

Risk Factors Comparison 2025-02-27 to 2024-02-26 Form: 10-K

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An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors as well as the other information in this Annual Report on Form 10-K, including our ~~unaudited~~ **audited** condensed consolidated financial statements and the related notes and “ Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and / or prospects or cause our actual results to differ materially from those contained in forward- looking statements we have made in this Annual Report on Form 10-K and those we may make from time to time. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. You should consider all of the risk factors described when evaluating our business.

Risk Factors Summary Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks include, among others, the following:

- We have incurred net losses and anticipate that we will continue to incur net losses in the foreseeable future. ~~We do not expect meaningful future revenue from the sale of sotrovimab for the treatment of COVID-19, even if it were reauthorized by the FDA. If the FDA were to revise or revoke our EUA, our business could be adversely impacted.~~
- Our limited operating **commercialization** history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We may require substantial additional funding to finance our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our **research and** development programs or other operations.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our product candidates.
- Our future success is substantially dependent on the successful clinical development, regulatory approval and commercialization of our product candidates in a timely manner. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate product revenue will be adversely affected.
- The development of additional product candidates is risky and uncertain, and we can provide no assurances that we will be able to **successfully develop the additional product candidates we identify or** replicate our approach for other diseases.
- **We are developing, and in the future may develop, product candidates in combination with other therapies.**
- Success in preclinical studies or ~~earlier~~ **early-stage** clinical ~~trials~~ **studies** may not be indicative of results in future clinical ~~trials~~ **studies** and we cannot assure you that any ongoing, planned or future clinical ~~trials~~ **studies** will lead to results sufficient for the necessary regulatory approvals and marketing authorizations. We have and may continue to commit substantial financial resources with respect to clinical ~~trials~~ **studies** that may not be successful, and we may not be able to recoup those investments.
- **Interim, “ top line ” and preliminary data from our clinical studies that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.**
- **Although the combination of tobevibart and elebsiran has received Fast Track and Breakthrough Therapy designation from the FDA, as well as PRIME designation from the EMA and European orphan drug designation, in each case for the treatment of CHD, there can be no assurance that any of our product candidates that receive such designations in the U. S. or similar designations in any other regulatory jurisdictions will maintain such designations or receive regulatory approval any sooner than other product candidates that do not have such designations, or at all.**
- **Clinical product development involves a lengthy and expensive process. We may incur additional costs and encounter substantial delays or difficulties in our clinical studies.**
- Enrollment and retention of patients in clinical ~~trials~~ **studies** is an expensive and time- consuming process and could be delayed, made more difficult or rendered impossible by multiple factors outside our control.
- **Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences following any potential marketing approval.**
- We are a party to strategic collaboration and license agreements pursuant to which we are obligated to make substantial payments upon achievement of milestone events and, in certain cases, have relinquished important rights over the development and commercialization of certain current and future product candidates. We ~~may also intend to~~ explore additional strategic collaborations, which may never materialize or may require that we spend significant additional capital or that we relinquish rights to and control over the development and commercialization of our product candidates.
- The deployment of **AI artificial intelligence** in our, or our collaborators’, efforts to discover ~~and,~~ **develop and engineer** next- generation antibodies or other investigational products, could adversely affect our business, reputation, or financial results, **and furthermore our competitors may be able to utilize such technologies more effectively than we can.**
- Even if any of our product candidates receive marketing approval, they may fail to achieve adoption by physicians, patients, third- party payors or others in the medical community necessary for commercial success.
- We rely on third parties to produce clinical ~~and commercial~~ supplies of our product candidates. **There could be delays or supply shortages beyond our control limiting our access to clinical supplies.**
- We rely on third parties to conduct, supervise and monitor our preclinical ~~and clinical~~ **studies and clinical trials**, and if those third parties perform in an unsatisfactory manner, it may harm our business.
- If we breach our license agreements or any of the other agreements under which we acquired, or will acquire, the intellectual property rights to our product candidates, we could lose the ability to continue the development and commercialization of the related product candidates.
- If we are unable to obtain and maintain patent protection for our product candidates and technology, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our

product candidates and technology may be adversely affected. • ~~The exercise by the Bill & Melinda Gates Foundation of its licenses to certain of our intellectual property and its development and commercialization of products that we are also developing and commercializing could have an adverse impact on our market position.~~ • We are highly dependent on our key personnel, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical and scientific personnel, our business ~~will could~~ be harmed. • ~~We have experienced significant~~ **Our success depends on our ability to manage our** growth in our organization in recent years and expect to continue to expand, and we may experience difficulties in managing this growth, which could disrupt our operations. • If our information systems, or those maintained on our behalf, fail or suffer security breaches, such events could result in, without limitation, the following: a significant disruption of our product development programs; an inability to operate our business effectively; unauthorized access to or disclosure of the personal information we process; and other adverse effects on our business, financial condition, results of operations and prospects. • The market price of our common stock has been, and in the future, may be, volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock. Risks Related to Our Financial Position and Capital Needs Although we recorded net income for the years ended December 31, 2022, and 2021, we have otherwise incurred net losses since inception in April 2016. We had net loss of \$ **522.0 million and \$ 615.1 million** and net income of \$ **515.8 million** for the years ended December 31, **2024 and 2023** and ~~2022~~, respectively. As of December 31, ~~2023~~ **2024**, we had an accumulated deficit of \$ **237.759**.8 million. We expect to continue to incur significant expenses and will continue to incur net losses in the foreseeable future ~~as~~. Since inception, we ~~develop~~ **have devoted substantially all of our efforts to identifying, researching and conducting preclinical and clinical activities of our product candidates, acquiring and developing our technology platforms and product candidates, organizing and staffing our company, business planning, raising capital and establishing our intellectual property portfolio.** It could be several years, if ever, before we are able to commercialize any of our product candidates. Any net losses we incur may fluctuate significantly from quarter to quarter and year to year. To become profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical **and clinical** studies ~~and clinical trials~~ of our current and future product candidates, obtaining regulatory approval, procuring commercial- scale manufacturing and marketing, **and selling any products for which we obtain regulatory approval (including through third parties), as well as discovering or acquiring and developing additional product candidates.** We are only in the preliminary stages of most of these activities ~~We, and we~~ may never **attain a level of commercial success that will** succeed in these activities and, even if we do, may not be able to continue to generate **sufficient** revenue that is sufficient to offset our expenses and maintain profitability. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of expenses, or if we will be able to return to profitability. If we are required by regulatory authorities to perform studies ~~and trials~~ in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical ~~trials~~ **studies** or the development of any of our product candidates, our expenses could increase. Our failure to return to being profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. ~~Since~~ **In May 2021, we, along with our partner GSK, received an Emergency Use Authorization, or our founding** EUA, from the U. S. Food and Drug Administration, or FDA, for the sale of sotrovimab for the treatment of COVID-19. In March and April 2022, the FDA amended the EUA fact sheet to exclude sotrovimab use in geographic regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant based on available information, including variant susceptibility to these drugs and regional variant frequency. With this EUA revision, sotrovimab is not currently authorized for use in any U. S. region, and we cannot predict whether (if at all) or to what extent sotrovimab may be reauthorized for use by the FDA in any U. S. region in the future. In addition, there can be no assurance with respect to how long the EUA will remain in effect or whether the EUA will be further revised or revoked by the FDA following the termination of the underlying public health emergency declaration on May 11, 2023 or for other reasons. Furthermore, due to the evolving COVID-19 landscape and based on discussions with the FDA, we and Glaxo Wellcome UK Limited and GlaxoSmithKline Biologicals S. A. (individually and collectively referred to as GSK) do not plan to file a Biologics License Application, or BLA, for sotrovimab at this time. In May 2021, we and our partner GSK also received a positive scientific opinion from the Committee for Human Medicinal Products, or CHMP, in the European Union, or EU, for sotrovimab and to date, sotrovimab has obtained emergency authorization, temporary authorization or marketing approval (under the brand name Xevudy®) for early treatment of COVID-19, and has been supplied in more than 30 countries. However, foreign regulatory authorities may impose similar limitations to the FDA on the use of sotrovimab in jurisdictions where sotrovimab has been granted EUA, temporary authorization or marketing approval. For example, although certain countries outside the U. S. continue to maintain access to 500 mg IV while noting that the clinical efficacy is unknown or uncertain against existing and emerging Omicron variants, we cannot predict whether other countries will further limit the use of sotrovimab. Furthermore, based on the evolving COVID-19 landscape and our expectations for future sales in light of these factors, there are no assurances that we will secure future supply commitments from governments. In addition, COVID-19 treatment standards are susceptible to rapid changes in epidemiology and the emergence of new variants or subvariants, which may render sotrovimab inferior or obsolete in the future. In addition, there can be no assurance with respect to how long the EUA will remain in effect or whether the EUA will be further revised or revoked by the FDA following the termination of the underlying public health emergency declaration on May 11, 2023, or for other reasons. Any such revision or revocation of our EUA by the FDA could adversely impact our business in a variety of ways, including having to absorb related manufacturing and overhead costs as well as potential inventory write-offs. Furthermore, if we or our collaborators experience inventory revaluation adjustments, lower of cost or market inventory adjustments, and excess inventory, it may be necessary to write down or write-off inventory or incur an impairment charge with respect to the facility where such product is manufactured, which could adversely affect our operating results. For example, during the year ended December 31, 2023, we

