Risk Factors Comparison 2025-04-01 to 2024-04-01 Form: 10-K

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An investment in our common stock involves a high degree of risk. You should carefully consider the following risk factors and the other information in this Annual Report on Form 10- K before investing in our common stock. Our business and results of operations could be seriously harmed by any of the following risks. The risks set out below are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and / or operating results. If any of the following events occur, our business, financial condition and results of operations could be materially adversely affected. In such case, the value and trading price of our common stock could decline, and you may lose all or part of your investment. Risks Related to Our Operations and Need for Additional Capital We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations. We are using the proceeds from our sales of securities to advance REQORSA through clinical development, and to advance our other preclinical development programs as well as for other corporate purposes. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional future capital to complete clinical development and commercialize REQORSA and for preclinical and clinical development and commercialization of our gene therapy for diabetes, GPX- 002, and our other product candidates. If the FDA requires that we perform additional preclinical studies or clinical trials beyond what we currently anticipate, our expenses will further increase beyond what we currently expect and the anticipated timing of any potential approval of REQORSA, GPX- 002, and our other current or future product candidates would likely be delayed. Furthermore, there can be no assurance that the costs to obtain regulatory approval of these product candidates will not increase. We will continue to require substantial additional capital to continue our preclinical and clinical development and commercialization readiness activities. Because successful development of our current and potential product candidates is uncertain, we are unable to estimate the actual amount of funding we will require to complete research and development and commercialize our current and future product candidates. The amount and timing of our future funding requirements will depend on many factors, including, but not limited to: ● the progress, costs, results and timing of our preclinical development and clinical trials for REQORSA, GPX- 002, and other current or future product candidates; ● the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals; ● the ability of third parties to deliver materials and provide services for us; ● the costs associated with securing and establishing commercialization and manufacturing capabilities; ● market acceptance of our current and future product candidates; ● the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies; ● our ability to obtain, maintain, expand and enforce intellectual property rights for our products and product candidates, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights; ● our need and ability to hire additional management and scientific and medical personnel; ● the effect of competing drug candidates and new product approvals; ● our need to implement additional internal systems and infrastructure, including financial and reporting systems; and ● the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future. Some of these factors are outside of our control. Although we expect that our existing cash will be sufficient to fund our current operations and planned clinical trial activities into the ~~third~~ **second** quarter of ~~2024~~ **2025** , this period could be shortened if there are any significant increases in planned spending on current or additional development programs or more rapid progress of these development programs than anticipated. Furthermore, we believe that our existing capital will not be sufficient to enable us to complete the development and commercialization of REQORSA, GPX- 002, and our other current or future product candidates. Accordingly, we expect that we will need to raise additional funds in the future. We have raised and may continue to raise capital through a variety of sources that may be available to us. On March 1, 2023, we completed a registered direct offering, in which we sold to an accredited healthcare- focused institutional investor an aggregate of (i) 95, 239 shares of our common stock and (ii) warrants to purchase up to 95, 239 shares of our common stock, at a combined offering price of $ 42. 00 per share of common stock and accompanying warrant, for net proceeds of approximately $ 3. 6 million. On July 21, 2023, we completed a registered direct offering priced at the market under Nasdaq rules, in which we sold to accredited healthcare- focused institutional investors an aggregate of (i) 185, 644 shares of our common stock, and (ii) warrants to purchase up to 185, 644 shares of our common stock, at a combined offering price of $ 40. 40 per share of common stock and accompanying warrant, for net proceeds of approximately $ 6. 7 million. On December 13, 2023, we entered into an At The Market (" ATM ") Offering Agreement (the " **ATM** Agreement ") with H. C. Wainwright & Co., LLC, serving as agent (" H. C. Wainwright " or the " Agent ") with respect to an at- the- market offering program under which we may offer and sell through the Agent, from time to time at our sole discretion, up to such number or dollar amount of shares of our common stock (the " Shares ") as registered on the prospectus supplement covering the ATM offering, as may be amended or supplemented from time to time. We have agreed to pay the Agent a commission equal to three percent (3 %) of the gross sales proceeds of any Shares sold through the Agent under the **ATM** Agreement, and also have provided the Agent with customary indemnification and contribution rights. As of December 31, ~~2023~~ **2024 ,** we had ~~not~~ sold ~~any~~ **7, 684, 953** Shares **for net proceeds to us totaling $ 6, 100, 562** through the Agent under the **ATM** Agreement. From January 1, ~~2024~~ **2025** through the date of filing of this Annual Report on Form 10- K, we have sold ~~158~~ **13** , ~~474~~ **278, 666** Shares for net proceeds to us totaling $ ~~881~~ **6** , ~~946~~ **028, 104** through the Agent under the **ATM** Agreement. On March 21, 2024, we completed a registered direct offering, in which we sold to an institutional investor

an aggregate of (i) 165, 000 shares of our common stock, (ii) March 2024 Pre- Funded Warrants **(the " March 2024 Pre- Funded Warrants ")** exercisable for up to an aggregate of 1, 377, 112 shares of our common stock, and (iii) **common warrants (the "** March 2024 Common Warrants **")** exercisable for up to an aggregate of 1, 542, 112 shares of our common stock **. The** ~~, at a combined~~ offering price **for each share** of **common stock and accompanying March 2024 Common Warrant was** $ 4. 215 **, and the offering price** ~~per share of common stock (or~~ **for each** ~~$ 4. 2149 per~~ March 2024 Pre- Funded Warrant ~~in lieu thereof)~~ and accompanying March 2024 Common Warrant ~~, for~~ **was $ 4. 2149. The March 2024 Pre- Funded Warrants were exercisable immediately upon issuance at an exercise price of $ 0. 0001 per share and expired when exercised in full. The March 2024 Common Warrants are exercisable immediately upon issuance at an exercise price of $ 4. 09 per share and will expire in five years from the date of issuance. The Company received** net proceeds of approximately $ 5. 8 million **after commissions and expenses, excluding any proceeds received from any exercise of the March 2024 Common Warrants** . In connection with the ~~March 2024 registered direct~~ offering, ~~we~~ **the Company also** amended certain existing warrants to **purchase up to an aggregate of 194, 248 shares of common stock that were previously issued to investors in March 2023 and July 2023, with exercise prices of $ 44. 00 and $ 35. 40 per share and expiration dates of March 1, 2028 and July 21, 2028 for $ 0. 125 per amended warrant, such that the amended warrants have a** ~~reduce~~ **reduced** ~~the~~ exercise price **of $ 4. 09 per share and** ~~and~~ **an expiration date** ~~extend the term thereof as discussed above in Part I, Item 1~~ of **five years from** ~~this Annual Report in~~ the **closing of the** ~~section captioned Recent Developments —~~ March 2024 ~~Registered Direct Offering~~ **offering** ~~"~~ **. As of December 31, 2024, all of the 1, 377, 112 March 2024 Pre- Funded Warrants had been exercised for shares of common stock of the Company** . We may seek additional funding through a combination of equity offerings, drawdowns on our ATM pursuant to our **ATM** ~~At The Market Offering~~ Agreement with H. C. Wainwright as Agent **and / or through other third- party ATM agreements in the future** , debt financings, government or other third- party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, some of which may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us. Additional funding may not be available to us on acceptable terms, if at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. Any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our existing capital stock. In addition, the issuance of additional shares by us may cause the market price of our shares to decline and result in dilution to our stockholders. Any debt financing secured by us in the future could involve restrictive covenants relating to our capital- raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our preclinical or clinical development programs, our ability to continue to support our business growth and to respond to business challenges could be significantly limited, and we may be required to curtail or cease operations. Accordingly, our business may fail, in which case you would lose the entire amount of your investment in our securities. Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern. We have recognized recurring losses, and as of December 31, ~~2023~~ **2024** , had an accumulated deficit of approximately $ ~~133~~ **154** . ~~9~~ **8** million. We anticipate operating losses to continue for the foreseeable future due to, among other things expenses related to ongoing activities to research, develop and commercialize our product candidates. We expect the cash and cash equivalents of approximately $ **1.** 6 ~~. 7~~ million at December 31, ~~2023~~ **2024** to be insufficient to meet our operating and capital requirements at least 12 months from the filing of this Annual Report on Form 10- K. Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative and research and development activities are forward- looking statements and involve risks and uncertainties. The financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern. As further described below, our ability to continue as a going concern is dependent on our ability to raise additional working capital through public or private equity or debt financings or other sources, which may include collaborations with third parties as well as disciplined cash spending. Should we be unable to raise sufficient additional capital, we may be required to undertake cost- cutting measures including delaying or discontinuing certain clinical activities. The sale of equity and convertible debt securities may result in dilution to our stockholders and certain of those securities may have rights senior to those of our common stock. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations. Any other third- party funding arrangement could require us to relinquish valuable rights. The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate some or all of our planned clinical trials. These factors among others create a substantial doubt about our ability to continue as a going concern. We have never been profitable, we have no products approved for commercial sale, and to date we have not generated any revenue from product sales. As a result, our ability to reduce our losses and reach profitability is unproven, and we may never achieve or sustain profitability. We have never been profitable and do not expect to be profitable in the foreseeable future. We have not yet submitted any drug candidates for approval by regulatory authorities in the United States or elsewhere. From our inception on April 1, 2009, to December 31, ~~2023~~ **2024** , we incurred an accumulated deficit of approximately $ ~~133~~ **154** . ~~9~~ **8** million. We incurred net losses of approximately $ ~~31~~ **21** . ~~0~~ **1** million and approximately $ ~~23~~ **31** . ~~7~~ **0** million for the years ended December 31, **2024 and** 2023 ~~and 2022~~ , respectively. To date, we have devoted most of our financial resources to our corporate overhead and research and development, including our preclinical development activities, manufacturing processes and clinical trials. We have not generated any revenues from product sales. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our current and potential product candidates, prepare for and begin the

