Nasdaq. In accordance with Nasdaq Listing Rule 5810 (c) (3) (A), the Company has 180 calendar days, or until March 25, 2024, or the Compliance Date, to regain compliance with the Minimum Bid Price Requirement. According to the written notice, if, at any time during this 180- day period, the closing bid price for our common stock is ~~delisted from The Nasdaq Global Select Market, the liquidity~~ **at least $ 1. 00 per share for a minimum** of ~~our~~ **ten consecutive business days, the Staff will provide written confirmation of compliance and the** common stock **will remain** ~~would be adversely affected and the market price of our common stock could decrease. Our common stock is currently~~ listed on The Nasdaq Global ~~Select~~ Market **. If we do not regain compliance with the Minimum Bid Price Requirement by the Compliance Date, we may be eligible for** ~~and~~ **an** ~~closed at $ 2~~ **additional 180 calendar day compliance period** . **To qualify** ~~20 on March 1~~ , ~~2023.~~ **we would be required to transfer our listing to** The Nasdaq ~~Stock~~ **Capital** Market ~~LLC,~~ **and meet the continued listing requirement** ~~or~~ **for the market value of publicly held shares and all other applicable initial listing standards for The** Nasdaq **Capital Market** , ~~has~~ **with the exception of the** ~~minimum~~ **Minimum Bid Price** ~~requirements~~ **Requirement , and would need to provide written notice to Nasdaq of our intention to cure the deficiency during the additional 180- day compliance period, such as by effecting a reverse stock split, if necessary. As part of its review process, the Staff will make a determination of whether it believes we will be able to cure this deficiency. If the Staff determines** that **we will not be able** ~~a company must meet in order~~ to ~~remain listed on~~ **cure the deficiency, then the Staff will provide us written notice that our common stock will be subject to delisting. At that time, we may appeal the Staff' s delisting determination to a** Nasdaq ~~markets, including~~ **Hearing Panel. There can be no assurance** that **, if** we ~~maintain~~ **receive** a ~~minimum~~ **delisting notice and appeal the delisting determination by the Staff to the Nasdaq Hearing Panel, such appeal would be successful. We intend to monitor the** closing bid price of ~~$ 1. 00 per share. If we fail to maintain such minimum requirements and a final determination is made by Nasdaq that~~ our common stock **and may** ~~must be delisted~~ , **if appropriate, consider available options to regain compliance with** the ~~liquidity~~ **Minimum Bid Price Requirement. However, we can provide no assurance that actions taken or not taken by us will restore compliance with Nasdaq' s listing requirements, stabilize the market price** of our common stock **, improve** ~~would be adversely affected and~~ the **liquidity** ~~market price~~ of **our common stock or prevent future non- compliance with Nasdaq' s listing requirements. Additionally, if our common stock is not listed on, or becomes delisted from, Nasdaq for any reason, trading** our common stock could ~~decrease. Our failure to~~ be **conducted only in the over- the- counter, or OTC, market or on an electronic bulletin board established for unlisted securities such as the OTC Bulletin Board, an inter- dealer automated quotation system for equity securities that is not a national securities exchange, and the liquidity and price of our common stock may be more limited than if we were quoted or** listed on Nasdaq or another national securities exchange ~~would have a material adverse effect on the value of~~ **. In such circumstances, you may be unable to sell** your ~~investment in us~~ **common stock unless a market can be established or sustained** . We do not intend to pay dividends on our common stock, so any returns will be limited to the value of our stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Furthermore, future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their 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. As of March 1, ~~2023~~ **2024** , our executive officers, directors and their affiliates beneficially held, in the aggregate, approximately ~~21~~ **11** . ~~9~~ **2** % of our outstanding voting stock. These stockholders, acting together, would be able to significantly influence ~~all~~ matters requiring stockholder approval. For example, these stockholders would be able to significantly influence elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. 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 EGC as defined in the JOBS Act, enacted in April 2012. For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, or Section 404, reduced disclosure obligations regarding executive compensation and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may remain an EGC until December 31, 2025, although circumstances could cause us to lose that status earlier. We will remain an EGC until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, or 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 the prior June 30th, and (ii) the date on which we have issued more than $ 1. 0 billion in non- convertible debt during the prior three- year period. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting obligations by providing only two years of audited financial statements. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. Under the JOBS Act, EGCs can also delay adopting new or revised accounting standards until such time as those standards apply to private companies, which may make our financial statements less comparable to companies that comply with new or