released approximately \$ 35.7 million of constraint related to sotrovimab due to changes in estimated allowable manufacturing expenses as agreed to with GSK. Due to the evolving COVID-19 landscape and based on discussions with the FDA, we and GSK do not plan to file a BLA for sotrovimab at this time. Furthermore, foreign regulatory authorities may impose similar limitations to the FDA on the use of sotrovimab in jurisdictions where sotrovimab has been granted EUA, temporary authorization or marketing approval. Although certain countries outside the U. S. continue to maintain access to 500 mg IV while noting that the clinical efficacy is unknown or uncertain against existing and emerging Omicron variants, we cannot predict whether other countries will limit the use of sotrovimab. Even if we were to file a BLA or marketing applications in other jurisdictions, it is possible that the FDA and other regulatory authorities may not grant sotrovimab full marketing approval for the treatment of COVID-19, or that any such marketing approvals, if granted, may have similar or other significant limitations on its use. If the FDA does not reauthorize the use of sotrovimab in the U. S., and / or if countries outside of the U. S. continue to limit its use, we may be unable to sell sotrovimab in or outside of the U. S. The FDA may revise or revoke an EUA if the circumstances justifying its issuance no longer exist, the criteria for its issuance are no longer met, or other circumstances make a revision or revocation appropriate to protect public health or safety. An EUA may also be terminated upon a declaration by the Secretary of HHS that the public health emergency has ended. The public health emergency declarations related to COVID-19 ended on May 11, 2023. At this point, it is unclear how, if at all, these developments will impact our EUA. We, therefore, cannot predict how long our EUA will remain in effect, and we may not receive advance notice from the FDA regarding revocation of our EUA. If our EUA is terminated or revoked, sotrovimab cannot be reauthorized by the FDA in the U. S. unless and until we have obtained FDA approval of a BLA for the product. Changing policies and regulatory requirements could limit, delay or prevent further commercialization of sotrovimab and could adversely impact our business, financial condition, results of operations and prospects. For all of these reasons, we do not currently expect meaningful future revenue from sotrovimab for the treatment of COVID-19. We are a company founded in April 2016 and, our operations to date have been largely focused on identifying, researching and conducting preclinical and clinical activities of our product candidates, acquiring and developing our technology platforms and product candidates, organizing and staffing our company, business planning, raising capital and establishing our intellectual property portfolio. As an organization, beyond sotrovimab for COVID-19, we have not yet demonstrated an ability to successfully manufacture a BLA- approved, commercial- scale product or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives, including with respect to our technology platforms and product candidates. As of December 31, 2023-2024, we had cash, cash equivalents and investments of \$ 1.63 billion. Based upon our current operating plan, we believe that **this amount the \$ 1.63 billion as of December 31, 2023** will fund our current operating plans for at least the next 12 months. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional financing to fund our long- term operations sooner than planned. Moreover, it is particularly difficult to estimate with certainty our future revenue and expenses given the dynamic and rapidly evolving nature of our business. We may also need to raise additional capital to complete the development and commercialization of our product candidates and fund certain of our existing manufacturing and other commitments. Other unanticipated costs may also arise. Because the design and outcome of our clinical **trials studies** are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of our product candidates, **, if approved,** or any future product candidates that we develop. We expect to finance our cash needs through public or private equity or debt financings, third- party (including government) funding and marketing and distribution arrangements, as well as **clinical trial financing and** other collaborations, strategic alliances and licensing arrangements **with other companies**, or any combination of these approaches. Our future capital requirements will depend on many factors, including: • the timing, progress and results of our ongoing preclinical **and clinical** studies and **clinical trials** of our product candidates; • the scope, progress, results and costs of preclinical development, laboratory testing and clinical **trials studies** of other **potential** product candidates that we may pursue; • our ability to establish and maintain collaboration, license, grant and other similar arrangements, and the opt- in mechanisms contained in, and the financial terms of, any such arrangements, including timing and amount of any future milestones, royalty or other payments due thereunder; • the costs, timing and outcome of regulatory **review reviews** of our product candidates; • the costs and timing of commercialization activities, including product manufacturing, marketing, sales and distribution, for our product candidates for which we receive marketing approval; • the amount of revenue received from commercial sales of any product candidates for which we receive marketing approval; • the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property- related claims; • any expenses needed to attract, hire and retain skilled personnel; • the costs of operating as a public company; and • the extent to which we acquire or in- license other companies' product candidates and technologies. General economic conditions, both inside and outside the U. S., including **heightened inflation,** capital market volatility, interest rate and currency rate fluctuations, and economic slowdown or recession, **as well as including the evolution of new and existing variants of COVID-19, and geopolitical events, including civil or political unrest, terrorism, insurrection or war** (such as the ongoing **war between Israel conflicts in the Middle East and Eastern Europe Hamas and Ukraine and Russia**), **and also investor concerns regarding the U. S. or international financial systems,** have **in the past** resulted in, **and may in the future cause,** a significant disruption of **global** financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital **or increased costs of financing through higher interest rates or costs or tighter financial and operating covenants**, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments. **In addition, market volatility, high levels of inflation and interest rate fluctuations may increase our cost of financing or restrict our access to potential sources of future liquidity.** Adequate

additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether terminate our research and development programs or commercialization efforts, which may adversely affect our business, financial condition, results of operations and prospects. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. ~~Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches.~~ To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest in our company may be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights. If we raise additional capital through future collaborations, strategic alliances or licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our **research and product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.** ~~Adverse developments affecting~~ **We do not expect meaningful future revenue from the sale of sotrovimab** ~~financial services industry, including events or~~ **for concerns involving liquidity the treatment of COVID- 19** ~~defaults or nonperformance even if it were reauthorized by financial institutions~~ **the FDA. In December 2024** ~~the FDA revoked the EUA that we and GSK had received in May 2021 for the sale of sotrovimab to treat COVID- 19. Even prior to the FDA's revocation of our EUA, sotrovimab had not been authorized for use in any U. S. region for the treatment of COVID- 19 since the FDA's exclusionary revisions to our EUA in March and April 2022.~~ **Due to the evolving COVID- 19 landscape and based on discussions with the FDA, we and GSK do not plan to file a BLA. While sotrovimab still maintains emergency authorization, temporary authorization or marketing approval (under the brand name Xevudy®) for early treatment of COVID- 19 in certain territories outside of the United States, we did not earn meaningful revenue from sales of sotrovimab during the most recent fiscal year ended December 31, 2024. Moreover, foreign regulatory authorities may impose similar limitations to the FDA on the use of sotrovimab in jurisdictions where sotrovimab has been granted EUA, temporary authorization or other marketing approval, which could further reduce revenue** ~~adversely affect our business, financial condition or results of operations. We hold our cash, cash equivalents and investments that we use to meet our working capital and operating expense needs in accounts at multiple financial institutions. The balance held in these accounts typically exceeds the Federal Deposit Insurance Corporation, or FDIC, standard deposit insurance limit of \$ 250, 000. Should events, including limited liquidity, defaults, nonperformance or other adverse developments, occur with respect to the banks or other financial institutions that hold our funds, or that affect financial institutions or the financial services industry generally, or concerns or rumors arise about any events of these kinds or other similar risks, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact our short-term liquidity and ability to meet our operating expense obligations. For example, although certain countries outside~~ **in March 2023 Silicon Valley Bank, or SVB, and Signature Bank were each closed by state regulators and the FDIC was appointed receiver for each bank. Prior to such events, we held cash deposits at SVB in excess of government insured limits. The FDIC created successor bridge banks and all deposits of SVB and Signature Bank were transferred to bridge banks under a systemic risk exception approved by the United States Department of the Treasury, the Federal Reserve and the FDIC. If financial institutions in which we hold funds** ~~continue to maintain access to 500 mg IV while noting that the clinical efficacy is unknown for~~ **or working capital uncertain against existing and emerging Omicron variants** ~~operating expenses were to fail~~ **, we cannot provide any predict whether other countries will further limit the use of sotrovimab. There are no assurances that we will secure future supply commitments from governments for sotrovimab, or that sotrovimab will be effective against any new COVID- 19 variants or subvariants. Even if we and GSK were to file a BLA or marketing applications in other jurisdictions, it is possible that the FDA and other regulatory authorities may not grant sotrovimab full marketing approval for the treatment of COVID- 19, or that any such marketing approvals, if granted, may have governmental agencies would take action to protect our uninsured deposits in a similar or manner. In addition, investor concerns regarding the other significant U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it its more difficult use. If the FDA does not reauthorize the use of sotrovimab in the U. S., and / or if countries outside of the U. S. continue to limit its use, we may be unable to sell sotrovimab in or outside of the U. S. For these reasons, we do not currently expect meaningful future revenue from sotrovimab for the treatment** ~~us to acquire financing on terms favorable to us, or at all, and could have a material adverse effect on our liquidity, our business, financial condition or results of operations~~ **COVID- 19. Risks Related to Development and Commercialization Our future success is substantially dependent on the successful clinical development, regulatory approval and commercialization of our product candidates in a timely manner. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate product revenue will be adversely affected. We have invested a significant portion of our time and financial resources in the development , in-licensing and acquisition** ~~of our product candidates and have initiated clinical trials studies for multiple product candidates. Our~~ **Accordingly, our** ~~business is dependent on our ability to successfully complete~~ **clinical** ~~development of, obtain regulatory~~