commercialization of any approved products, and add infrastructure and personnel to support our continuing product development efforts. We anticipate that any such losses could be significant for the next several years. If REQORSA, GPX- 002, or any of our other current or future product candidates fail in clinical trials or does not gain regulatory approval, or if our drug candidates do not achieve market acceptance, we may never become profitable. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or if, or when, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our drug candidates. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on an annual basis, which may make it difficult to predict our future performance. We are a clinical stage company with a limited operating history. Our operations to date have been limited to conducting clinical and preclinical research and development. We have not yet obtained any regulatory approvals for any of our drug candidates. Consequently, any predictions made about our future success or viability may not be accurate. Our operating results are expected to significantly fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include: ● any delays in regulatory review and approval (assuming that our data support approval) of our current and future product candidates in clinical development, including our ability to receive approval from the FDA for REQORSA or GPX- 002; ● delays in the commencement, enrollment and timing of clinical trials; ● the success of our current and future product candidates through all phases of preclinical and clinical development, including the ability of our third- party suppliers or manufacturers to supply or manufacture our products on a timely, consistent basis in a manner sufficient and appropriate as is commensurate to meet our clinical trial timing, courses of treatment, and other requisite fulfillment considerations necessary to adequately advance our development programs; ● potential side effects of our current and future product candidates that could delay or prevent approval or cause an approved drug to be taken off the market; ● our ability to obtain additional funding to develop our current and future product candidates; ● our identification and development of additional drug candidates beyond REQORSA, GPX- 002, and our other current product candidates; ● competition from existing products or new products that continue to emerge; ● the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for our products; ● our ability to adhere to clinical trial requirements directly or with third parties such as contract research organizations (**" "** CROs **" "**); ● our dependency on third- party suppliers or manufacturers to manufacture our key ingredients and / or raw materials, products and / or product components and successfully carry out a sustainable, reproducible and scalable manufacturing process in accordance with specifications or applicable regulations; ● our ability to establish or maintain collaborations, licensing, sponsored research or other arrangements, particularly with MD Anderson and UP and otherwise relating to REQORSA, and GPX- 002; ● our ability to defend against any challenges to our intellectual property including claims of patent infringement; ● our ability to enforce our intellectual property rights against potential competitors; ● our ability to secure additional intellectual property protection for our product candidates and associated technologies as may be required or desirable as the development of the product candidates progresses; ● our ability to attract and retain key personnel to manage our business effectively; and ● potential product liability claims. Our ability to utilize our net operating loss carryforwards may be limited, resulting in income taxes sooner than currently anticipated. As of December 31, ~~2023~~ **2024** , we had federal net operating loss carryforwards (" NOLs ") of approximately $ ~~80~~ **96** . ~~5~~ **3** million for federal income tax purposes of which approximately $ 1. 3 million will begin to expire in 2030 and approximately $ ~~79~~ **86** . ~~2~~ **6** million can be carried forward indefinitely. These NOLs may be used to offset future taxable income, to the extent we generate any taxable income, and thereby reduce or eliminate our future federal income taxes otherwise payable. Section 382 of the Internal Revenue Code of 1986, as amended (the " Code "), imposes limitations on a corporation' s ability to utilize NOLs if it experiences an ownership change as defined in Section 382. In general terms, an ownership change may result from transactions increasing the ownership of certain stockholders in the stock of a corporation by more than 50 % over a three- year period. In the event that an ownership change has occurred, or were to occur, utilization of our NOLs would be subject to an annual limitation under Section 382 determined by multiplying the value of our stock at the time of the ownership change by the applicable long- term tax- exempt rate as defined in the Code. Any unused annual limitation may be carried over to later years. We may be found to have experienced an ownership change under Section 382 as a result of events in the past or the issuance of shares of common stock in the future. If so, the use of our NOLs, or a portion thereof, against our future taxable income may be subject to an annual limitation under Section 382, which may result in expiration of a portion of our NOLs before utilization. The utilization of our NOLs may also be limited under state laws. In addition, under the 2017 Tax Cuts and Jobs Act (the " TCJA "), tax losses generated in taxable years beginning after December 31, 2017 may be utilized to offset no more than 80 % of taxable income annually. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities. For these reasons, we may not be able to realize a tax benefit from the use of our NOLs, whether or not we attain profitability. Risks Related to Development and Commercialization of Our Current and Future Product Candidates Our success depends greatly on the success of our development of REQORSA for the treatment of NSCLC and SCLC, and our other product candidates, including GPX- 002 for the treatment of diabetes. At this time, we are actively pursuing the development of REQORSA for NSCLC through our Acclaim- 1 ~~and Acclaim- 2~~ clinical ~~trials~~ **trial** and for SCLC through our Acclaim- 3 clinical trial, which are ~~all~~ **both** currently enrolling patients. We are also pursuing the development of preclinical gene therapy GPX- 002 for Type 1 and Type 2 diabetes, as well as earlier discovery programs. In particular, we are dependent on the success of REQORSA and GPX- 002. We cannot provide you any assurance that we will be

able to successfully advance REQORSA, GPX- 002 or any of our other current or future product candidates through the development process, or that any development problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved. **For example, as previously announced in August 2024, based on a number of factors, including enrollment challenges and delays due to competition for investigators and eligible patients with numerous other trials involving the same patient population, we decided to cease enrollment of new patients in the Acclaim- 2 trial (which involved a combination of REQORSA and Merck & Co.' s Keytruda ® (pembrolizumab) in patients with late- stage NSCLC whose disease has progressed after treatment with Keytruda) to prioritize our resources and focus on the other two Acclaim trials in SCLC and NSCLC, respectively.** We may also experience delays in the development of a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, or developing or validating product release assays in a timely manner, which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all. Immunotherapy, gene therapy and biopharmaceutical product development are highly speculative undertakings and involve a substantial degree of uncertainty. Because REQORSA, GPX- 002 and our other current product candidates are based upon novel technology, it is difficult to predict whether, either as stand- alone therapies or in combination with other drugs, they will show consistently favorable results and to predict the time and cost of their development and of subsequently obtaining regulatory approval. We believe only a few gene therapy products have been approved in the United States or Europe. We have found it difficult to enroll patients in our clinical studies in the past, have experienced certain difficulties in enrolling patients in our current trials and may continue to find it difficult in the future, which could delay or prevent clinical studies of REQORSA or other current or future product candidates **. Examples of such difficulties include the Acclaim- 2 trial noted above and also for Acclaim- 1, which as previously announced in August 2024, we decided to limit our enrollment efforts moving forward to patients who received only prior Tagrisso treatment and cease enrollment of the second cohort (patients who received prior Tagrisso treatment and chemotherapy) due to slow enrollment, resource prioritization and to focus on the patients for whom REQORSA is most likely to show a benefit** . We may encounter other delays in our preclinical or clinical studies, or we may fail to demonstrate safety and efficacy to the satisfaction of FDA and other regulatory authorities. We may not be successful in our efforts to identify or discover additional product candidates, or to develop product candidates that we have identified. In addition, the clinical trial requirements of the FDA, the European Commission, the European Medicines Agency (" EMA "), the competent authorities of the Member States of the European Union (" EU ") and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of such product candidates. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or more extensively studied product candidates. Even if we are successful in developing product candidates, it is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for these product candidates in either the United States or the EU, or how long it will take to commercialize any other products for which we receive marketing approval. In addition, any future marketing authorization granted by the European Commission may not be indicative of what the FDA may require for approval and vice versa. **The biopharmaceutical industry is subject to extensive regulatory obligations and policies that may be subject to change, including due to judicial challenges. The U. S. biopharmaceutical industry is highly regulated and subject to frequent and substantial changes, including as a result of new judicial or government actions. Legislative and regulatory agendas as they relate to the biopharmaceutical industry are currently uncertain. Changes in the regulatory approval process, or substantial reductions in the personnel who oversee that process, could affect our ability to obtain regulatory approval for our product candidates or the timeline in which we can obtain that approval. We and our current and future third party collaborators may rely on government programs or agencies, such as the National Institutes for Health (" NIH "), as a source of grant funding for scientific research relevant to our product candidates. Funding from government agencies such as the NIH can fluctuate and is subject to the political process, which is often unpredictable. Reductions in NIH grants to us or our third party collaborators may adversely impact our ability to develop our existing product candidates and our ability to identify new product candidates. In addition, on June 28, 2024, the U. S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) " must exercise their independent judgment " and " may not defer to an agency interpretation of the law simply because a statute is ambiguous. " The decision could have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework may increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies could be subject to increased litigation and judicial scrutiny. We cannot predict how other future federal or state legislative or administrative changes relating to healthcare reform or the biopharmaceutical industry, or the regulatory agencies that oversee the biopharmaceutical industry, will affect our business.** If we are unable to secure contract manufacturers with capabilities to produce the products that we require, we could experience delays in conducting our planned clinical trials. Manufacturing REQORSA involves several manufacturing steps. Historically, part of our manufacturing process was conducted in manufacturing facilities at MD Anderson. We have transferred all of the steps of our manufacturing process to CDMOs and scaled- up clinical production in order to supply our Acclaim- 1 ~~, Acclaim- 2~~ and Acclaim- 3 clinical trials. We also are preparing for commercial readiness for REQORSA through the development of an integrated supply chain network of manufacturing vendors and continue to work to identify cutting edge manufacturing technologies to optimize manufacturing processes and shelf life. With the advancement of the development of GPX- 002, we also are working to optimize the manufacture of this product candidate and to source high quality and integrated vendors capable of producing it in accordance with GMP. Although we have contracted with CDMOs to produce our products, no assurance can be given that such

CDMOs will be able to continue to produce the products that we require. In addition, the tremendous growth in the gene therapy sector has created increasing demand for the services of CDMOs with gene therapy capabilities which may impact our ability to schedule production runs of our products or product components to meet our needs on a timely basis. Furthermore, manufacturing gene- based therapies is complex and highly regulated and a CDMO with which we have contracted may fail to produce our products or product components timely or in accordance with our specifications or applicable regulations. We have experienced a variety of these challenges to varying degrees in connection with performance by our CDMOs, which have resulted in delays in our Acclaim ~~- 1, Aeclaim- 2 and Aeclaim- 3~~ clinical trials in the past **. Additionally, our CDMOs may get acquired or change ownership structure, enter into new lines of business or depart existing lines of business, or go out of business altogether; all of which could require us to find new CDMOs and adversely affect our business** . Changing our current or future contract manufacturers may be difficult and could be costly, which could result in our inability to manufacture our clinical product candidates and a delay in the development of our clinical product candidate. Further, in order to maintain our development timelines, any changes to, or the addition of a new, third- party contract manufacturers may result in our incurring higher costs to manufacture our clinical product candidates. Any delay in the availability of product supply or product component supply could result in a delay in our clinical trials, including our Acclaim- 1 ~~, Aeclaim- 2~~ and Acclaim- 3 clinical trials as well as the commencement of clinical trials for GPX- 002. Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our current and potential product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our current and potential product candidates. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our current and potential product candidates or demand for any products we may develop. Adverse events in our clinical trials, even if not ultimately attributable to our current and potential product candidates, and the resulting publicity could lead to increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. Concern about the environmental spread of our product, whether real or anticipated, could also hinder the commercialization of our products. Prior to receiving REQORSA in our Acclaim- 1 clinical trial, patients are required to undergo genetic screening to detect EGFR mutations. Genetic testing has raised concerns regarding the appropriate utilization and the confidentiality of information provided by genetic testing. Genetic tests for assessing a person' s likelihood of developing a chronic disease have focused public attention on the need to protect the privacy of genetic information. Genetic testing information is also subject to significant restrictions under both federal and state law. For example, concerns have been expressed that insurance carriers and employers may use these tests to discriminate on the basis of genetic information, resulting in barriers to the acceptance of genetic tests by consumers. This could lead to governmental authorities restricting genetic testing or calling for limits on or regulating the use of genetic testing, particularly for diseases for which there is no known cure. Any of the foregoing could decrease demand for REQORSA or our other product candidates. Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow- up depends on many factors, including the size of the patient population; the nature of the trial protocol; the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; the availability of appropriate clinical trial investigators; support staff; and proximity of patients to clinical sites; ability to comply with the eligibility and exclusion criteria for participation in the clinical trial; and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post- treatment procedures or follow- up to assess the safety and effectiveness of our product candidates or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products. In addition, our ability to successfully initiate, enroll and complete clinical trials in any foreign country is subject to numerous risks of conducting business in foreign countries, including: ● difficulty in establishing or managing relationships with CROs and physicians; ● different standards for the conduct of clinical trials; ● our inability to locate qualified local consultants, physicians and partners; and ● the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, **such as we have experienced with the Acclaim- 2 clinical trial for example,** we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business. Delays in the commencement, enrollment and completion of clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for REQORSA and other current or future product candidates. Clinical development is very expensive and can take many years. Delays in the commencement, enrollment and / or completion of our Acclaim- 1 ~~, Aeclaim- 2~~ and Acclaim- 3 clinical trials or any future clinical trials could increase our product development costs or delay or limit the regulatory approval of REQORSA or other product candidates. We have experienced delays in opening our clinical sites for our Acclaim- 1 and Acclaim- 2 trials in the past; for example, during the COVID- 19 pandemic there was a delay due to a back- log in protocol review at the clinical trial sites **and with Acclaim- 2 due to competition for investigators and eligible patients with numerous other trials involving the same patient population** . We do not know and cannot predict whether future trials or studies of other current or future product candidates, including later stages of our Acclaim trials, and any for GPX- 002, will begin as planned, if at all, and we do not know and cannot predict whether our Acclaim- 1 ~~, Aeclaim- 2~~ and Acclaim- 3 clinical trials or any future trials or