revised accounting pronouncements as of public company effective dates. We are also a " smaller reporting company, " meaning that the market value of our shares held by non- affiliates is less than $ 700 million and our annual revenue was less than $ 100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non- affiliates is less than $ 250 million or (ii) if the market value of our shares held by non- affiliates is more than $ 250 million but less than $ 700 million and our annual revenue was less than $ 100 million during the most recently completed fiscal year. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, 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 emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. We will continue to incur significant costs as a result of operating as a public company, and our management may be required to devote substantial time to new compliance initiatives. As a public company, we incur, and we will continue to incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes- Oxley Act, as well as rules subsequently adopted by the SEC and the Nasdaq Global Select Market to implement provisions of the Sarbanes- Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial reporting controls and changes in corporate governance practices. Further, in July 2010, the Dodd- Frank Wall Street Reform and Consumer Protection Act, or the Dodd- Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd- Frank Act that require the SEC to adopt additional rules and regulations in these areas such as " say on pay " and proxy access. Recent legislation permits EGCs to implement many of these requirements over a longer period and up to five years from the pricing of our IPO. The costs associated with operating as a public company may decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products, if approved, or services. Additionally, stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock. We are required to disclose changes made in our internal controls and procedures on a quarterly basis, and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an EGC, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an EGC for up to five years. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management' s assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected. We have broad discretion in the use of our existing cash, cash equivalents and marketable securities and may not use them effectively. Our management has broad discretion in the application of our existing cash, cash equivalents and marketable securities. Because of the number and variability of factors that will determine our use of our existing cash, cash equivalents and marketable securities, their ultimate use may vary substantially from their currently intended use. Our management might not apply our existing cash, cash equivalents and marketable securities in ways that ultimately increase the value of our common stock. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest our cash, cash equivalents and marketable securities in short- term, investment- grade, interest- bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our cash, cash equivalents and marketable securities in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline. Anti- takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate

attempts by our stockholders to replace or remove our current management. Our amended and restated certificate of incorporation and amended and restated bylaws, contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include: • a board of directors divided into three classes serving staggered three- year terms, such that not all members of the board will be elected at one time; • a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders; • a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office; • advance notice requirements for stockholder proposals and nominations for election to our board of directors; • a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two- thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors; • a requirement of approval of not less than two- thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and • the authority of the board of directors to issue convertible preferred stock on terms determined by the board of directors without stockholder approval and which convertible preferred stock may include rights superior to the rights of the holders of common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, or DGCL, which may prohibit certain business combinations with stockholders owning 15 % or more of our outstanding voting stock. These anti- takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then- current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline. Our amended and restated bylaws will designate certain courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to litigate disputes with us in a different judicial forum. Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (v) any action asserting a claim governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, or the Delaware forum provision. The Delaware forum provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Unless we consent in writing to the selection of an alternate forum, the United States District Court for the District of Delaware shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the federal forum provision, as we are incorporated in the State of Delaware. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware forum provision and the federal forum provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U. S. federal securities laws and the rules and regulations thereunder. The Delaware forum provision and the federal forum provision may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware. In addition, these forum selection clauses in our bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are " facially valid " under Delaware law, there is uncertainty as to whether other courts will enforce our federal forum provision. The federal forum provision may also impose additional litigation costs on stockholders who assert the provision is not enforceable or invalid, and if the federal forum provision is found to be unenforceable, we may also incur additional costs associated with resolving such matters. The Court of Chancery of the State of Delaware and the United States District Court for the District of Delaware may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders. Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders. We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors, and consultants under our

stock incentive plans. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products, or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.