approval for, and successfully commercialize our product candidates, if approved, in a timely manner. We may face unforeseen challenges in our product development strategy, and we can provide no assurances that our product candidates will be successful in clinical ~~trials studies~~ or will ultimately receive regulatory approval. Prior to obtaining approval to commercialize any product candidate in the United States or abroad, we must demonstrate with substantial evidence from well- ~~controlled-designed~~ **registrational clinical trials studies**, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidate is safe and effective ~~for to treat~~ its intended ~~uses indications~~. Results from preclinical studies ~~and clinical trials~~ can be interpreted in different ways. Even if we believe that the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval for further development, manufacturing or commercialization of our product candidates by the FDA and other regulatory authorities. The FDA or other **comparable foreign** regulatory authorities may also require us to conduct additional preclinical ~~or clinical studies or clinical trials~~ for our product candidates, either prior to or post- approval, or ~~it may object to elements of our clinical development program, and requiring require their alteration-us to alter them~~. Even if we eventually complete clinical testing and receive approval of ~~an a new drug application, or NDA, BLA, or foreign marketing application~~ for our product candidates, the FDA or ~~the comparable foreign regulatory authorities may grant an approval or other marketing authorization that is~~ contingent on the performance of costly additional clinical ~~trials studies~~, including post- ~~market marketing~~ clinical trials. **Furthermore, The FDA or the these comparable foreign regulatory authorities also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA or comparable foreign regulatory authorities may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a our product candidate candidates.** Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would adversely impact our business and prospects. In addition, the FDA or comparable foreign regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain applicable regulatory approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act, Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other “pivotal study” of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late- stage clinical ~~trials studies~~ of FDA- regulated products. Specifically, **as further detailed in FDA’s Draft Guidance entitled, “ Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies ” issued in June 2024**, actions plans must include the sponsor’s goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. ~~In addition to The Trump Administration’s January 2025 Executive Order pausing certain diversity, equity and inclusion efforts has left uncertain how, whether or when these the statute’s requirements will become operative~~, the legislation directs the FDA to issue new guidance on diversity action plans. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical ~~trials studies~~, our development plans may be impacted. Furthermore, even if we obtain regulatory approval for our product candidates, we may still need to develop a commercial organization, establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third- party and government payors, including government health administration authorities. As a company, we have no prior experience in these areas. If we are unable to successfully commercialize our product candidates or if there is an insufficient demand for our product candidates, we may not be able to generate sufficient revenue to continue our business. A core element of our business strategy is to ~~expand successfully develop~~ our product candidate pipeline. Efforts to identify, acquire or in- license, and then develop product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. ~~Our Even when we are successful in identifying and acquiring or in-licensing potential product candidates, such as our license to three clinical- stage TCEs from Sanofi, our efforts may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development, approved products or commercial revenue for many reasons. We have limited financial and management resources and, as a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater market potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, strategic alliances, licensing or other royalty arrangements in circumstances under which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. In addition, we may not be successful in replicating our approach to development for other disease indications. If we are unsuccessful in identifying and developing additional product candidates or are unable to do so, or if the product candidates that we identify and acquire or in- license do not meet our expectations or fail to result in viable products~~, our business may be harmed. Furthermore, we intend to seek approval to market our product candidates outside of the U. S., and may also do so for future product candidates. If we market approved products outside of the U. S., we expect that we will be subject to additional risks in commercialization. As a company, we have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by many of the individual countries in which we may operate, with which we will need to comply. Many biopharmaceutical companies have found the process of marketing their products in foreign countries to be challenging. We are developing, and in the future may develop, ~~other product candidates in combination with other therapies, which exposes us to additional risks. We are pursuing a developing elebsiran and tobevibart for the functional cure of hepatitis B virus, or HBV, CHB based on a combination regimen of tobevibart and elebsiran, with or without PEG- IFNα, as well as developing the~~

combination of tobevibart and elebsiran as a treatment for CHD the chronic treatment of hepatitis delta virus, or HDV. Each of these product candidates has **demonstrated direct antiviral activity and** the potential to stimulate an effective immune response **and has direct antiviral activity against HBV**. We believe that a functional cure for **HBV CHB** will require an effective immune response, in addition to antiviral activity, based on the **latest functional cure data and on the** observation that severe immunosuppression can reactivate **CHB HBV disease**. **Accordingly, a combination Monotherapy---- therapy with each that includes both** of these agents **components** may **provide be needed to achieve** a functional cure in some patients, while combination therapy may be necessary for others. **We For CHB, we** have an ongoing Phase 2 clinical trial **trials that** combines **evaluating the combination of tobevibart and** elebsiran, with pegylated interferon **or without PEG** - alpha **IFN α** , and **we** a Phase 2 clinical trial that combines elebsiran with tobevibart. We are also evaluating additional combinations with other immunotherapy agents and direct **-** acting antiviral agents. **We also For CHD, we** have **a an ongoing** Phase 2 clinical trial evaluating elebsiran and tobevibart as a monotherapy or in combination **with elebsiran, and we have a planned registration trial program that will further evaluate the doublet combination. In our early- stage oncology programs, we are evaluating VIR- 5818 in combination with pembrolizumab in a Phase 1 basket study in multiple tumor types, including metastatic breast cancer and metastatic CRC. The inclusion of critically ill patients in our oncology clinical studies may result in serious adverse medical events, including death, due to other therapies for- or the treatment of chronic HDV medications that such patients may be using or in combination with our product candidates**. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate. There is also a risk that safety, efficacy, manufacturing or supply issues could arise with these other existing therapies. For example, the other therapies may lead to toxicities that are improperly attributed to our product candidates or the combination of our product candidates with other therapies may result in toxicities that the product candidate or other therapy does not produce when used alone. This could result in our own products being removed from the market or being less successful commercially. We may also evaluate our future product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval. If the FDA or comparable foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain **approvals that will facilitate the successful commercialization of our product candidates. Success in preclinical testing and early- stage clinical studies does not ensure that later clinical studies will generate similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Certain of our clinical programs have not yielded positive results in late- stage studies (such as our Phase 2 clinical study of VIR- 2482 for the prevention of symptomatic influenza A illness, which did not meet primary or secondary efficacy endpoints, as announced in July 2023), and our product candidates currently under development may similarly fail to meet efficacy endpoints or otherwise show the desired characteristics in clinical development sufficient to obtain regulatory approval -Success-, despite positive results in preclinical studies or earlier having successfully advanced through early- stage clinical studies trials may not be indicative of results in future clinical trials and we cannot assure you that any ongoing, planned or future clinical trials will lead to results sufficient for the necessary regulatory approvals and market authorizations**. We have and may continue to commit substantial financial resources with respect to clinical **trials studies** that may not be successful, and **we** may not be able to recoup those investments. **If Success in preclinical testing and earlier clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Success in preclinical studies and earlier clinical trials does not ensure that later efficacy trials will be successful, nor does it predict final results. Our product candidates may fail to show the desired characteristics in clinical development sufficient to obtain regulatory approval, despite positive results in preclinical studies or having successfully advanced through earlier clinical trials. We have and may continue to commit substantial financial resources with respect to clinical trials that may not be successful, and we are may not be able to recoup those investments. For example, in July 2023, we announced that our Phase 2 clinical trial of VIR- 2482 for the prevention of symptomatic influenza A illness did not meet primary or secondary efficacy endpoints. We committed substantial financial resources and made substantial capital commitments with third party contract development manufacturing organizations, or CDMOs, with respect to the raw materials and manufacturing in connection with VIR- 2482. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval, which could mean we will suffer setbacks that**. **Any such setbacks could negatively impact our business, financial condition, results of operations and prospects**. **Moreover, our inability to bring a product to market or a significant delay in the expected approval and related launch date of a new product could have a negative effect on our stock price and related market capitalization, which could result in a significant impairment of goodwill, other intangible assets and long- lived assets**. Interim, “ top- line ” and preliminary data from our clinical **trials studies** that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim, “ top- line ” or preliminary data from our clinical **trials studies**. Interim data from clinical **trials studies** that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or “ top- line ” data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data is available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Clinical In June 2024 and December 31, 2024, we announced that the FDA granted Fast Track designation and Breakthrough Therapy designation, respectively, for the combination of tobevibart and elebsiran for the treatment of CHD. In addition, the combination received PRIME designation from the EMA and European orphan drug designation in December 2024 in the same indication. We can provide no assurances that the combination of tobevibart and elebsiran or any of our other product development involves candidates that receive Fast Track, Breakthrough Therapy, Priority Review or similar designations in the U. S., EU or in any other regulatory jurisdictions will receive regulatory approval any sooner than other product candidates that do not have such designations, or at all. The FDA, EMA or other foreign regulatory authorities may also withdraw or revoke any such designation, or elect to treat designated candidates in a lengthy and expensive process manner different from what was originally indicated, if determined that any such product candidates that receive such designations no longer meet the relevant criteria. We may incur Failure to realize the potential benefits of any of these designations could materially and adversely affect our business, financial condition, cash flows and results of operations. For additional costs information, see the sections titled “ Government Regulation and encounter substantial delays or difficulties Product Approval — Expedited Development and Review Programs ” and “ Government Regulation and Product Approval — Foreign Regulation ” in our clinical trials “ Part I, Item 1. Business ” in this Annual Report on Form 10-K. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials studies to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We do not know whether our planned clinical trials studies will begin or enroll on time, will be conducted as planned, will need to be redesigned or will be completed on schedule, if at all. A failure or significant delay of one or more clinical studies can occur at any stage of testing. For example, during initial dose escalation studies, we, the FDA or comparable foreign regulatory authorities have in the past and may in the future impose restrictions relating to chemistry, manufacturing and control (CMC) standards, and such restrictions could then delay or limit our evaluation of a product candidate and its subsequent advancement to late-stage studies. Also, the availability of superior or competitive therapies coupled with changing standards of care could limit our ability to perform placebo-controlled trials studies and / or require us to enroll a larger number of subjects to address competing treatments. A failure or significant delay of one or more clinical trials can occur at any stage of testing. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical and clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. We may experience numerous Any of these or other unforeseen events that we may experience prior to, during, or as a result of clinical studies trials that could delay or prevent us from our ability to receive receiving marketing approval or and ultimately commercialize commercializing our product candidates. Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future product sales or other sources. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring competing products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects. Additionally, if the results of our clinical trials studies are inconclusive or if there are safety concerns or SAEs serious adverse events associated with our product candidates, we may: • be delayed in obtaining marketing approval, or not obtain marketing approval at all; • obtain approval for indications or patient populations that are not as broad as intended or desired; • obtain approval with labeling that includes significant use or distribution restrictions or safety warnings; • be subject to additional post-marketing testing requirements; • be required to perform additional clinical trials studies to support approval or be subject to additional post-marketing testing requirements; • have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of a risk evaluation and mitigation strategy (REMS); • be subject to the addition of labeling statements, such as warnings or contraindications; • be sued subject to lawsuits, investigations or other legal or regulatory proceedings; or • experience damage to our reputation. Our product development costs may be greater than anticipated or may increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will be conducted as planned, will need to be restructured or will be completed on schedule, if at all. For example, enrollment and retention of patients in clinical trials could be disrupted by geopolitical events, including civil or political unrest, terrorism, insurrection or war (such as the ongoing war between Israel and Hamas and Ukraine and Russia), man-made or natural disasters, or public health pandemics or epidemics or other business interruptions, including the COVID-19 pandemic and future outbreaks of the disease. Furthermore, our product candidates are based on certain innovative technology platforms, which makes it even more difficult to predict the time and cost of product candidate development and obtaining necessary regulatory approvals, particularly for our cytomegalovirus, or CMV, vector technologies. In addition, the compounds we are developing may not demonstrate in patients the chemical and pharmacological properties ascribed to them in preclinical studies, and they may interact with human biological systems in unforeseen, ineffective or harmful ways. As part of our T cell platform, our approach is to use human CMV, or HCMV, as a vaccine vector to potentially treat and prevent pathogens refractory to current vaccine technologies because HCMV may induce potent and long-lasting T cell responses to a broader range of epitopes than observed for other viral vaccines. Also, because our HCMV-vector technology is novel, regulatory agencies may lack experience with product candidates such as VIR-1388, which may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates. In addition, our HCMV-vector technology utilizes live-attenuated, genetically-modified organisms for which the FDA, the European Medicines Agency, or EMA, and other comparable foreign