studies of other current or future product candidates will be completed on schedule, if at all. The start or end of a clinical study may be delayed or halted due to regulatory requirements, changes in the proposed regulatory approval pathway for a drug candidate, manufacturing challenges, including delays or shortages in available raw materials required to manufacture the drug product, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparative drug or required prior therapy, clinical outcomes or financial constraints. For instance, delays or difficulties in patient enrollment or difficulties in retaining trial participants can result in increased costs, longer development times or termination of a clinical trial **, such as the Acclaim- 2 program** . Clinical trials of a new product candidate require the enrollment of a sufficient number of patients, including patients who are suffering from the disease the product candidate is intended to treat and who meet other eligibility criteria, such as mutation of the EGFR which is required for the Acclaim- 1 trial and is present in a minority of NSCLC patients. Rates of patient enrollment are affected by many factors, including the size of the patient population, the eligibility criteria for the clinical trial, which include the age and condition of the patients and the stage and severity of disease, the nature of the protocol, the proximity of patients to clinical sites and the availability of effective treatments and / or availability of other investigational treatment options for the relevant disease. We have initiated our Acclaim- 1 ~~, Acclaim- 2~~ and Acclaim- 3 clinical trials pursuant to an existing IND. We have previously filed with the FDA amendments to our IND consisting of an updated chemistry, manufacturing and controls section, and the protocol for the respective clinical trial. We cannot be sure that issues will not arise in the future in connection with potential subsequent amendments or otherwise that might result in the FDA imposing a clinical hold which could result in the delay of any of these clinical trials. For GPX- 002 we have not yet filed an IND and cannot predict all of the challenges and issues that may arise in connection with the preparation and filing of an IND, or whether this IND will be filed at all. Fast track designation of our products by FDA and designation under any other FDA expedited development program may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates. REQORSA has received three fast track designations from the FDA. We may in the future seek additional fast track designations for our products and / or request breakthrough therapy designation, accelerated approval or priority review of applications for approval. FDA has broad discretion whether or not to grant these designations and requests, so even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA will grant them. Even with fast track designation and other FDA expedited development programs, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation and other expedited program designations if it believes that the requirements of the program are no longer met. We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates. In August 2023, the FDA granted Orphan Drug Designation to REQORSA for the treatment of SCLC. Upon receipt of regulatory approval, orphan drug status will provide us with seven years of market exclusivity in the United States under the Orphan Drug Act. We may seek other orphan drug designations in the future in the United States and in the European Union for our product candidates. However, there is no guarantee that the FDA will grant orphan drug designation for any of our other drug candidates for any future indication, which would make us ineligible for the additional exclusivity and other benefits of orphan drug designation for those other drug candidates in the future. Moreover, there can be no assurance that another company also holding orphan drug designation for the same indication or which may receive orphan drug designation in the future will not receive approval prior to us, in which case our competitor would have the benefit of the seven years of market exclusivity, and we would be unable to commercialize our product for the same indication until the expiration of such seven- year period. Even if we are the first to obtain approval for the orphan drug indication, there are circumstances under which a competing product may be approved for the same indication during our seven- year period of exclusivity. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200, 000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the Unites States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to $ 400, 000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee. If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug' s orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant' s product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. There can be no assurance that we will receive orphan drug designation for any of our drug candidates for any additional indications, if we elect to seek such designation. Even if orphan designation is granted it may be withdrawn by the FDA for non- compliance with regulations. A product candidate can fail at any stage of preclinical and clinical development. The historical failure rate for product candidates is high due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The results from preclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in later phase clinical trials of the product candidate. We, the FDA or other applicable regulatory authorities may suspend clinical trials of a product candidate at any time for various reasons, including, but not limited to, a belief that subjects participating in such trials are being exposed to unacceptable health risks or adverse side

effects, or other adverse initial experiences or findings. We may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any problems or other unforeseen events that delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including: ● inability to obtain sufficient funds required for clinical development; ● inability to reach agreements on acceptable terms with current or prospective vendors, CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different vendors, CROs and trial sites; ● negative or inconclusive results from our clinical studies or the clinical studies of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program; ● serious and unexpected side effects experienced by subjects in our clinical trials or by individuals using drugs similar to our current and future product candidates; ● conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials; ● unexpected results from preclinical testing and development; ● inability or delays in enrolling research subjects in clinical trials; ● high drop- out rates and high fail rates of research subjects; ● inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of preclinical or clinical testing; ● greater than anticipated clinical trial costs; ● poor effectiveness of our current and potential product candidates during clinical trials; or ● unfavorable FDA or other regulatory agency inspection and review of a clinical trial site or vendor. REQORSA ®, GPX- 002, and any other product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval. Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize our product candidates, and the approval may be for a narrower indication than we seek. Clinical failure can occur at any stage of our clinical development. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or nonclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Additionally, our partners, clients, other vendors, and / or other stakeholders may not agree with our interpretation (s) of data obtained from our clinical trials, which could potentially cause a variety of issues, including, but not limited to, delays, the necessity for additional studies and analyses, dependence on third- party validation, and / or other unforeseen challenges. Success in preclinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Later- stage clinical trials could differ in significant ways from early- stage clinical trials, including changes to inclusion and exclusion criteria, efficacy endpoints, dosing regimen and statistical design. For example, the small number of patients in our completed Phase 1 Monotherapy clinical trial of REQORSA and the Phase 1 / 2 Combination Tarceva trial may make the results of these trials less predictive of the outcome of later clinical trials. In addition, although we observed encouraging clinical activity in the Phase 1 Monotherapy and Phase 1 / 2 Combination Tarceva trial, the primary objectives of the Phase 1 Monotherapy Trial and the Phase 1 portion of the Phase 1 / 2 Combination Tarceva trial were safety and MTD and not to demonstrate efficacy. The assessments of clinical activity from these clinical trials, some of which were not pre- specified, may not be predictive of the results of later clinical trials of REQORSA. Furthermore, safety events may be observed in later trials that alter the anticipated risk- benefit profiles of REQORSA or other product candidates. In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. We do not know whether any clinical trials we conduct will demonstrate the consistent or adequate efficacy and safety that would be required to obtain regulatory approval and market any products. If REQORSA, GPX- 002 or other current or future product candidates are found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business would be harmed. If we are unable to bring REQORSA, GPX- 002 or other product candidates to market, or acquire other products that are on the market or can be developed, our ability to create stockholder value will be limited. Regulatory authorities also may approve a product candidate for more limited indications than requested, or they may impose significant limitations in the form of narrow indications. These regulatory authorities may require warnings or precautions with respect to conditions of use or they may grant approval subject to the performance of costly post- marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims or allow the promotional claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and materially and adversely affect our business, financial condition, results of operations and prospects. Even if we obtain regulatory approval of our current and future product candidates, the products may not gain market acceptance among physicians, patients, hospitals, treatment centers, third- party payors and others in the medical community. Ethical, social and legal concerns about gene therapy and genetic research could result in additional regulations restricting or prohibiting the products and processes we may use. Even with the requisite approvals, the commercial success of REQORSA, GPX- 002 and any of our other current or future product candidates will depend in part on the medical community, patients, and third- party payors accepting gene therapy products in general, and our current and future product candidates in particular, as medically useful, cost- effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, hospitals, treatment centers, third- party payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of these product candidates, if approved for commercial sale, will depend on a number of factors, including: ● the clinical indications for which our current and potential product candidates are approved; ● physicians, hospitals, treatment centers and patients considering our product candidates as a safe and effective treatment; ● the potential and perceived advantages of our product candidates over alternative treatments; ● the prevalence and severity of any side effects; ● product labeling or product insert requirements of the FDA or other regulatory authorities; ● limitations or warnings contained in the

labeling approved by the FDA; ● the timing of market introduction of our product candidates as well as competitive products; ● the cost of treatment – both in absolute terms and in relation to alternative treatments; ● the availability of coverage, reimbursement and pricing by third- party payors and government authorities and the adequacy thereof; ● the willingness of patients to pay out- of- pocket in the absence of coverage by third- party payors, including government authorities; ● the willingness, ability and availability of healthcare providers that can comply with the transportation, handling, and temperature-controlled storage requirements associated with our product candidates; ● relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and ● the effectiveness of our sales and marketing efforts, which are subject to various limitations under applicable law. Our efforts to educate the medical community and third-party payors about the benefits of our product candidates may require significant resources and may never be successful. REQORSA ®, GPX- 002, and other current or future product candidates may have undesirable side effects that may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales. Undesirable side effects for REQORSA, GPX- 002, or any of our other current or future product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. A showing that REQORSA, GPX- 002, or any of our other current or future product candidates cause undesirable or unacceptable side effects could interrupt, delay or halt clinical trials and result in the failure to obtain or suspension or termination of marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities only with restrictive label warnings. If REQORSA, GPX- 002, or any of our other current or future product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products: ● regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies; ● we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product; ● we may be subject to limitations on how we may promote the product; ● sales of the product may decrease significantly; ● regulatory authorities may require us to take our approved product off the market; ● we may be subject to litigation or product liability claims; and ● our reputation may suffer. Any of these events could prevent us or our potential future collaborators from achieving or maintaining market acceptance of our products or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating revenues from the sale of our products. If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business. The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We currently carry product liability insurance relating to our clinical trials only. Such insurance coverage may not protect us against any or all of the product liability claims that may be brought against us in the future. We may not be able to acquire or maintain adequate product liability insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. In the event our product candidate is approved for sale by the FDA or other regulatory agency and commercialized, we may need to substantially increase the amount of our product liability coverage. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have an adverse effect on our business. Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer. In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, as well as personally identifiable information of clinical trial participants and employees. Similarly, our CROs, contractors and consultants possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite the implementation of security measures, our internal computer systems and those of our CROs, CMOs, and other contractors and consultants are vulnerable to damage from cyberattacks, malicious intrusion, computer viruses, unauthorized access, loss of data privacy, natural disasters, terrorism, war and telecommunication, electrical failures or other significant disruption. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs and commercialization efforts. For example, the loss of clinical study data from completed or ongoing clinical studies for any of our drug candidates 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 and the further development or commercialization of our drug candidates could be delayed. While we have not experienced any such event to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our independent drug development programs. For example, the loss of clinical trial data from ongoing or future clinical trials for any of our product candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. Our information security systems are also subject to laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, HIPAA and its implementing regulations impose, among other requirements, certain regulatory and contractual requirements regarding the privacy and security of personal health information. In addition to HIPAA, numerous other federal, state, and international laws, including, without limitation, state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure and storage of personal information. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information or personal health information, we could incur substantial liability, our reputation would be damaged, and the further development of our product candidates could be delayed. We face risks related to health epidemics