regulatory authorities and other public health authorities, such as the Centers for Disease Control and Prevention and hospitals involved in clinical trials, have established additional safety and contagion rules and procedures, which could establish additional hurdles for the development, manufacture or use of our vectors. These hurdles may lead to delays in the conduct of clinical trials or in obtaining regulatory approvals for further development, manufacturing or commercialization of our product candidates. Further, we, the FDA, a foreign regulatory authority or an institutional review board may place a full or partial hold on our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice, or GCP, regulations, that we are exposing participants to unacceptable health risks, or if the FDA or foreign regulatory authority finds deficiencies in our IND applications or clinical trial applications, respectively, or the conduct of these trials. Moreover, we may not be able to file INDs to commence additional clinical trials on the timelines we expect because our filing schedule is dependent on further preclinical and manufacturing progress. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenue from our product candidates may be delayed. Our inability to bring a product to market or a significant delay in the expected approval and related launch date of a new product for any of the reasons discussed above could have a negative effect on our stock price and related market capitalization and could result in a significant impairment of goodwill, other intangible assets and long-lived assets.

Identifying and qualifying patients to participate in our clinical trials studies is critical to our success. In particular, clinical trials studies for prophylaxis are impacted by many factors including competing therapies that tend to require enrollment of a larger number of subjects than clinical trials studies for treatments. We may encounter difficulties in enrolling patients in our clinical trials studies, thereby delaying or preventing development and approval of our product candidates. Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials studies. Patient enrollment and retention in clinical trials studies depend on many factors, including the size of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data, changing standards of care, the number and nature of competing treatments and ongoing clinical trials studies of competing therapies for the same indication, the proximity of patients to clinical trial sites and the eligibility criteria for the trial. The enrollment and retention of patients in our clinical trials studies may be disrupted or delayed as a result of, for example, regulatory feedback, clinicians' and patients' perceptions as to the potential advantages of therapies in development in relation to other available therapies, including products that have been recently authorized under EUAs or approved and licensed through NDAs and BLAs. In addition, enrollment and retention of patients in clinical trials studies could be disrupted by geopolitical events, including civil or political unrest, terrorism, insurrection or war (such as the ongoing war between Israel and Eastern Europe, Hamas and Ukraine and Russia), as well as man-made or natural disasters, or public health pandemics or epidemics, or other business interruptions, including the current COVID-19 pandemic and future outbreaks of the disease. Our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. Any negative results we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible. In addition, we may rely on contract research organizations, or CROs, and clinical trial sites to ensure proper and timely conduct of our future clinical trials studies and, while we intend to enter into agreements governing their services, we will be limited in our ability to ensure their actual performance. Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, which may limit their commercial potential or result in significant negative consequences following any potential marketing approval rejection of the data generated at particular clinical trial sites or delays in the completion of our future clinical studies. During the conduct of clinical trials studies, patients report changes in their health, including illnesses, injuries and discomforts, to their doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions and may require us to pause our clinical trials studies or require additional testing to confirm these determinations, if they occur. In addition, it is possible that as we test our product candidates in larger, longer and more extensive clinical trials studies, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were not observed in earlier trials studies, as well as conditions that did not occur or went undetected in previous trials studies, will be reported by subjects or patients. Many times, side effects are only detectable after investigational products are tested in large-scale pivotal trials studies or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our product candidates have side effects or cause serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would harm our business, financial condition, results of operations and prospects. We are a party to various strategic collaboration and license agreements that are important to our business and to our current and future product candidates pursuant to which we license a number of technologies to form our technology platforms and in-license certain product candidates. These agreements contain obligations that require us to make substantial payments in the event certain milestone events are achieved. For additional information regarding these and other collaboration, license and grant agreements, see the section titled "Business — Our Collaboration, License and Grant Agreements". A core element of our business strategy includes continuing to acquire or in-license additional technologies or product candidates for the treatment and prevention of serious infectious diseases, cancer and other serious conditions. As a result, we intend to periodically explore a variety of possible strategic collaborations or licenses in an effort to gain access to additional product candidates, technologies or resources. At this time, we cannot predict what form such strategic collaborations

or licenses might take. We are likely to face significant competition in seeking appropriate strategic collaborators, **and in addition such strategic collaborations and licenses and similar arrangements can be complicated-complex. We have in the past and may in the future need to renegotiate such arrangements from time to time,** and we may not be able to negotiate strategic collaborations **these arrangements** on acceptable terms, or at all. If we are unable to enter into new strategic collaborations or licenses related to our **current or potential** product candidates in certain geographies for certain indications, **or if we are unable to maintain our current strategic collaborations or license on acceptable terms,** we may not be able to develop and commercialize certain of our product candidates, which would harm our business prospects, financial condition and results of operations. Our current and future strategic collaborations and licenses could subject us to a number of risks, including the following: • we may be required to assume substantial actual or contingent liabilities **or pay regulatory or commercial milestone payments, which may make it difficult to predict the final cost to complete the related clinical programs or commercialize a product candidate**; • we may, during any transition period with respect to in- licensed clinical programs, be reliant on licensors to continue serving as regulatory sponsors (and executing all appropriate sponsorship responsibilities or delegations of such responsibilities) until a complete transition of sponsorship can be made • we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates; • strategic collaborators may select dosages or indications, or design clinical **trials studies**, in a way that may be less successful than if we were doing so or in a way that may differ from our strategy, which could negatively impact our development, manufacturing and commercialization of the same or a similar product candidate; • strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement due to development programs based on data readouts, changes in their strategic focus as a result of an acquisition of competitive products or other internal pipeline advancements, availability of funding or other external factors, that diverts resources or creates competing priorities; • disputes may arise between us and our strategic collaborators that result in costly litigation or arbitration that diverts management's attention and consumes resources; • strategic collaborators may experience financial difficulties; • strategic collaborators may not properly maintain, enforce or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation, **or may allege such claims against us**; and • strategic collaborators could terminate the arrangement or not exercise their opt- in rights, which may delay the development **or, may** increase the cost of developing our product candidates and result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. **If Furthermore, license agreements we enter into in the these or other risks from our current or potential future strategic collaborations may not provide exclusive rights to use intellectual property and licenses occur, technology in all relevant fields of use and in all territories in which we may wish to develop or our business, financial condition, commercialize our technology and products. As a result results, we may not of operations or prospects could be harmed** able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. The deployment of artificial intelligence in our, or our collaborators', efforts to discover, develop, and engineer next-generation antibodies or other investigational products, could adversely affect our business, reputation, or financial results . We integrate **artificial intelligence and machine learning, or AI**, in our efforts to develop and engineer next- generation antibodies, and we might utilize AI in the future in connection with drug discovery activities. AI may be difficult to deploy successfully due to operational and technical issues inherent in such methods. In particular, AI algorithms might utilize machine learning and predictive analytics which may lead to flawed, biased or inaccurate results, which could lead to ineffective product or target candidates and exposure to competitive and reputational harm . **In addition, perceived or actual technical, legal, compliance, privacy, security, ethical or other issues relating to the use of AI may cause regulators' or the public's confidence in AI to be undermined, which could impede our ability to develop products using AI.** In addition, any latency, disruption, or failure in our AI operations or infrastructure could result in failures, delays or errors in our discovery and development of next-generation antibodies or other investigational products. Developing, testing and deploying resource- intensive AI systems may also require additional investment and increase our costs, and there is no guarantee that our investment in such systems will lead to more effective or efficient discovery or development of antibodies or other investigational products, or lead to eventual regulatory approval or commercialization of any new products. If the market opportunities for our product candidates are smaller than we believe they are or any approval we obtain is based on a narrower definition of the patient population, our business may suffer. We currently focus our product development on product candidates for the treatment and prevention of serious infectious diseases, **cancer** and other serious conditions. Our eligible patient population, pricing estimates and available coverage and reimbursement may differ significantly from the actual market addressable by our product candidates. Our estimates of the number of people who have these diseases, the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, and the market demand for our product candidates are based on our beliefs and analyses. These estimates have been derived from a variety of sources, including the scientific literature, patient foundations or market research, and may prove to be incorrect. Further, new **trials studies** may change the estimated incidence or prevalence of the diseases we are targeting . **The FDA or the comparable foreign regulatory authorities also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request** . Additionally, the availability of superior or competitive therapies from our competitors could negatively impact or eliminate market demand for our product candidates. If the market opportunities for our product candidates are smaller than we estimate, it could have an adverse effect on our business, financial condition, results of operations and prospects. We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do. The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and an emphasis on proprietary products. We face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. **Our commercialization**

potential could. In addition, regulatory **Regulatory** incentives to develop products for treatment of infectious diseases have increased interest and activity in this area and may lead to increased competition for clinical investigators and clinical trial subjects, as well as for future prescriptions, if any of our product candidates are successfully developed and approved. Our **Compared to us, our** competitors may have significantly greater financial resources, established presence in the market, and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals, and **ultimately marketing and obtaining** reimbursement and marketing approved products. **The licensing or acquisition of third-party intellectual property rights is a competitive area as well, and more established companies may have greater success in pursuing strategies to license or acquire third- party intellectual property rights than that we do may consider attractive or necessary.** These competitors also compete with us in acquiring third- party contract manufacturing capacity and raw materials, recruiting and retaining qualified scientific, sales, marketing and management personnel, establishing clinical trial sites and patient registration for clinical ~~trials studies~~, as well as in acquiring technologies **that are** complementary to, or necessary for, our programs. Smaller or **early-earlier** - stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions may result in even more resources being concentrated in our competitors. Our success is also subject to the risk be **significant** reduced or eliminated if our competitors, **particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions may result in even more resources being concentrated amongst our competitors. If our competitors are able to utilize new technologies more effectively (including but not limited to those that may involve AI or be created using AI) to discover,** develop and commercialize products that **compete with any of** are safer, more effective, have fewer or **our product candidates** less severe side effects, are more convenient or **potential commercial** are less expensive than products that we may develop. The key, **such technologies could adversely impact our ability to** competitive --- **compete. As a result of these** factors affecting the success of all our programs are likely to be efficacy, **our safety, convenience and timing.** Our competitors also may **achieve patent protection or** obtain FDA or other regulatory approval for **or authorization of** their products **before more rapidly than we are able to** may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. **In addition, regulatory incentives to develop.....** develop or commercialize our product candidates. Our competitors may also develop therapies that are safer, more effective, **have fewer or less severe side effects, are more convenient,** more widely accepted or less expensive than ours, and may also be more successful than we are in manufacturing **and,** marketing **or obtaining reimbursement** their products. These advantages could render our product candidates obsolete or non- competitive before we can recover the costs of such product candidates' development and commercialization. For additional information regarding our competitors, see the section titled "Business—Competition" **in " Part I, Item 1. Business " of this Annual Report on Form 10- K.** Even if any of our product candidates receive marketing approval, they may fail to achieve adoption by physicians, patients, third- party payors and others in the medical community. If such product candidates 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 any product candidate, if approved for commercial sale, will depend on a number of factors, including but not limited to: • the convenience and ease of administration compared to alternative treatments and therapies; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • the efficacy and potential advantages compared to alternative treatments and therapies; • the effectiveness of sales and marketing efforts; • acceptance in the medical and patient communities of our product candidates as a safe and effective treatments; • the cost of treatment in relation to alternative treatments and therapies, including any similar generic treatments; • our ability to offer such ~~product~~ **products** for sale at competitive prices; • the strength of marketing and distribution support; • the availability of third- party coverage and adequate reimbursement, **and as well as** patients' willingness to pay out- of- pocket in the absence of third- party coverage or adequate reimbursement; • the products' safety profile **including as compared to alternative treatments and therapies**; and • any restrictions on the use of the product together with other medications. If any of our product candidates are approved but fail to achieve market acceptance among physicians, patients, third- party payors and others in the medical community, we will not be able to generate significant revenue, which would compromise our ability to become profitable. Even if we obtain regulatory approvals for our product candidates, they will remain subject to ongoing regulatory oversight and potential enforcement actions. Even if we obtain regulatory approval in a jurisdiction, the regulatory authority may still impose significant restrictions on the indicated uses or marketing of our product candidates, or impose ongoing requirements for potentially costly post- approval ~~trials studies~~, post-market surveillance or patient or drug restrictions. Additionally, the holder of an approved BLA is required to comply with FDA rules and is subject to FDA review and periodic inspections, in addition to other potentially applicable federal and state laws, to ensure compliance with ~~current good manufacturing practices, or cGMP-~~ **GMP**, and adherence to commitments made in the BLA. If we or a regulatory agency discovers 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, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. Moreover, product labeling, advertising and promotion for any approved product will be subject to regulatory requirements, continuing regulatory review and review by other government agencies and third parties. For example, a company may not promote " off- label " uses for its drug products. An off- label use is the use of a product for an indication that is not described in the product' s FDA- approved or authorized label in the United States or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off- label uses. Although the FDA and comparable foreign regulatory agencies do not regulate a physician' s choice of drug treatment made in the physician' s independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off- label uses of products for which marketing clearance has not been issued. Failure to comply with such requirements, when and if applicable, could subject us to a number of actions

ranging from warning **or untitled** letters to product seizures or significant fines or monetary penalties, among other actions. The FDA and other agencies, including the **U. S.** Department of Justice (~~or the DOJ~~), closely regulate and monitor the marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off- label use and if we market our medicines for uses other than their respective approved indications, we may be subject to DOJ- led enforcement actions for off- label marketing. Violations of the **FDCA Food, Drug, and Cosmetic Act** and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws, which violations may result in the imposition of significant administrative, civil and criminal penalties. Any government investigation of alleged violations of laws or regulations 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 generate revenue. For additional information regarding regulatory approval and ongoing regulatory oversight, see the section titled "**Business—Government Regulation and Product Approval**," in "**Part I, Item 1. Business**" of this Annual Report on Form 10- K. Even if we obtain and maintain approval for our product candidates from the FDA, we may never obtain approval outside of the United States, which would limit our market opportunities. Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of our product candidates outside of the United States will be subject to foreign regulatory requirements governing clinical **trials studies** and marketing approval. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical **or clinical** studies ~~or clinical trials~~. In many countries outside of the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for any product candidates, if approved, is also subject to approval. **In particular, Obtaining obtaining** approval for our product candidates in the EU from the **EC European Commission** following the opinion of the EMA if we choose to submit a marketing authorization application there, would be a lengthy and expensive process. Even if a product candidate is approved, the EMA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time- consuming additional clinical **trials studies** or reporting as conditions of approval. Approval of certain product candidates outside of the United States, particularly those that target diseases that are more prevalent outside of the United States will be particularly important to the commercial success of such product candidates. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and **additional** costs for us and could delay or prevent the introduction of our product candidates in certain countries. Negative developments and negative public opinion of new technologies on which we rely may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates. The clinical and commercial success of our product candidates will depend in part on public acceptance of the use of new technologies for the prevention or treatment of human diseases. ~~For example, we use CMV, a commonly occurring virus in humans, as a vaccine vector to prevent and treat pathogens refractory to current vaccine technologies. We also use CRISPR gene editing technology as a research tool to systematically identify human genes that control infection. Public perception may be influenced by claims that CMV technology is unsafe and products incorporating this technology may not gain the acceptance of the public or the medical community, or that CRISPR gene editing technology is unethical or immoral.~~ Adverse public attitudes may adversely impact our ability to enroll clinical **trials studies**. Moreover, our success will depend upon physicians specializing in our targeted diseases prescribing, and their patients being willing to receive, our product candidates as treatments in lieu of, or in addition to, existing, more familiar, treatments for which greater clinical data may be available. Any increase in negative perceptions of the technologies that we rely on may result in fewer physicians prescribing our products or may reduce the willingness of patients to utilize our products or participate in clinical **trials studies** for our product candidates. Increased negative public opinion or more restrictive government regulations in response thereto, would have a negative effect on our business, financial condition, results of operations or prospects and may delay or impair the development and commercialization of our product candidates or demand for such product candidates. **For example, perceived or actual technical, legal, compliance, privacy, security, ethical or other issues relating to the use of AI may cause regulators' or the public' s confidence in AI to be undermined, which could impede our ability to develop products using AI.** Adverse events in our preclinical **or clinical** studies ~~or clinical trials~~ or those of our competitors or of academic researchers utilizing similar technologies, even if not ultimately attributable to product candidates we may discover and develop, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of potential product candidates we may identify and develop, stricter labeling requirements for those product candidates that are approved, a decrease in demand for any such product candidates and a suspension or withdrawal of approval by regulatory authorities of our product candidates. Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop. In addition, our insurance policies may be inadequate and potentially expose us to unrecoverable risks. We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical **trials studies** and may face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against claims that any such product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any product candidate that we may develop; • loss of revenue; • substantial monetary awards to trial participants or patients; • significant time and costs to defend the related litigation; • withdrawal of clinical trial participants; • increased insurance costs; • the inability to