and outbreaks ~~, including COVID- 19,~~ which could significantly disrupt our preclinical studies and clinical trials. Our business has previously been adversely affected by the coronavirus pandemic which delayed our clinical trials and disrupted our supply chain. **Any** ~~A potential resurgence of COVID- 19, or any~~ future disease outbreak, epidemic or pandemic, could disrupt our clinical trials and supply chain and materially adversely affect our business and operations. Disease outbreaks, epidemics and pandemics, ~~including~~ **such as we experienced previously with** COVID- 19, in regions where we have concentrations of clinical trial sites and other business operations, could adversely affect our business, including by causing significant disruptions in our operations and / or in the operations of manufacturers and CROs upon whom we rely. Disease outbreaks, epidemics and pandemics may have negative impacts on our ability to initiate new clinical trial sites, enroll new patients and maintain existing patients who are participating in clinical trials, which may result in increased clinical trial costs, longer timelines and delays in our ability to obtain regulatory approvals of our product candidates, if at all. For example, patient enrollment and recruitment could be delayed due to local clinical trial site protocols designed to protect staff and patients from certain outbreaks, which could delay the expected timelines for data readouts of our preclinical studies and clinical trials. Additionally, general supply chain issues may be exacerbated during disease outbreaks, epidemics or pandemics and may also impact the ability of our clinical trial sites to obtain basic medical supplies used in our trials in a timely fashion, if at all. Moreover, the extent to which disease outbreaks, epidemics and pandemics may impact our business, results of operations and financial position will depend on future developments, which are highly uncertain and cannot be predicted with confidence. New health epidemics or pandemics may emerge that result in similar or more severe disruptions to our business. A future disease outbreak, epidemic or pandemic adversely affects our business, financial condition, results of operations and growth prospects. Our business operations were previously interrupted and delayed as a result of the COVID- 19 pandemic. Specifically, we experienced delays in engaging clinical sites as a result of a backlog of clinical trial protocols requiring site review created by an accumulation of protocols while clinical trials and the clinical trial review process had been widely disrupted during the pandemic. Additionally, site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring, data analysis, and laboratory research activities had been paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the COVID- 19 pandemic. During the COVID- 19 pandemic, we had also experienced disruptions in our supply chain regarding our manufacturing and testing operations. The **impacts** ~~future progression~~ of **a potential new** ~~the COVID- 19~~ epidemic ~~and its effects on our~~ **or pandemic** ~~business and operations are uncertain. The impacts of a potential resurgence of COVID- 19~~ could pose the risk that we or our employees, suppliers, customers and others may be restricted or prevented from conducting business activities for indefinite or intermittent periods of time, including as a result of employee health and safety concerns, shutdowns, shelter in place orders, travel restrictions and other actions and restrictions that may be prudent or required by governmental authorities. This could disrupt our ability to operate our business, including producing drug product and administering our preclinical and clinical studies. In addition, fluctuations in demand and other implications associated with **such** ~~the COVID- 19~~ pandemic ~~have resulted in, and~~ could ~~continue resulting~~ --- **result** in ~~,~~ certain supply chain constraints and challenges in the broader markets and economy generally, which could impact our business and supply sources, including our CDMOs. We face competition from other biotechnology and pharmaceutical companies, particularly those that are gene therapy companies, and our operating results will suffer if we fail to compete effectively. The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. This is particularly so in the fast-growing gene therapy space. We face competition from domestic and international competitors including major multinational pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and other public and private research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in- license novel compounds that could make the product candidates that we develop obsolete. As a result of these factors, our competitors may succeed in obtaining patent protection and / or FDA or other regulatory approval or in discovering, developing and commercializing drugs for the indications that we are targeting before we do or may develop drugs that are deemed to be more effective or gain greater market acceptance than ours. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. If our competitors market products that are more effective, safer or less expensive or reach the market sooner than our future products, if any, we may not achieve commercial success. In addition, because of our limited resources, it may be difficult for us to stay abreast of the rapid changes in all technologies that are or may become competitive with ours. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. Risks Related to Regulatory Approval and Marketing of Our Current and Future Product Candidates and Other Legal Compliance Matters We cannot provide assurance that REQORSA, GPX- 002, or any of our other current or future product candidates will receive regulatory approval, and without regulatory approval we will not be able to market them. Our business currently depends largely on the successful development and commercialization of REQORSA, GPX- 002, and our other current product candidates. Our ability to generate revenue related to product sales will depend on the successful development and regulatory approval of REQORSA for the treatment of cancer and / or GPX- 002 for diabetes. Even if we complete the necessary clinical studies, we cannot predict when or if we will obtain regulatory approval to commercialize a product candidate. Further, even if we obtain regulatory approval, it may only apply to a narrower indication than we expect and our products will remain subject to

regulatory scrutiny. We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the United States and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States until we receive approval of a BLA from the FDA. We have not submitted any marketing applications for any of our current and potential product candidates. BLAs must include extensive preclinical and clinical data and supporting information to establish the product candidate' s safety and effectiveness for each desired indication. BLAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of a BLA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA review processes can take years to complete, and approval is never guaranteed. If we submit a BLA to the FDA, the FDA must decide whether to file the BLA or refuse to file it. We cannot be certain that any submissions will be filed and reviewed by the FDA. In addition, regulators in other jurisdictions have their own procedures for approval of product candidates. The FDA or regulators in other jurisdictions could delay, limit or deny approval of a product candidate for many reasons, including because they: ● may not deem our product candidate to be safe and effective; ● determine that the product candidate does not have an acceptable benefit- risk profile; ● determine in the case of a BLA seeking accelerated approval that the BLA does not provide evidence that the product candidate represents a meaningful advantage over available therapies; ● determine that the results on our primary endpoints are not clinically meaningful; ● may not agree that the data collected from preclinical studies and clinical trials are acceptable or sufficient to support the approval of a BLA or other submission or to obtain regulatory approval, and may impose requirements for additional preclinical studies or clinical trials; ● may determine that adverse events experienced by participants in our clinical trials represent an unacceptable level of risk; ● may determine that population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval; ● may disagree regarding the formulation or the specifications of our product candidates; ● may not approve the manufacturing processes associated with our product candidate or may determine that a manufacturing facility does not have an acceptable compliance status; or ● may change approval policies or adopt new regulations. Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time- consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. Furthermore, regulatory approval for any of our future product candidates may be withdrawn after approval. If we are unable to obtain approval from the FDA or other regulatory agencies for REQORSA, GPX- 002, or our other current or future product candidates, or if, subsequent to approval, we are unable to successfully commercialize REQORSA, GPX- 002, or our other current or future product candidates, we will not be able to generate sufficient revenue to become profitable or to continue our operations. In addition, the clinical trial requirements of the FDA, the EMA, and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Regulatory requirements governing gene therapy products have changed frequently and may continue to change in the future. For example, in January 2017, the FDA Oncology Center of Excellence, or the Center of Excellence, was created to leverage the combined skills of regulatory scientists and reviewers with expertise in drugs, biologics, and devices (including diagnostics). While the Center of Excellence is designed to help expedite the development of oncology and malignant hematology- related medical products and support an integrated approach in the clinical evaluation of drugs, biologics and devices for the treatment of cancer, the Center of Excellence may, at times, create confusion within the FDA and especially in the Center of Biologics and Research, which is the primary review division for REQORSA. Gene therapy clinical trials conducted at institutions that receive funding for recombinant DNA research from the NIH, are also subject to review by NExTRAC. In August 2018, the NIH Director issued a statement describing a proposal intended to streamline the federal framework for oversight of gene therapy. The proposal, which the NIH developed in conjunction with the FDA, included amending the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or NIH Guidelines, to eliminate duplicative review and reporting requirements for human gene transfer protocols. The statement also described NIH' s effort to refocus the role of the RAC to be closer to its original mandate – a transparent forum for science, safety, and ethics of emerging biotechnologies. Accordingly, the NIH Guidelines have been updated to reflect these changes. Additionally, before a clinical trial can begin at an NIH- funded institution, that institution' s IRB, and its Institutional Biosafety Committee will have to review the proposed clinical trial to assess the safety of the study. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for performing studies or for obtaining approval of any of our current and potential product candidates. The regulatory changes discussed herein as well as other existing and future regulatory developments may cause unexpected delays and challenges for companies seeking approval of gene therapy products, like REQORSA, GPX- 002, and our other current or future product candidates. These regulatory review committees and advisory groups, and the new guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our current and potential product candidates or lead to significant post- approval limitations or restrictions. As we advance our current and potential product candidates, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. Any delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient revenue to maintain our business. Even if we

obtain regulatory approval for our product candidates, our products will remain subject to regulatory oversight. Our product candidates for which we obtain regulatory approval will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, record- keeping and submission of safety and other post- market information. Any regulatory approvals that we receive for our product candidates also may be subject to the specific obligations imposed as a condition for marketing authorization by equivalent authorities in a foreign jurisdiction, particularly by the European Commission, 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 quality, safety and efficacy of the product. For example, in the United States, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with the Federal Food, Drug, and Cosmetic Act (" FDCA ") and implementing regulations and are subject to FDA oversight and post- marketing reporting obligations, in addition to other potentially applicable federal and state laws. In the EU, any future advertising and promotion of our products will be subject to EU laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other legislation adopted by individual EU Member States may apply to the advertising and promotion of medicinal products. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with health care professionals. These laws require that promotional materials and advertising for medicinal products are consistent with the product' s Summary of Product Characteristics (" SmPC ") as approved by the competent authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comport with the SmPC is considered to constitute off- label promotion, which is prohibited in the EU. The applicable laws at EU level and in the individual EU Member States also prohibit the direct- to-consumer advertising of prescription- only medicinal products. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. In addition, product manufacturers and their facilities may be subject to payment of application and program fees and are subject to continual review and periodic inspections by FDA and other regulatory authorities for compliance with cGMP, requirements and adherence to commitments made in the BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or disagree with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we fail to comply with applicable regulatory requirements for any product following approval, a regulatory authority may: ● issue a warning or untitled letter asserting that we are in violation of the law; ● seek an injunction or impose administrative, civil or criminal penalties or monetary fines; ● suspend or withdraw regulatory approval; ● suspend any ongoing clinical trials; ● refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners; ● restrict the marketing or manufacturing of the product; ● seize or detain the product or otherwise demand or require the withdrawal or recall of the product from the market; ● refuse to permit the import or export of products; ● request and publicize a voluntary recall of the product; or ● refuse to allow us to enter into supply contracts, including government contracts. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and adversely affect our business, financial condition, results of operations and prospects. If the FDA does not find the manufacturing facilities of our current or future contract manufacturers acceptable for commercial production, we may not be able to commercialize REQORSA, GPX- 002, or any of our other current or future product candidates. We do not have the internal infrastructure or facilities to manufacture ourselves REQORSA, or earlier stage GPX- 002 which is in preclinical development, or any other current or future product candidate, and intend to rely on CDMOs for clinical trial needs and commercial supply. However, our strategy could change in the future and we could choose to develop such infrastructure. We do not have agreements for all of the steps relating to the ongoing supply of REQORSA or any of our other product candidates, and we may not be able to reach agreements with these or other contract manufacturers for sufficient supplies to complete clinical development and commercialize REQORSA or any of our other product candidates, if any of them are approved. The manufacture of gene therapy products is complex, and for CDMOs with whom we have agreements, there is no guarantee that they will be able to perform as required on a timely, consistent basis under the applicable governing agreement. Additionally, the facilities used by our contract manufacturers to manufacture product candidates must be the subject of a satisfactory inspection before the FDA approves the product candidate manufactured at that facility. We are completely dependent on our third- party manufacturers for compliance with the requirements of U. S. and non- U. S. regulators for the manufacture of our finished products. If our manufacturers cannot successfully manufacture materials that conform to our specifications and the FDA' s cGMP standards and other requirements of any governmental agency to whose jurisdiction, we are subject, our product candidates will not be approved or, if already approved, may be subject to recalls. Reliance on third- party manufacturers entails risks including: ● the possibility that we are unable to enter into manufacturing agreements with third parties to manufacture our product candidates on acceptable terms; ● the possibility that our contract manufacturers may breach the terms of their manufacturing agreements with us; ● the possibility that our contract manufacturers may experience failures in product production; and ● the possibility of termination or nonrenewal of any manufacturing agreement we may enter into. Any of these factors could cause the delay of approval or commercialization of our product candidates, cause us to incur higher costs or prevent us from commercializing our