commercialize any product candidate that we may develop; and • injury to our reputation and significant negative media attention. Any such outcomes could negatively impact our business, financial condition, results of operations and prospects. Furthermore, although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate **in the future**. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify such as cybersecurity- related issues; however, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Conditions in the insurance markets relating to nearly all areas of traditional corporate insurance change rapidly and may result in higher premium costs, higher policy deductibles and lower coverage limits. For some risks, we may not have or maintain insurance coverage because of **high cost and / or limited** availability. Risks Related to Regulatory Compliance Any **biologic** product candidates for which we intend to seek approval may face competition sooner than anticipated. **If Even if** we are successful in achieving regulatory approval to commercialize any **biologic** product candidate faster than our competitors, such product candidates may face competition from biosimilar **or generic** products. **In For example, in** the United States, biologic product candidates are subject to approval and licensure under the BLA pathway, **and small molecules, such as our siRNA product elebsiran, are subject to approval and licensure under the NDA pathway**. The **Biologics Price Competition and Innovation Act of 2009, or BPCIA**, creates an abbreviated pathway for the approval of biosimilar and interchangeable biologic products following the approval of an original BLA. **The Hatch- Waxman Act creates a similar pathway for seeking approval of a generic version of an approved, small molecule innovator drug product.** For additional information regarding biosimilars and exclusivity, see the section titled “**Business — Government Regulation and Product Approval — Biosimilars and Regulatory Exclusivity**” **in “ Part I, Item 1. Business ” of this Annual Report on Form 10- K**. If competitors are able to obtain marketing approval for **generics or** biosimilars referencing our licensed **small molecule or** biologic products after the expiration of applicable periods of regulatory exclusivity, our products may become subject to competition from such **generics or** biosimilars, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval. In addition, the extent to which any regulatory exclusivity may apply to competing products authorized under an EUA is unclear and may not apply. **For additional information regarding competition, see the section titled “ Business — Competition ”.** Our relationships with customers, physicians, and third- party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Healthcare providers, physicians and third- party payors in the United States and elsewhere play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third- party payors subject us to various federal and state fraud and abuse laws and other healthcare laws, such as the U. S. federal Anti- Kickback Statute, federal civil and criminal false claims laws, the healthcare fraud provisions of **the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA**, and the Physician Payments Sunshine Act. These laws may impact the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any product candidates, if approved. For additional information regarding these laws, see the section titled “**Business — Government Regulation and Product Approval**” **in “ Part I, Item 1. Business ” in this Annual Report on Form 10- K**. Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will likely continue to be costly. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government- funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant civil, criminal or administrative sanctions, including exclusions from government- funded healthcare programs. Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have an adverse effect on our ability to compete in the marketplace. If we obtain regulatory approval in the United States, coverage and adequate reimbursement may not be available for any product candidates that we commercialize, which could make it difficult for us to sell profitably. Even if we obtain regulatory approval in the United States, market acceptance and sales of any product candidates that we commercialize may depend in part on the extent to which reimbursement for these product and related treatments will be available from third- party payors, including government health administration authorities, managed care organizations and other private health insurers. Third- party payors decide which therapies they will pay for and establish reimbursement levels. While no uniform policy for coverage and reimbursement exists in the United States, third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of

reimbursement to be provided for any product candidates that we develop will be made on a payor- by- payor basis . ~~Therefore, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product.~~ Additionally, a third- party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. The position on a payor's list of covered drugs and biological products, or formulary, generally determines the co- payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third- party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. In addition, because certain of our product candidates are physician- administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may only be reimbursed for providing the treatment or procedure in which our product is used. Third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize any product candidates that we develop. Healthcare legislative reform measures may have a negative impact on our business, financial condition, results of operations and prospects. In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U. S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. We expect that additional U. S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U. S. federal government will pay for healthcare products and services, which could result in reduced demand for our current or any future product candidates or additional pricing pressures. ~~For example, in August 2022, the Inflation Reduction Act, or IRA, was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B, to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.~~ While it is currently unclear how **certain new measures, including the drug pricing provisions of the IRA** , will **ultimately** be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition . **In addition, it is unclear whether the new Trump Administration will reverse or modify any existing regulatory requirements, pursue new reform initiatives or otherwise influence the overall healthcare regulatory environment, and even if proposed, whether such changes or modifications would be implemented or withstand potential litigation** . For additional information regarding other healthcare legislative reform measures, see the ~~section sections~~ **sections** titled **"Business — Government Regulation and Product Approval — Healthcare Reform "** and **" Government Regulation and Product Approval — Pharmaceutical Prices "** in **" Part I, Item 1. Business "** in this **Annual Report on Form 10- K** . Should we seek and obtain regulatory approval in the United States, we expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, which could have an adverse effect on demand for our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. We are subject to anti- corruption, anti- bribery, anti- money laundering, and similar laws, and non- compliance with such laws can subject us to criminal and / or civil liability and harm our business. We are subject to anti- bribery and anti- money laundering laws in the countries in which we conduct activities. Anti- corruption and anti- bribery laws have been enforced aggressively in recent years and are interpreted broadly to generally prohibit companies and their employees and third- party intermediaries from authorizing, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We interact with officials and employees of government agencies and government- affiliated hospitals, universities and other organizations. In addition, we may engage third- party intermediaries to promote our clinical research activities abroad or to obtain necessary permits, licenses and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third- party intermediaries, our employees, representatives, contractors, collaborators and agents, even if we do not explicitly authorize such activities. While we have policies and procedures to address compliance with such laws in the United States, we cannot assure you that all of our employees and agents will not take actions in violation of our policies and applicable law, for which we may be ultimately held responsible. Detecting, investigating and resolving actual or alleged violations can require a significant diversion of time, resources and attention from senior management. In addition, noncompliance with anti- corruption, anti- bribery or anti- money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions,

suspension and / or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas or investigations are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, financial condition, results of operations and prospects could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Enforcement actions and sanctions could further harm our business, reputation, financial condition, results of operations and prospects.

Risks Related to Our Dependence on Third Parties We are currently conducting process development and manufacturing material for product candidates of three different therapeutic modalities: mAbs, **HCMV-based vaccines and siRNAs and TCEs**. Except for limited early- clinical phase process, analytical and formulation development, cell line development, small- scale non- GMP manufacturing for preclinical studies, and quality control testing capabilities in certain of our facilities that is either established or is currently being built, we do not own or operate facilities for full process development or product manufacturing, storage and distribution, or testing. We are dependent on third parties, including strategic collaborators and ~~contract development and manufacturing organizations, or~~ CDMOs, to develop the **large- scale** manufacturing process and manufacture the clinical supplies of our current and any future product candidates. We have established relationships with multiple third parties that have developed the **large- scale** manufacturing processes and produced material to support our preclinical, Phase 1, 2, and 3 clinical **trials studies**. We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our future product candidates. Certain of our product candidates may have to compete with existing and future products ~~, such as the annual flu vaccine,~~ that may have a lower price point. The actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates. The facilities used by our **CDMOs third party manufacturers** to develop and manufacture our product candidates must be approved by the FDA or other regulatory authorities pursuant to inspections that will be conducted after we submit our **EUA, NDA or BLA** to the FDA or foreign marketing application to the appropriate regulatory authority. We do not control the manufacturing process of, and are completely dependent on, our **CDMOs third party manufacturers** for compliance with cGMP requirements. If our **CDMOs third party manufacturers** cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or ~~others~~ **other health authorities**, we will not be able to secure and / or maintain regulatory approval for our product candidates. In addition, we have no control over the ability of our **CDMOs third party manufacturers** to maintain adequate quality control, quality assurance, qualified personnel or oversight of their subcontractors. If the FDA or a comparable foreign regulatory authority does not approve our **CDMOs third party**' s 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 impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a **CDMO third party manufacturer** could considerably delay completion of our clinical **trials studies**, product testing and potential regulatory approval of our product candidates. We also intend to rely on **CDMOs third party manufacturers** to supply us with sufficient quantities of our product candidates to be used, if approved, for commercialization. There is, however, no assurance that our **CDMOs third party manufacturers** will have sufficient manufacturing capacity to meet demand for our product candidates, meet our working assumptions of manufacturing titer and yield per batch of our product candidates or consistently manufacture product meeting our quality requirements. Any shortfall in manufacturing capacity or reduction in anticipated manufacturing titer, yield per batch or batch success rates may adversely impact our ability to meet market demand for any approved product. Furthermore, if we are not able to produce supply at low enough costs, it would negatively impact our ability to generate revenue, harm our reputation, and could have an adverse effect on our business, financial condition, results of operations and prospects. In addition, we currently rely on strategic collaborators and ~~foreign third- party~~ suppliers and CDMOs ~~, that operate outside the United States~~ and will likely continue to rely on **these organizations** strategic collaborators and foreign suppliers and manufacturers in the future. ~~Foreign~~ **Such** third - party suppliers and **CDMOs manufacturers, and third party suppliers and manufacturers operating in foreign countries, may be subject to trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. For example, the biopharmaceutical industry in China is strictly regulated by the Chinese government. Changes to Chinese regulations or government policies affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our strategic collaborators, third- party suppliers and ~~manufacturers~~ **CDMOs** operating in China which could have an adverse effect on our business, financial condition, results of operations and prospects. Evolving changes in China's public health, economic, political, and social conditions and the uncertainty around China's relationship with other governments, such as the United States and the U. K., could also negatively impact our ability to manufacture or supply our product candidates for our planned clinical **trials studies** or have an adverse effect on our ability to secure government funding, which could adversely affect our financial condition and cause us to delay our clinical development programs ~~. For example, on February 12, 2024, a group of bipartisan U. S. lawmakers sent a letter to Commerce Secretary Gina Raimondo, Treasury Secretary Janet Yellen, and Defense Secretary Lloyd Austin calling on them to investigate Chinese biotech company WuXi AppTec and its subsidiary, WuXi Biologics, one of our CDMOs, citing ties to the Chinese military, the Chinese Communist Party, and potential threats to U. S. intellectual property and national security, and requesting that U. S. agencies consider adding the companies to the U. S. Department of Defense's Chinese Military Companies List (1260H list), the Department of Commerce's Bureau of Industry and Security Entity List, and the Department of Treasury's Non- SDN Chinese Military- Industrial Complex Companies List.~~ Further, our reliance on third- party suppliers and ~~manufacturers~~ **CDMOs** entails risks to which we would not be exposed to or that may be reduced if we conducted process development or manufactured product candidates ourselves, including: • delay or**