product candidates successfully. Furthermore, if our product candidates are approved for commercialization and our contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis at commercially reasonable prices, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the government agencies that regulate our products. We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and other federal and state healthcare laws, and the failure to comply with such laws could result in substantial penalties. Our employees, independent contractors, consultants, principal investigators, CROs, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. State and federal regulatory and enforcement agencies continue actively to investigate violations of health care laws and regulations, and the United States Congress continues to strengthen the arsenal of enforcement tools. The Bipartisan Budget Act of 2018 increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti- Kickback Statute. Enforcement agencies also continue to pursue novel theories of liability under these laws. Government agencies have increased regulatory scrutiny and enforcement activity with respect to programs supported or sponsored by pharmaceutical companies, including reimbursement and co- pay support, funding of independent charitable foundations and other programs that offer benefits for patients. Several investigations into these types of programs have resulted in significant civil and criminal settlements. We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, principal investigators, CROs, commercial partners 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 similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and similar foreign regulatory bodies; comply with manufacturing standards we have established; comply with federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations 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 for any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws would increase significantly, and our costs associated with compliance with such laws would likely 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 and interactions with physicians and other health care providers. In particular, 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 and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, including off- label uses of our products, structuring and commission (s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of patient recruitment for clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 fines or other sanctions. The laws that may affect our ability to operate include, but are not limited to: ● the Federal Anti- Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; ● federal civil and criminal false claims laws and civil monetary penalty laws, including the civil False Claims Act, which impose criminal and civil penalties, through government, civil whistleblower or qui tam actions, on individuals and entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third- party payors that are false, fictitious or fraudulent, or knowingly making, using or causing to be made or used, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act; ● HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; ● HIPAA, as amended by HITECH and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization; ● the federal physician payment transparency requirements, sometimes referred to as the " Physician Payments Sunshine Act, " created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (the Affordable Care Act) and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies for which

payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; ● the U. S. FDCA, which prohibits, among other things, the adulteration or misbranding of drugs; ● the Foreign Corrupt Practices Act and similar worldwide anti- bribery laws, which generally prohibit companies and their intermediaries from making improper payments to non- U. S. officials for the purpose of obtaining or retaining business; ● federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and ● state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws and regulations will involve substantial costs. 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 civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our current and potential product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. Coverage and reimbursement may be limited or unavailable in certain market segments for REQORSA, GPX- 002, and our other current or future product candidates, if approved, which could make it difficult for us to sell REQORSA, GPX- 002, and our other current or future product candidates profitably. The commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, insurance companies and other third- party payors, and others in the medical community. Even if we obtain approval to commercialize our current and potential product candidates outside of the United States, a variety of risks associated with international operations could materially affect our business. Due to the novel nature of our technology, we face uncertainty related to pricing and reimbursement for our current and potential product candidates. The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue. If market opportunities for our current and potential product candidates are smaller than we believe they are, our revenues may be adversely affected and our business may suffer. Successful sales of our products, if our current and potential product candidates are approved, depend on the availability of coverage and adequate reimbursement from third- party payors. In addition, because our current and potential product candidates represent new approaches to the treatment of cancer and diabetes, we cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our current and potential product candidates. 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 are critical to new product acceptance. Government authorities and other third- party payors, such as private health insurers and health maintenance organizations, 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, but not limited to, 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. In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors, and coverage and reimbursement for 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 and to justify the level of coverage and reimbursement relative to other therapies, with no assurance that coverage and adequate reimbursement will be obtained. Third party payors may also have difficulty in determining the appropriate coverage of REQORSA and our other current and future product candidates that are combination products, if approved, due to the fact that they are combination products that include another drug. To the extent there are any delays in determining such coverage or inadequate coverage and reimbursement for all aspects of our combination therapies, it would adversely affect the market acceptance, demand and use of our current and potential product candidates. Any denial in coverage or reduction in reimbursement from Medicare or other government programs may result in a similar denial or reduction in payments from private payors, which may adversely affect our future profitability. 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 European Union, the pricing of biologics is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our current and potential product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our current and potential product candidates will depend significantly on the availability of coverage and adequate reimbursement from third- party

payors for our current and potential product candidates and may be affected by existing and future health care reform measures. Concerns about gene therapy, genetic testing, and genetic research could result in new and / or additional government regulations and requirements that restrict or prohibit the processes we use or delay or prevent the regulatory approval of our current and potential product candidates. Ethical, social, and legal concerns about gene therapy, genetic testing, and genetic research could result in additional regulations restricting or prohibiting the processes we may use. Federal and state agencies, congressional committees and foreign governments have expressed interest in further regulating biotechnology. More restrictive regulations or claims that our products are unsafe or pose a hazard could prevent us from commercializing any products. New government requirements may be established that could delay or prevent regulatory approval of our current and potential product candidates. It is impossible to predict whether legislative changes will be enacted, regulations, policies, or guidance changed, or interpretations by agencies or courts changed, or what the impact of such changes, if any, may be. Healthcare legislative reform measures may have a material adverse effect on our business and results of operations. Third- party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could affect our ability to sell our products profitably. In particular the Affordable Care Act and its implementing regulations, among other things, subjected biological products to potential competition by lower- cost biosimilars, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs and certain biologics, including our current and potential product candidates, under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government' s comparative effectiveness research. More recently, other legislative changes that affect the pharmaceutical industry have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, the Inflation Reduction Act of 2022 included, among other things, a provision that authorizes CMS to negotiate a " maximum fair price " for a limited number of high- cost, single- source drugs every year, and another provision that requires drug companies to pay rebates to Medicare if prices rise faster than inflation. In addition, various states have adopted or are considering adopting laws that require pharmaceutical companies to provide notice prior to raising prices and to justify price increases. We expect that additional healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and / or impose price controls may adversely affect: ● the demand for our current and potential product candidates, if we obtain regulatory approval; ● our ability to set a price that we believe is fair for our products; ● our ability to generate revenue and achieve or maintain profitability; ● the level of taxes that we are required to pay; and ● the availability of capital. We are subject to a variety of risks associated with international operations which could materially adversely affect our business. We anticipate that we will be subject to additional risks in commercializing our product candidates outside the United States, including the following, any one or combination of which could have a material adverse effect on our business: ● different regulatory requirements for approval of product candidates in foreign countries; ● reduced protection for intellectual property rights; ● unexpected changes in tariffs, trade barriers and regulatory requirements; ● economic weakness, including inflation, or political instability in particular foreign economies and markets ; ● ● compliance with tax, employment, immigration and labor laws for employees living or traveling abroad ; compliance with international data privacy laws, including GDPR; ● foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country ; ● workforce uncertainty in countries where labor unrest is more common than in the United States ; ● production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad ; and ● business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods, fires and medical epidemics. 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 may become subject to federal, state, local, and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and certain waste products, including numerous environmental, health and safety laws and regulations, such as those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may in the future involve the use of hazardous materials, including chemicals and biological materials. Our operations may also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. 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 may also result in substantial fines, penalties or other sanctions. Risks Related to Our Dependence on Third Parties We may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect our ability to develop our current and future product candidates and our financial condition and operating results could be adversely affected.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we have and may continue to enter into collaborations with companies that have the required expertise. Additionally, if any of our product candidates receive marketing approval, we may enter into sales and marketing arrangements with third parties. If we are unable to enter into arrangements on acceptable terms, or at all, we may be unable to effectively market and sell our products in our target markets. We expect to face competition in engaging collaborators. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements for the development of our current and potential product candidates. When we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the timing and future success of that product candidate to such third party. One or more of our collaboration partners may not devote sufficient resources to the development and commercialization of our product candidates or may otherwise fail in these efforts. The terms of any collaboration or other arrangement that we establish may contain provisions that are not favorable to us. In addition, any collaboration that we enter into may not be successful in the development and commercialization of our product candidates. In some cases, we may be responsible for continuing preclinical and initial clinical development of a product candidate or research program under a collaboration arrangement, and the payment we receive from our collaboration partner may be insufficient to cover the cost of such development. If we are unable to reach agreements with suitable collaborators for our product candidates, we may face increased costs, we may be forced to limit the number of our product candidates we can commercially develop or the territories in which we commercialize them. As a result, we may be unable to commercialize products or programs if we are unable to engage a suitable collaborator, which may have a material adverse effect on our operating results and financial condition. We rely, in part, and expect to continue to rely, in part, on third parties to conduct, supervise and monitor our clinical trials, and if these third parties perform in an unsatisfactory manner, it may harm our business. We rely in part on CROs and clinical trial sites to ensure our clinical trials are conducted properly and on time. While we have or will have agreements governing their activities, we may have limited influence over their actual performance because we control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. We and our CROs are required to comply with good clinical practices (" GCPs ") for conducting, recording and reporting the results of clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces these GCPs through periodic inspections of study sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving any marketing applications. In addition, our ongoing and future clinical trials will require a sufficient number of test subjects to evaluate the safety and effectiveness of our current and potential product candidates. Accordingly, if our CROs fail to comply with applicable regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would delay the regulatory approval process. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects may be harmed, our costs could increase and our ability to generate revenues could be limited or delayed. **Changes in the U. S. political and regulatory environment could affect availability of government funding that we or our third party collaborators may rely on, which could negatively impact the development of our product candidates. We and our current and future third party collaborators may rely on government programs or agencies, such as the NIH, as a source of grant funding for scientific research relevant to our product candidates. Funding from government agencies such as the NIH can fluctuate and is subject to the political process, which is often unpredictable. For example, on February 7, 2025, the NIH issued Notice Number NOT- OD- 25- 068, a guidance document pronouncing that funding in NIH grants to cover certain indirect costs would be capped at 15 % for existing and future grant recipients, a rate that is substantially lower than the existing rates. Reductions in NIH grants to us and our third party collaborators may adversely impact our ability to develop our existing product candidates and our ability to identify new product candidates.** We rely, and expect to continue to rely, on third parties to distribute, manufacture and perform release testing for our current and future product candidates and other key materials and if such third parties do not carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approvals for our product candidates. We rely, and expect to continue to rely on third- party CDMOs to produce REQORSA and expect to do so with GPX- 002 and other current and future product candidates and other key materials and on third- party contract testing organizations, or CTOs, for the establishment and performance of validated product release assays. Additionally, any CDMO may not have specific experience producing our product candidates at commercial levels and may not achieve the necessary regulatory approvals or produce our products at the quality, quantities, locations and timing needed to support commercialization. We do not have full control of these CDMOs, and they may prioritize other customers or be unable to provide us with enough manufacturing capacity to meet our objectives. We may change our manufacturing process, and there can be no guarantee that the regulatory authorities will approve any new process in a timely manner, or ever. Also, as a consequence of the manufacturing change, there may be a requirement to conduct additional preclinical safety or efficacy studies, develop new manufacturing and release assays and / or repeat all or part of the ascending dose safety study in animals or humans. Regulatory requirements ultimately imposed could adversely affect our ability to test, manufacture or market products. Historically, part of our manufacturing process was