inability to procure or expand sufficient manufacturing capacity; • delays in process development; • issues related to scale-up of manufacturing; • excess manufacturing capacity or excess raw materials due to insufficient market demand for our product candidates and responsibility for the associated costs; • costs and validation of new equipment and facilities required for scale-up; • inability of our **CDMOs** ~~third-party manufacturers~~ to execute process development, manufacturing, technology transfers, manufacturing procedures and other logistical support requirements appropriately or on a timely basis; • inability to negotiate development and manufacturing agreements with third parties under commercially reasonable terms, if at all; • **greater costs and competition for access to an increasingly smaller pool of potential CDMOs as a result of consolidation in the contract manufacturing industry**; • breach, termination or nonrenewal of development and manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; • reliance on single sources for product raw materials or components; • lack of qualified backup suppliers for those raw materials or components that are currently purchased from a sole or single-source supplier; • lack of ownership to the intellectual property rights to any improvements made by our third parties in the manufacturing process for our product candidates; • price increases or decreased availability of product raw materials or components; • disruptions to operations of our third-party suppliers and ~~manufacturers~~ **CDMO** by conditions unrelated to our business or operations, including supply chain issues, capacity constraints, transportation and labor disruptions, global competition for resources, the bankruptcy of the ~~manufacturer~~ **supplier or CDMO** and / or general economic conditions ; ~~heightened inflation~~, interest rate and currency rate fluctuations, and economic slowdown or recession; • disruptions caused by geopolitical events, including civil or political unrest, terrorism, insurrection or war (such as the ongoing ~~war between Ukraine conflicts in the Middle East and Eastern Europe~~ **Russia, and between Israel and Hamas**), **as well as** man-made or natural disasters , or public health pandemics or epidemics ; including, for example, the ~~COVID-19 pandemic~~; and • carrier disruptions or increased costs that are beyond our control, including increases in material, labor or other manufacturing-related costs or higher supply chain logistics costs. We may be unable to obtain product raw materials or components for an indeterminate period of time if any of our third-party suppliers and ~~manufacturers~~ **CDMOs** were to cease or interrupt production or otherwise fail to supply these materials or components to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier or ~~manufacturer~~ **CDMO** , failure by the supplier or ~~manufacturer~~ **CDMO** to comply with cGMP, facility outages (including due to contamination), business interruptions, or labor shortages or disputes. Suppliers and ~~manufacturers~~ **CDMOs** may extend lead times, limit supplies, change manufacturing schedules, increase prices, or require significant upfront fees due to capacity and material supply constraints or other factors beyond our control . **For example, recent increased demand for GLP- 1 therapeutics could result in increased competition for our CDMOs' services and limited capacity, which could limit our access to, and increase our costs for, manufacturing production and potentially harm our business and results of operations** . We cannot be sure that single source suppliers for our product raw materials or components will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce our product raw materials or components for our intended purpose. In addition, the lead time needed to establish a relationship with a new raw material or component supplier or ~~manufacturer~~ **CDMO** can be lengthy and we may experience delays in meeting demand in the event we must switch to a new supplier or ~~manufacturer~~ **CDMO** . The time and effort to **technology transfer to a new CDMO or** qualify a new supplier or ~~manufacturer~~ **CDMO** could result in manufacturing delays, additional costs, diversion of resources or reduced manufacturing capacity or yields, any of which would negatively impact our operating results. Furthermore, **we there are a limited number of suppliers and manufacturers that supply synthetic siRNAs**. We currently rely on a limited number of third -party suppliers and CDMOs **that are able to meet our supply requirements** for our supply of synthetic siRNAs. There are risks inherent in pharmaceutical manufacturing that could affect the ability of our CDMOs to meet our delivery time requirements or provide adequate amounts of synthetic siRNAs to meet our needs. Included in these risks are potential extended lead times, delays or shortages of raw materials and components, synthesis and purification failures and / or contamination during the manufacturing process, as well as other issues with the CDMO 's facility and ability to comply with the applicable manufacturing requirements, including cGMP requirements, which could result in unusable product. This would cause delays in our manufacturing timelines and ultimately delay our clinical ~~trials~~ **studies** and potentially put at risk commercial supply, as well as result in additional expense to us. To fulfill our siRNA supply requirements, we may need to secure alternative suppliers of synthetic siRNAs and / or key raw materials and components, and such alternative third -party suppliers are limited and may not be readily available, or we may be unable to enter into agreements with them on reasonable terms and in a timely manner. Further, alternative suppliers would require filing and regulatory approvals. ~~In addition, third-party manufacturers may have little or no experience with viral vector products and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our HCMV vector-based product candidates.~~ The challenges to HCMV-based vaccine manufacturing include the large size of the virus, which precludes terminal sterile filtration, and that some vectors have a restricted growth phenotype in cells that reduces yields during manufacturing. To address these challenges, we have made significant investments in process development and scale-up, largely funded by grants from the Bill & Melinda Gates Foundation. We have established a cGMP process in support of Phase 1 and Phase 2 clinical trials that has been successfully transferred and executed at a CDMO specializing in live vaccine manufacturing. However, the existing process will require additional process development and scale-up for later stages of clinical development and commercial supply. To fulfill our HCMV supply requirements, we may need to secure alternative suppliers and manufacturers viral vector products and / or key raw materials and components, and such alternative suppliers and manufacturers may not have the manufacturing experience or capacity required for HCMV-based vaccine manufacturing, or we may be unable to enter into agreements with them on reasonable terms and in a timely manner. Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize, manufacture or supply our current or any future product candidates once approved. Some of these events could be the basis for FDA action, including injunction, request for recall, seizure or total

or partial suspension of production. Any such recall, seizure or suspension could adversely impact our business in a variety of ways, including having to absorb related manufacturing and overhead costs as well as potential inventory write-offs. Changes in U. S. and international trade policies, particularly with respect to China, may adversely impact our business and operating results. The U. S. government has made statements and taken actions that have led to certain changes and may lead to additional changes to U. S. and international trade policies. **For example, including imposing several rounds President Trump has imposed a series of tariffs affecting on certain products manufactured outside in China. In addition, the United States Chinese government took certain actions, and it including tariffs, which affect certain products manufactured in the U. S. It is unknown whether and to what extent new-additional tariffs (or other new laws or regulations) will be adopted, or the effect that any such actions would have on us or our industry.** Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may affect the demand for our product candidates, the competitive position of our product candidates, and import or export of raw materials and product used in our drug development and clinical manufacturing activities; particularly with respect to raw materials and product that we import from China, including pursuant to our development and manufacturing arrangements with WuXi Biologics. If any new tariffs, export controls, legislation and / or regulations are implemented, or if existing trade agreements are renegotiated or if the U. S. government takes retaliatory trade actions due to the **ongoing recent U. S.- China trade tension-tensions**, such changes could have an adverse effect on our business, financial condition and results of operations. **For example, on February 12, 2024, a group of bipartisan U. S. lawmakers sent a letter to Commerce Secretary Gina Raimondo, Treasury Secretary Janet Yellen, and Defense Secretary Lloyd Austin calling on them to investigate Chinese biotech company WuXi AppTec and its subsidiary, WuXi Biologics, one of our CDMOs, citing ties to the Chinese military, the Chinese Communist Party, and potential threats to U. S. intellectual property and national security, and requesting that U. S. agencies consider adding the companies to the U. S. Department of Defense's Chinese Military Companies List (1260H list), the Department of Commerce's Bureau of Industry and Security Entity List, and the Department of Treasury's Non-SDN Chinese Military-Industrial Complex Companies List.** Our business involves the use of hazardous materials and we and **our third- party suppliers and CDMOs must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do, or interrupt our, business. Our research and development activities and the activities of our third- party manufacturers and suppliers involve the generation must comply with environmental, storage health and safety laws and regulations, use which can be expensive and restrict how we do disposal of hazardous materials, including the components of or our product candidates interrupt our, business. Our research and development activities and the other activities of hazardous compounds and wastes. We and our third- party manufacturers and suppliers involve the generation, storage, use and CDMOs disposal of hazardous materials, including the components of our product candidates and other hazardous compounds and wastes. We and our manufacturers and suppliers are subject to environmental, health and safety laws and regulations governing, among other matters, the use, manufacture, generation, storage, handling, transportation, discharge and disposal of these hazardous materials and wastes and worker health and safety.** In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our **manufacturers CDMOs**' facilities pending their use, collection, and appropriate disposal. We cannot eliminate the risk of contamination or injury, which could result in an interruption of our commercialization efforts, research and development efforts and business operations, damages and significant cleanup costs and liabilities under applicable environmental, health and safety laws and regulations. We also cannot guarantee that the safety procedures utilized by our **CDMOs third- party manufacturers** for handling and disposing of these materials and wastes generally comply with the standards prescribed by these laws and regulations. We may be held liable for any resulting damages costs or liabilities, which could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and / or interrupt our business operations. Furthermore, environmental, health and safety laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. Failure to comply with these environmental, health and safety laws and regulations may result in substantial fines, penalties or other sanctions. We do not currently carry hazardous waste insurance coverage. We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our preclinical **and clinical studies and clinical trials**, and we expect to have limited influence over their actual performance. We **also** rely on CROs to monitor and manage data for our clinical programs, as well as the execution of future preclinical **and clinical studies. We While we** expect to control only certain aspects of our CROs' activities - **Nevertheless**, we will **nevertheless** be responsible for ensuring that each of our preclinical **and clinical studies and clinical trials** is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with **the good laboratory practices, or GLPs- GLP, and GCPs- GCP**, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The regulatory authorities enforce **GCPs- GCP** through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct GLP-compliant and GCP-compliant **pre- preclinical and clinical studies and clinical trials**, we remain responsible for ensuring that each of our GLP preclinical **and clinical studies and clinical trials** is conducted in accordance with its investigational plan and protocol and applicable laws and regulations. If we or our CROs fail to comply with **GCPs- GCP**, the clinical data generated in our clinical **trials studies** may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical **trials studies** before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical **trials studies**, which would delay the regulatory approval process. Our reliance on third parties to conduct clinical **trials studies** will result in less direct control over the management of data developed through clinical **trials studies** than would be the case if we were relying entirely upon our own staff. Communicating with CROs and other third parties can be challenging, potentially