conducted in manufacturing facilities at MD Anderson. We have completed the technology transfer from MD Anderson to experienced commercial contract development and manufacturing organizations and have scaled- up clinical production of REQORSA appropriate for our Acclaim- 1 ~~, Acclaim- 2~~ and Acclaim- 3 clinical trials. With the advancement of the development of GPX- 002, we also are working to optimize the manufacture of this product candidate and to source high quality and integrated vendors capable of producing it in accordance with GMP. No assurance can be given that such contract manufacturers will be able to, and will receive all approvals to, produce product sufficient for all of our clinical trial needs moving forward or for commercialization. **Additionally, our contract manufacturers may get acquired or change ownership structure, enter into new lines of business or depart existing lines of business, or go out of business altogether; all of which could require us to find new contract manufacturers and adversely affect our business.** In accordance with cGMPs, changing manufacturers may require the re- validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing our contract manufacturers may be difficult and could be costly if we do make such a change, which could result in our inability to manufacture our product candidates and a delay in the development of our product candidates and their commercial sale, should they be approved. Further, in order to maintain our development timelines in the event of a change in a third- party contract manufacturer, we may incur higher costs to manufacture our product candidates. There can be no guarantee that the regulatory authorities will approve any new process in a timely manner or ever. Regulatory requirements ultimately imposed could adversely affect our ability to test, manufacture or market products. In connection with our manufacturing activities, we may encounter technical or scientific issues related to manufacturing or development that we may be unable to resolve in a timely manner or with available funds. Further, we have not fully completed the characterization and validation activities necessary for commercial and regulatory approvals. If our manufacturing and testing partners do not enable such regulatory approvals, our commercialization efforts may be harmed. If such third- party manufacturers are unable to produce REQORSA, GPX- 002, or other product candidates in the necessary quantities, or in compliance with cGMP or in compliance with pertinent regulatory requirements, and within our planned time frame and cost parameters, the development and sales of our products, if approved, would be materially harmed. The manufacturing processes used by our contract manufacturers to manufacture product candidates must be approved by the FDA as part of our BLA package and the facilities used by our contract manufacturers must maintain a compliance status acceptable to the FDA pursuant to inspections that will be conducted after we submit our BLA to the FDA. Although we provide specifications, we do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs for the manufacture of our product candidates. If our CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory agencies, we will not be able to secure and / or maintain regulatory approval covering their manufacturing facilities. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly affect our ability to develop, obtain regulatory approval for or market our future product candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our current and future product candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation. In addition, any significant disruption in our supplier relationships could harm our business. We source key materials, devices and equipment from third parties, either directly through agreements with suppliers or indirectly through our manufacturers who have agreements with suppliers. There is a small number of suppliers for certain key materials and components that are used to manufacture our current and future product candidates. Such suppliers may not sell these key materials to our manufacturers at the times or quantities we need them or on commercially reasonable terms. We may not have any control over the process or timing of the acquisition of these key materials by our manufacturers. We also expect to rely on other third parties to store and distribute our products for our clinical trials. Any performance failure on the part of these third parties could delay clinical development or marketing approval of our current and future product candidates or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue. We have completed and may in the future complete related party transactions that were not and may not be conducted on an arm' s length basis. If we are successful in commercializing REQORSA, our lead drug candidate, we will owe IRI a 1 % royalty of our product sales. REQORSA is based upon patents and related technology covered by the 1994 MD Anderson License Agreement, under which we have rights to patents covering use of various genes, including the TUSC2 gene, for treatment of cancer, as well as know- how and related intellectual property. In 2007, the 1994 MD Anderson License Agreement was sublicensed by Introgen to IRI and in 2009 this sublicense was assigned by IRI to us, and we granted back to IRI a nonexclusive, royalty- free license to use and practice the licensed technology for non- commercial research purposes. As consideration for this assignment, we agreed to assume all of IRI' s obligations to MD Anderson under the 1994 MD Anderson License Agreement, including ongoing patent related expenses and royalty obligations. IRI also agreed in 2011, pursuant to the 2011 IRI Collaboration Agreement, to provide additional technology licensing opportunities and services to us in return for monthly payments and our obligation to pay to IRI a royalty of 1 % on sales of products licensed to us under the 1994 MD Anderson License Agreement. We also granted a non- exclusive, royalty- free sublicense to IRI in 2011 for non- commercial research purposes. IRI' s obligations to provide additional technology licensing opportunities and services to us, and our obligation to make monthly payments to IRI, were terminated in 2012; however, our obligation to pay the 1 % royalty to IRI upon sales of products licensed to us under the 1994 MD Anderson License Agreement is ongoing. This royalty obligation continues for 21 years after the later of the termination of the 1994 MD Anderson License Agreement and the termination of the sublicense assigned by IRI to us. IRI ~~is~~ **was** controlled by Rodney Varner and IRI is **currently** owned by trusts for the benefit of

Mr. Varner' s descendants. Mr. Varner **, who prior to** ~~is~~ **his passing in May** ~~currently Chairman of our board of directors, having joined our board of directors on August 15, 2012~~ - **2024** , **was** ~~and has been~~ our **President,** Chief Executive Officer ~~since August 29, 2012~~ and ~~President since August 10, 2020~~ **Chairman of our board of directors** ; ~~accordingly~~ **however** , in 2009 and 2011, when the above referenced agreements between IRI and Genprex were entered into, Mr. Varner was neither a member of our board of directors nor an executive officer of Genprex. When the 2011 IRI Collaboration Agreement was entered into, Mr. Varner was deemed to be an " affiliate " of the Company due to his beneficial ownership of approximately 39 % of our issued and outstanding shares at that time. Although we believe that these transactions were conducted on an arm' s length basis, it is possible that the terms were less favorable to us than they might have been in a transaction with an unrelated party. Disruptions in the global economy and supply chains may have a material adverse effect on our business, financial condition and results of operations. ~~The disruptions~~ **Disruptions** to the global economy since the COVID- 19 global pandemic commenced in 2020 ~~has~~ **have** impeded global supply chains, resulting in longer lead times and also increased critical component costs and freight expenses. We have experienced this impact most notably in **the past in** our manufacturing operations due to the delay in our ability to acquire raw materials for our drug product. This delay **, and / or future delays,** has the potential to impact the timing of the conduct of our clinical trials. We have taken steps to minimize the impact of these increased costs by working closely with our suppliers and locating redundant or comparable sources. Despite the actions we have undertaken to minimize the impacts from disruptions to the global economy, there can be no assurances that unforeseen future events in the global supply chain, **including the threat and risk of potential cross- border tariffs, the potential adoption and expansion of trade restrictions or the occurrence of trade wars** and inflationary pressures, will not have a material adverse effect on our business, financial condition and results of operations. Risks Related to Our Intellectual Property If we fail to comply with obligations pursuant to our license agreements, we could lose intellectual property and other rights that are important to our business; if we fail to obtain licenses to advance our research and development that may be required we may be unable to develop the affected product exclusively, on acceptable terms or at all. Pursuant to the 1994 MD Anderson License Agreement and subsequent Amendments thereto, as well as the 2020 MD Anderson License Agreement **and subsequent Amendments thereto** , we hold worldwide, exclusive license rights to certain inventions covering the therapeutic use of TUSC2 and other genes and polypeptides that have been shown to have cancer fighting properties, as well as a number of related technologies. In addition, pursuant to the **New** UP License ~~Agreements~~ - **Agreement** , UP granted us a worldwide, exclusive license to certain licensed technology, and a worldwide, non- exclusive license to use certain related know- how, all related to diabetes gene therapy. In addition, we expect to enter into additional license agreements in the future. Our existing and future license agreements may impose various payment and other obligations on us. If we fail to comply with our obligations under these agreements, our licensors may have the right to terminate our licenses, in which event we would not be able to market products covered by such licenses. Moreover, in the event we need to obtain licenses from third parties to advance our research and development or allow commercialization of our product candidates, including additional technology that may be required or advisable to advance REQORSA or GPX- 002, we may fail to obtain any of such licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to develop or license replacement technology, we may be unable to develop or commercialize the affected product candidates, which could harm our business significantly. We cannot provide any assurances that third- party patents do not exist which might be enforced against our current product candidates or future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties or that we may be estopped from acquiring such rights due to prior art. Specifically, mice and NHP studies for which we have disclosed data relating to our diabetes program includes a technology to which we do not have exclusive rights, though we expect, but are not guaranteed, that we will have exclusive rights to the final product (s) developed under this program. In certain cases, patent prosecution of our licensed technology may be controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including, but not limited to: ● the scope of rights granted under the license agreement and other interpretation- related issues; ● the extent to which our technology and processes infringe 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 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. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. The intellectual property rights we have licensed from MD Anderson and the ~~UP~~ **University of Pittsburgh** are subject to the rights of the U. S. government. The rights we have obtained pursuant to our license agreements with MD Anderson and ~~the~~ UP are made subject to the rights of the U. S. government to the extent that the technology covered by the licensed intellectual property was developed under a funding agreement between such institution and the U. S. government. Additionally, to the extent there is any conflict between our license agreement and applicable laws or regulations, applicable laws and regulations will prevail. Similarly, to the extent there is any conflict between our license agreement with one of these institutions and the institution' s funding agreement with the US government, the terms of the funding agreement will prevail. Some, and possibly all, of our licensed intellectual property rights have been developed in the course of research funded by the U. S. government. As a result, the U. S. government may have certain rights to intellectual property embodied in our

current or future products pursuant to the Bayh- Dole Act of 1980. Government rights in certain inventions developed under a government- funded program include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government has the right to require us, or an assignee or sublicensee to such inventions, to grant licenses to any of these inventions to a third party if the U. S. government determines that adequate steps have not been taken to commercialize the invention, that government action is necessary to meet public health or safety needs, that government action is necessary to meet requirements for public use under federal regulations, or the right to use or sell such inventions is exclusively licensed to an entity within the U. S. and substantially manufactured outside the U. S. without the U. S. government' s prior approval. Additionally, we may be restricted from granting exclusive licenses for the right to use or sell our inventions created pursuant to such agreements unless the licensee agrees to additional restrictions (e. g., manufacturing substantially all of the invention in the U. S.). The U. S. government also has the right to take title to these inventions if our licensors failed to disclose the invention to the government in a timely manner and / or failed to file an application to register the intellectual property within specified time limits. In addition, the U. S. government may acquire title in any country in which a patent application is not filed within specified time limits. Furthermore, certain inventions are subject to transfer restrictions during the term of these agreements and for a period thereafter, including sales of products or components, transfers to foreign subsidiaries for the purpose of the relevant agreements, and transfers to certain foreign third parties. If any of our intellectual property becomes subject to any of the rights or remedies available to the U. S. government or third parties pursuant to the Bayh- Dole Act of 1980, this could impair the value of our intellectual property and could adversely affect our business. If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology and product candidates, our competitive position could be harmed. Our commercial success will depend in part on our ability and the ability of our licensors to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our novel technologies and products that are important to our business. The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain. The steps we or our licensors have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside of the United States. Further, the examination process may require us or our licensors to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights already granted under any of our currently issued patents or those licensed to us and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we or our licensors are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected. It is also possible that we or our licensors will fail to identify patentable aspects of inventions made in the course of our development and commercialization. It is also possible that as research and development progresses, the direction of our intellectual property strategy and patent portfolio will change, resulting in strategic business decisions to allow certain patents or patent applications to be abandoned or lapse. With respect to patent rights, we do not know whether any of the pending patent applications relating to any of our current and future product candidates will result in the issuance of patents that effectively protect our technology or products, or if any of our licensors' issued patents will effectively prevent others from commercializing competitive technologies and products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our or our licensor' s patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third- party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. Third- party claims of intellectual property infringement may prevent or delay our development and commercialization efforts. Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and other post grant proceedings before the US Patent and Trademark Office (" USPTO ") and corresponding foreign patent offices. Numerous US and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk

increases that our current and future product candidates may be subject to claims of infringement of the patent rights of third parties. Third parties may in the future assert that we are employing their proprietary technology without authorization. There may be third- party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates 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 patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, or any final product itself, the holders of any such patents may be able to block our ability to develop and commercialize such product candidate until such patents expire unless we obtained a license under the applicable patents, which license may not be available on acceptable terms, if at all. Parties making claims against us may obtain injunctive or other equitable relief, which may hinder our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, may involve substantial litigation expense and diversion of our management' s attention. 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, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which licenses may not be on acceptable terms or require substantial time and monetary expenditure. We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in- licenses. Presently we believe that we have the necessary rights to the intellectual property, through licenses or other rights from third parties to develop our product candidates. 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. In addition, our product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in- license any compositions, methods of use, processes or other third- party intellectual property rights from third parties on reasonable terms, if at all. The licensing and acquisition of third- party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third- party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. If we are unable to successfully obtain rights to required third- party intellectual property, our business, financial condition and prospects for growth could suffer. Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property. We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time- consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. Our reliance on third parties may require us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. Because we rely on and intend to continue to rely on third parties to manufacture our current and future product candidates, and because we collaborate with various organizations and academic institutions on the advancement of our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our manufacturers, collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions of such agreements, the need to share trade secrets and other confidential information increases the risk that such trade secrets may become known by our competitors, may be inadvertently incorporated into the technology of others, may be used inappropriately to create new inventions or may be disclosed or used in violation of such agreements. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of research and development partnerships or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure may impair our competitive position and have a material adverse effect on our business. We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time- consuming and unsuccessful. Competitors may infringe our patents or the patents of our 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 a patent is not valid, is unenforceable and / or is not infringed, 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. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. Interference

proceedings provoked by third parties or brought by us 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 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. Our defense of litigation or interference proceedings may fail and, even if 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 intellectual property rights, 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. There could also 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 material 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 patents and / or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and / or applications. We employ an outside firm and rely on our outside counsel to pay these fees due to non- US patent agencies. The USPTO and various non- US governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Although an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market which would have a material adverse effect on our business. Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court. If we or one of our licensing partners, including MD Anderson or UP, 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 is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, 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 current and potential 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 and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our current and potential product candidates. Such a loss of patent protection would have a material adverse impact on our business. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. We currently and in the future may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors. Although we try to ensure that our employees, consultants and independent contractors 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 any of our employee' s 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, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and result in a diversion of management' s attention. We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may have potential ownership disputes arising, for example, from conflicting obligations of consultants, collaborators or others who are involved in developing our current and potential product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products. The United States has enacted and is currently implementing wide- ranging patent reform legislation. 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the

future. We have in the past and may again in the future have trademark applications in the United States and / or certain other countries, and failure to secure these registrations could adversely affect our business; additionally, we may need to enforce our trademark rights against third parties and expend significant resources to enforce such rights against infringement. We have obtained trademark registrations in the United States for GENPREX, ONCOPREX and REQORSA **, we have a pending application in the United States for the trademark CONVERGEN,** and we may in the future have pending trademark applications in the United States and / or certain other countries. During trademark registration proceedings, our application may be rejected. Although we would be given an opportunity to respond to the rejection of a trademark application, we may be unable to overcome such rejection. In addition, with respect to the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademark, and our trademark may not survive such proceedings. Additionally, we may need to enforce our trademark rights against third parties and expend significant additional resources to enforce such rights against infringement. Moreover, any name we propose to use with our current and potential product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents with respect to product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. 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. Risks Related to Employee Matters and Managing Growth We have no sales, marketing or distribution experience and we will have to invest significant resources to develop those capabilities or enter into acceptable third- party sales and marketing arrangements. We have no sales, marketing or distribution experience. To develop sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will need to be committed prior to any confirmation that our product candidates will be approved by the FDA. For product candidates for which we decide to perform sales, marketing and distribution functions ourselves or through third parties, we could face a number of additional risks, including that we or our third- party sales collaborators may not be able to build and maintain an effective marketing or sales force, and we may experience difficulty in managing the growth of our organization. If we use third parties to market and sell our products, we may have limited or no control over their sales, marketing and distribution activities on which our future revenues may depend. We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants. As of March 15, ~~2024~~ **2025** , we had ~~26~~ **15** total employees, all of which were full- time. As we advance our product candidates through preclinical studies and clinical trials, we will need to increase our clinical trial management, product development, manufacturing, regulatory, and administrative headcount to manage these programs. In addition, to meet our obligations as a public company, we may need to increase our general and administrative capabilities. We may not be able to attract or retain qualified personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy. We are highly dependent on the development, manufacturing, regulatory, commercialization and business development expertise of our management team, key employees and consultants. Any of our executive officers or key employees or consultants may terminate their employment or engagement with us at any time. If we lose one or more of our executive officers or key employees or consultants, our ability to implement our business strategy successfully could be seriously harmed. Replacing executive officers, key employees and consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel and consultants. Our failure to retain key personnel or consultants could materially harm our business.

As previously reported ~~in 2022~~ , our **prior** Chairman, President and Chief Executive Officer, Rodney Varner, ~~had been~~ **passed away unexpectedly in May 2024 due to complications following his** ~~diagnosed~~ **diagnosis** ~~with~~ **of** a cutaneous lymphoma ~~and~~ **in 2022. Mr. Confer** has been **serving** ~~undergoing chemotherapy and other treatments since then. Mr. Varner has~~ **as President** ~~been continuing in his roles at the Company during this period and expects to continue to do so~~ , **Chief Executive Officer** ~~although he has limited some business activities~~ and ~~travel. Our board of directors had taken steps in 2022 to ensure smooth continuity of business priorities and operations during periods when Mr. Varner was receiving treatments or otherwise unavailable due to his condition. For business continuity, our board of directors has determined that Ryan Confer, our~~ Chief Financial Officer **since May 8** , ~~can~~ **2024** and ~~shall act in covering when Mr. Varner is unavailable~~ **will continue to serve as Chief Financial Officer until a successor has been identified for that role** . In addition to our management team and key employees, we have scientific and clinical advisors and consultants who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us and typically they will not enter into non- compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success. Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on research and development programs for product candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement. If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks. We may evaluate and enter into various acquisitions and strategic partnerships, including licensing or acquiring additional products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including: ● increased operating expenses and cash requirements; ● the assumption of additional indebtedness or contingent liabilities; ● the issuance of our equity securities; ● assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel; ● difficulties in achieving anticipated cost savings, synergies, business opportunities, and growth prospects from any business combination; ● the diversion of our management' s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition; ● retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships; ● risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and ● our inability to generate revenue from acquired technology and / or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs. Moreover, we may not be able to locate suitable acquisition opportunities and such inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Risks Related to our Securities The market price of our common stock may be highly volatile, and you may lose all or part of your investment. The market price of our common stock has been volatile in the past and is likely to be volatile in the future. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following: ● inability to obtain additional funding; ● adverse results or delays in preclinical or clinical trials; ● ● reports of adverse events in other gene therapy products or clinical trials of such products; manufacturing and supply issues related to our existing or future products; ● any delay in filing an IND or BLA for our product candidates and any adverse development or perceived adverse development with respect to the FDA' s review of that IND or BLA; ● failure to develop successfully and commercialize our product candidates; ● failure to maintain our existing strategic collaborations or enter into new collaborations; ● failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights; ● changes in laws or regulations applicable to our products and product candidates; ● inability to obtain adequate product supply for our product candidates or inability to do so at acceptable prices; ● adverse regulatory decisions; ● introduction of new products, services or technologies by our competitors; ● failure to meet or exceed financial projections we may provide to the public; ● failure to meet or exceed the financial projections of the investment community; ● the perception of the pharmaceutical and biotechnology industries by the public, legislatures, regulators and the investment community; ● announcements of significant acquisitions, strategic partnerships, joint ventures, capital commitments or other material corporate transactions or events by us, our strategic collaboration partners or our competitors; ● disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; ● additions or departures of key scientific or management personnel; ● significant lawsuits, including patent or stockholder litigation; ● changes in the market valuations of similar companies; ● sales of our common stock by us or our stockholders; ● trading volume of our common stock; ● material announcements or changes impacting our common stock or our capitalization, or the perception that such changes could occur; and ● General economic conditions in the United States and abroad; and other events or factors, many of which may be out of our control, including, but not limited to, pandemics, war, or other acts of God. In addition, companies trading in the stock market in general, and The Nasdaq Capital Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market

and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. An active, liquid and orderly market for our common stock may not be sustained, and you may not be able to sell your common stock. Our common stock trades on the Nasdaq Capital Market. We cannot assure you that an active trading market for our common stock will be sustained. The lack of an active market may impair your ability to sell the common stock at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling common stock and may impair our ability to acquire other businesses, applications or technologies using our common shares as consideration, which, in turn, could materially adversely affect our business. We are currently listed on The Nasdaq Capital Market. If we **fail** ~~are unable~~ to ~~maintain~~ **regain compliance with the continued** listing **requirements** of ~~our securities on~~ Nasdaq **,** ~~or~~ **our** ~~any~~ **common** stock ~~exchange,~~ **may be delisted and the price of** our **common** stock ~~price~~ **and our ability to access the capital markets** could be **negatively** ~~adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired~~ **impacted** ~~and it may be more difficult for our stockholders to sell their securities~~. **Our** ~~Although our~~ common stock is currently listed **for trading** on ~~The~~ Nasdaq **. On November 19, 2024, we received a notice from Nasdaq stating that we no longer comply with the minimum stockholders' equity requirement under Nasdaq Listing Rule 5550 (b) (1) for continued listing. We submitted a plan of compliance to Nasdaq on December 30, 2024. On February 11, 2025, Nasdaq notified us that that it granted an extension until March 31, 2025 to regain compliance with the minimum stockholders' equity requirement, conditioned upon achievement of certain milestones included in the plan of compliance previously submitted to Nasdaq, including a plan to raise additional** ~~Capital~~ **capital** ~~Market,~~ **. If** we **fail to evidence compliance upon filing our periodic report for the quarterly period ending March 31, 2025 by May 15, 2025, we** may **be subject to delisting. If Nasdaq determines to delist our securities, we will have the right to appeal to a Nasdaq hearings panel. There can be** ~~not~~ **no assurance that we will** be able to ~~continue to meet~~ **regain compliance with** the **applicable Nasdaq** ~~exchange' s minimum~~ listing requirements **. In addition** , ~~including~~ **on February 7, 2025, we received notice from Nasdaq indicating that we are not in compliance with** the **requirement to maintain a** minimum bid price **of $ 1. 00 per share** ~~requirement and other applicable corporate governance requirements, or~~ **for continued** ~~those of any other national exchange. If we are unable to maintain~~ listing on Nasdaq **. We were provided a compliance period of 180 calendar days from the date of the notice** , **or until August 6, 2025, to regain compliance with the minimum closing bid requirement, pursuant to Nasdaq Listing Rule 5810 (c) (3) (A). We may be eligible for an additional 180 calendar day compliance period. There can be no assurance that we will regain compliance with the minimum closing bid price requirement during the 180- day compliance period, secure a second period of 180 days to regain compliance or maintain compliance with the other Nasdaq listing requirements. We will continue to monitor the closing bid price of** our common stock ~~may~~ **and assess potential actions to** ~~remain~~ **regain compliance** ~~thinly traded. The Listing Rules of Nasdaq require listing issuers to comply~~ with ~~certain standards~~ **the minimum closing bid price requirement and may, if appropriate, consider and effectuate available options, including implementation of a reverse stock split of our common stock. If we implement a reverse stock split** in order to remain listed on **Nasdaq** ~~its exchange. If~~ , **the announcement** ~~for~~ **or** ~~any reason, we should fail to maintain compliance with~~ **implementation of such a reverse stock split could negatively affect** ~~these~~ **the price of our common stock. We must satisfy Nasdaq' s continued** listing ~~standards~~ **requirements, including, among other things, a minimum stockholders' equity of $ 2. 5 million** and ~~Nasdaq should delist~~ **a minimum closing bid price of $ 1. 00 per share** ~~our~~ **or risk** ~~securities from trading on its exchange and we are unable to obtain listing~~ **delisting** ~~on another national securities exchange~~ , ~~a reduction in some or all of the following may occur, each of~~ which could have a material adverse effect on our **business. If** ~~stockholders: ● the liquidity of~~ our common stock ~~; ●~~ **is delisted from Nasdaq, it could materially reduce** the **liquidity** ~~market price~~ of our common stock **and result** ~~; ● our ability to obtain financing for the continuation of our operations; ● the number of investors that will consider investing~~ in **a corresponding material reduction in the price of** our common stock ~~; ●~~ **as a result of** the ~~number~~ **loss** of market ~~makers~~ **efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result** in **the potential loss of confidence by investors, suppliers, contractual counterparties, and employees and fewer business development opportunities. If** our common stock **were delisted, it could be more difficult to buy or sell** ~~; ● the availability of information concerning the trading prices and volume of~~ our common stock **or** ~~; and ● the number of broker- dealers willing~~ to ~~execute trades in shares~~ **obtain accurate quotations, and the price** of our common stock ~~;~~ **could suffer a material decline. Delisting could also impair our ability to raise capital on acceptable terms, if at all.** Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. Global credit and financial markets have experienced volatility and disruptions in past years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, concerns about medical epidemics, and uncertainty about economic stability. We cannot assure you that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. Failure to maintain effective internal control over our financial reporting in accordance with Section 404 of the Sarbanes- Oxley Act of 2002, as amended (" Sarbanes- Oxley Act ") could cause our financial reports to be inaccurate. We are required pursuant to Section 404 of the Sarbanes- Oxley Act, or Section 404, to maintain internal control over financial reporting

and to assess and report on the effectiveness of those controls. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Although we prepare our financial statements in accordance with accounting principles generally accepted in the United States, our internal accounting controls may not meet all standards applicable to companies with publicly traded securities. If we fail to implement any required improvements to our disclosure controls and procedures, we may be obligated to report control deficiencies, in which case we could become subject to regulatory sanction or investigation. Further, such an outcome could damage investor confidence in the accuracy and reliability of our financial statements. 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 or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. We have designed, implemented and tested the internal control over financial reporting required to comply with this obligation, which was and is time consuming, costly, and complicated. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system' s objectives will be met. Our management has concluded that our internal controls over financial reporting were, and continue to be, ineffective, and as of the year ended December 31, ~~2023~~ **2024** as a result of material weaknesses in our internal controls due to the lack of segregation of duties between accounting and other functions and the absence of sufficient depth of in- house accounting personnel with the ability to properly account for complex transactions. While management is working to remediate these material weaknesses, there is no assurance that such changes, when economically feasible and sustainable, will remediate the identified material weaknesses or that the controls will prevent or detect future material weaknesses. If we are not able to remediate the material weaknesses or maintain effective internal control over financial reporting, this could result in a material misstatement in our consolidated financial statements and a failure to meet our reporting and financial obligations, which could have a material adverse effect on our business. We have no intention of declaring dividends in the foreseeable future. We have never declared or paid cash dividends on our capital stock, and we do not currently anticipate declaring any dividends in the foreseeable future. We anticipate that we will retain all future earnings for the development, operation, and expansion of our business. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, contractual restrictions, general business conditions and other factors that our board of directors may deem relevant. Investors in our common stock should not expect to receive dividend income on their investment, and investors will be dependent on the appreciation of our common stock, if any, to earn a return on their investment. We will likely **continue to** incur increased costs and devote additional management time to public company reporting and compliance obligations as a result of exiting " emerging growth company " status. We no longer qualify as an emerging growth company under the JOBS Act (our eligibility to qualify as an emerging growth company ended on December 31, 2023, the last day of our fiscal year following the fifth anniversary of our initial public offering). While we were an emerging growth company, we were able to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including reduced disclosure obligations regarding executive compensation in 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. **Having** ~~Now that we have~~ exited emerging growth company status and ~~we are no~~ **not able** ~~longer eligible~~ to take advantage of the corresponding exemptions, we expect our management and other personnel **to continue** to devote more time and the Company to incur additional costs to comply with the more stringent reporting requirements applicable to companies that are not emerging growth companies. We expect that compliance with these requirements will **continue to** increase our legal and financial compliance costs and will make some activities more time consuming and costly. We cannot predict or estimate the amount of additional costs we may **continue to** incur as a result of our exit from emerging growth company status, or the timing of the incurrence of such costs. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall. If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline. As of December 31, ~~2023~~ **2024** , we had outstanding options to purchase an aggregate of ~~285~~ **283** , ~~883~~ **636** shares of our common stock at a weighted average exercise price of $ 121. ~~11~~ **67** per share and warrants to purchase an aggregate of ~~346~~ **1** , ~~440~~ **981, 079** shares of our common stock at a weighted average exercise price of $ ~~57~~ **10** . ~~79~~ **05** per share. The exercise of such outstanding options and warrants will result in further dilution of your investment, even if there is no relationship between such sales and the performance of our business. We are unable to predict the effect that sales may have on the market price of our common stock. If any shares of our common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline. Future sales and issuances of our securities could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall. We expect that significant additional capital will be needed in the future to continue our planned operations, including research and development, increased marketing, hiring new personnel, commercializing our products, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. We may sell a substantial number of shares of our common stock pursuant to our existing **ATM** ~~At The Market Offering~~ Agreement with H. C. Wainwright, pursuant to which we have the discretion to deliver placement notices to H. C. Wainwright at any time throughout the term of the **ATM** ~~At The Market Offering~~ Agreement covering up to such number or dollar amount of shares of our common stock as registered on the prospectus supplement covering the ATM offering, as may be amended or supplemented from time to time; pursuant to such agreement, we have the discretion, subject to market demand, to vary the timing, prices, and quantity of shares sold, and there is no minimum or

maximum sales price. Any sales of equity securities, whether pursuant to our **existing ATM** ~~At The Market Offering~~ Agreement **or other third- party ATM agreements in the future,** or otherwise, may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders. If securities or industry analysts do not publish research or reports about us, or if they adversely change their recommendations regarding our common stock, then our stock price and trading volume could decline. The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us, our industry and our market. If no analyst elects to cover us and publish research or reports about us, the market for our common stock could be severely limited and our stock price could be adversely affected. In addition, if one or more analysts ceases coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. If one or more analysts who elect to cover us issue negative reports or adversely change their recommendations regarding our common stock, our stock price could decline. Certain provisions in our organizational documents could enable our board of directors to prevent or delay a change of control. We are authorized to issue up to 10, 000, 000 shares of preferred stock, none of which are outstanding as of March 15, ~~2024~~ **2025** . This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. The ability of our board of directors to issue preferred stock also could have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of our common stock. In addition, our organizational documents contain provisions that may have the effect of discouraging, delaying or preventing a change of control of, or unsolicited acquisition proposals, that a stockholder might consider favorable. These include provisions: ● requiring at least 66- 2 / 3 % of the voting power of all of our then- outstanding shares of capital stock entitled to vote generally in the election of directors, voting together as a single class, to amend the Amended and Restated Bylaws; ● providing that the authorized number of directors may be changed only by resolution of the board of directors; ● providing that the directors may only be removed with cause and the affirmative vote of the holders of at least 66- 2 / 3 % of the voting power of all of our then outstanding shares of capital stock entitled to vote generally at the election of directors; ● providing that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum; ● dividing our board of directors into three classes; ● requiring that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent; ● providing that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder' s notice; ● that do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and ● providing that special meetings of our stockholders may be called only by the Chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors. In addition, Delaware law makes it difficult for stockholders that recently have acquired a large interest in a corporation to cause the merger or acquisition of the corporation against the directors' wishes. Under Section 203 of the Delaware General Corporation Law, a Delaware corporation may not engage in any merger or other business combination with an interested stockholder for a period of three years following the date that the stockholder became an interested stockholder except in limited circumstances, including by approval of the corporation' s board of directors. Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws contain an exclusive forum provision with respect to certain actions which may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable and discourage lawsuits against us or our current or former directors or officers and / or stockholders in such capacity. Our Amended and Restated Certificate of Incorporation, as may be further amended and restated from time to time, and Amended and Restated Bylaws, as may be further amended from time to time, provide that, unless we consent in writing to the selection of an alternative forum, the following actions must be brought solely and exclusively in the Court of Chancery of the State of Delaware (i) any derivative action or proceeding brought on behalf of us ; (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to us or our stockholders ; (iii) any action asserting a claim against us or any director or officer or other employee of the Company arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws ; or (iv) any action asserting a claim against us or any director or officer or other employee of the Company governed by the internal affairs doctrine. We believe that the exclusive forum provision may not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. We believe that to the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, we believe that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. This choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers or other employees. Alternatively, if a court were to find the choice of forum provision contained in our Amended and Restated Certificate of Incorporation or Amended and Restated Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on our business, results of operations, and financial condition. General Risk Factors Obligations associated with being a public company in the United States are

expensive and time- consuming, and our management will be required to devote substantial time to compliance matters. As a publicly traded company we incur significant legal, accounting and other expenses. The obligations of being a public company in the United States require significant expenditures and places significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended (" Exchange Act ") and the rules and regulations regarding corporate governance practices, including those under the Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, and the listing requirements of The Nasdaq Capital Market. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, the reporting requirements, rules, and regulations will make some activities more time- consuming and costly, particularly now that we are no longer an " emerging growth company " (our eligibility to qualify as an emerging growth company ended on December 31, 2023, the last day of our fiscal year following the fifth anniversary of our initial public offering). Further, in the event that in the future we were to no longer be eligible to qualify as a " smaller reporting company, " and / or if we become subject to the requirements applicable to accelerated filers or large accelerated filers, including complying with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, our compliance burdens and expenses will further increase. In addition, and as a general matter, we expect the foregoing public company rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential consequences. Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations, and those of our CROs, contract manufacturers and other contractors, vendors and consultants, could be subject to power shortages, telecommunications failures, wildfires, water shortages, floods, earthquakes, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and pandemics and other natural or man- made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to obtain clinical supplies of our current and potential product candidates could be disrupted if the operations of our contract manufacturers are affected by a man- made or natural disaster or other business interruption. In addition, the global macroeconomic environment could be negatively affected by, among other things, new ~~variants of the COVID- 19 pandemic~~ **pandemics** or ~~other~~ epidemics, instability in global economic markets, increased U. S. trade tariffs and trade disputes with other countries, supply chain weaknesses, instability in the global credit markets, severely diminished liquidity and credit availability, rising interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates, uncertainty about economic stability, instability in the geopolitical environment, the Russian invasion of the Ukraine and other political tensions, including in the Middle East, and foreign governmental debt concerns. In 2023, the closures of Silicon Valley Bank, or SVB, and Signature Bank and their placement into receivership with the Federal Deposit Insurance Corporation, or the FDIC, created bank- specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at SVB and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market- wide liquidity shortages, impair the ability of market participants to access near- term working capital needs, and create additional market and economic uncertainty. There can be no assurance that any such continuing or future credit and financial market instability, liquidity shortages and a deterioration in confidence in economic conditions will not occur. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets, which could adversely affect our business, financial condition or results of operations. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans. We do not carry insurance for all categories of risk that our business may encounter. There can be no assurance that we will secure adequate insurance coverage or that any such insurance coverage will be sufficient to protect us from potential liability in the future. Any significant uninsured liability may require us to pay substantial amounts, which may adversely affect our financial position and results of operations. We may be at risk of securities class action litigation. We may be at risk of securities class action litigation. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business and results in a decline in the market price of our common stock. ~~75~~