leading to mistakes as well as difficulties in coordinating activities. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines or fail to comply with regulatory requirements, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical **trials studies** may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed. ~~While we will have agreements governing their activities, our CROs will not be our employees and we will not control whether or not they devote sufficient time and resources to our future clinical and preclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities which could harm our business. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our relationship with any of these CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. While we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business, financial condition, results of operations and prospects.~~ In addition, principal investigators for our clinical **trials studies** may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval or rejection of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our product candidates.

Risks Related to Our Intellectual Property We license a number of technologies to form our antibody platform, and ~~T-cell~~ **we license the PRO- XTEN™ platform, from Sanofi and the we license** siRNA technology from Alnylam ~~Pharmaceuticals, Inc.~~ We have also developed certain product candidates using intellectual property licensed from third parties **or in- licensed certain product candidates from third parties**. A core element of our business strategy includes continuing to acquire or in- license additional technologies or product candidates for the treatment and prevention of serious infectious diseases and other serious conditions. If we fail to meet our obligations under these agreements, our licensors may have the right to terminate our licenses. If any of our license agreements are terminated, and we lose our intellectual property rights under such agreements, this may result in a complete termination of our product development and any commercialization efforts for the product candidates which we are developing under such agreements. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under such agreements, we may not be able to do so in a timely manner, at an acceptable cost or at all. We may also be subject to risks related to disputes between us and our licensors regarding the intellectual property subject to a license agreement **. We could also be subject to expensive litigation which would detract us from our core business of researching and developing product candidates**. Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and our technology. We and our licensors have sought, and intend to seek, to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and our technology that are important to our business. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file a patent application relating to any particular aspect of a product candidate. ~~Furthermore, if third parties have filed such patent applications with a priority date before March 16, 2013, an interference proceeding in the United States can be initiated by such third party, or by the U. S. Patent and Trademark Office, or USPTO, itself, to determine who was the first to invent any of the subject matter covered by the claims of our patent applications or issued patents.~~ The patent prosecution process is expensive, time- consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications or patents at a reasonable cost or in a timely manner **. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party**. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. In addition, changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the term, enforcement or defense of issued patents. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or have licensed or that we may obtain in the future **. 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. In addition, in an infringement proceeding, a court may decide that a patent**

of ours or our licensors is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. We or our licensors have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our product candidates in every country or territory in which we may sell our products, if approved. 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 infringing our patents in all countries outside of the United States, or from selling or importing products that infringe our patents in and into the United States or other jurisdictions. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued and its scope can be reinterpreted after issuance. Even if the patent applications we license or own do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In addition, if the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates, or could result in licensees seeking release from their license agreements. Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our owned and in-licensed patent rights and technology was funded in part by the U. S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. ~~When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a nonexclusive license authorizing the government to use the invention for noncommercial purposes.~~ These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U. S. industry. ~~In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States.~~ Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects. Obtaining and maintaining our patent rights depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and / or patent applications will have to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and / or applications and any patent rights we may own or license in the future. We rely on our service providers or our licensors to pay these fees. The USPTO and various non-U. S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, nonpayment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or technologies, **or if our patent rights become limited**, including as a result of geopolitical events (such as civil or political unrest ~~(the Russian Federation's recent limitations on patents originating from certain countries that have supported Ukraine,~~ including the **United States** ~~ongoing war between Ukraine and Russia and recent events in Israel)~~), we may not be able to use such patents and patent applications or stop a competitor from marketing products that are the same as or similar to our product candidates, which would have an adverse effect on our business. In many cases, 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, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business. In addition, if we fail to apply for applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patent rights. In addition, if we are responsible for patent prosecution and maintenance of patent rights in-licensed to us or out-licensed by us, any of the foregoing could expose us to liability to the applicable patent owner or licensee, respectively. Patent terms may be inadequate to protect our competitive position on our product candidates or any products approved in the future for an adequate amount of time and additional competitors could enter the market with generic or biosimilar versions of such products. Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent and the protection it affords is limited. In addition, although upon issuance in

the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our products, our competitors may be able to take advantage of our investment in development and clinical **trials studies** by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, which could adversely affect our business and results of operations. Given the amount of time required for the development, testing and regulatory review of our product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we have or will obtain patent rights. In the United States, the Hatch- Waxman Act permits a patent term extension of up to five years beyond the normal expiration of the patent, provided that the patent is not enforceable for more than 14 years from the date of drug approval, which is limited to the approved indication (or any additional indications approved during the period of extension). Furthermore, only one patent per approved product can be extended and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and **accordingly they** may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical **trials studies** by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any of our owned or in-licensed patents are successfully challenged by litigation, the affected product could immediately face competition, and its sales would likely decline rapidly. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects. Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business. Our commercial success depends, in part, upon our ability and the ability of others with whom we may collaborate to develop, manufacture, market and sell our current and any future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. ~~As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that sotrovimab and other product candidates may give rise to claims of infringement of the patent rights of others.~~ We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future product candidates and technology, including interference proceedings, derivation proceedings, post grant review and **inter partes review before the USPTO, or as counterclaims in litigation initiated by us.** If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidate (s) and technology. Under any such license, we would most likely be required to pay various types of fees, milestones, royalties or other amounts, **and any such license could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us.** Moreover, we may not be able to obtain any required license on commercially reasonable terms or at all, **including because companies that perceive us to be a competitor may be unwilling to assign or licenses rights to use,** and if such an instance arises, our ability to commercialize our product candidates may be impaired or delayed, **or we may have to abandon development of the related program or product candidate,** which could in turn significantly harm our business. Parties making claims against us may also seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. ~~The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may also pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have an adverse effect on our business, financial condition, results of operations and prospects. Furthermore, even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments.~~ We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidate. We may also have to redesign our products, which may not be commercially or technically feasible or require substantial time and expense. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. We may be required to indemnify collaborators or contractors against such claims. ~~A finding of infringement could prevent us from manufacturing and commercializing our current or any future product candidates or force us to cease some or all of our business operations, which could harm our business.~~ Even if we are successful in defending against such claims, litigation can be expensive and time- consuming and would divert management's attention from our core business. **Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios.** 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 an adverse effect on the price of our common stock. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects. We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. Certain of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or **pharmaceutical biopharmaceutical** companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications **because as a result** of the work they performed on our behalf. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties or defend claims that they may bring against us **in order** to determine the ownership of what we regard as our intellectual property. ~~We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time-consuming and unsuccessful. Competitors may infringe, misappropriate or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming and are likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our owned or licensed patents at risk of being invalidated or interpreted narrowly and could put our owned or licensed patent applications at risk of not issuing. The initiation of a claim against a third party might also cause the third party to bring counterclaims against us, such as claims asserting that our patent rights are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity 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, non-enablement or lack of statutory subject matter. The outcome following legal assertions of invalidity and unenforceability is unpredictable. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business. 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. Our business could be harmed if in litigation the prevailing party does not offer us a license, or if the license offered as a result is not on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.~~ We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business. Filing, prosecuting and defending patents covering our current and any future product candidates and technology platforms in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents, and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing. Issued patents may be challenged by third parties in the courts or patent offices in various countries throughout the world. Invalidation proceedings may result in patent claims being narrowed, invalidated or held unenforceable. Uncertainties regarding the outcome of such proceedings, as well as any resulting losses of patent protection, could harm our business. 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 **to the same degree as in the United States**, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate **outside the United States**, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Some countries do not enforce patents related to medical treatments, or limit enforceability in the case of a public emergency. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. If ~~the U. S. government, the World Trade Organization, or WTO, or other governmental body imposes an intellectual property rights waiver, our ability to successfully commercialize our COVID-19 product candidates and protect our related technology could be adversely affected. On June 17, 2022, the WTO adopted a Ministerial Decision to waive certain intellectual property rights for COVID-19 vaccines. The waiver allows certain developing countries to permit the manufacture and use of COVID-19 vaccines without the consent of the patent holder (s) to the extent necessary to address the COVID-19 pandemic. The waiver is in effect initially for five years from the date of the Ministerial Decision and will be reviewed annually. The WTO is considering whether to extend the waiver to diagnostics and therapeutics. The WTO may consider additional waivers, the ultimate timing and scope of which, if approved, are unknown. The scope and timing of such extensions and / or additional waivers will likely be subject to extensive negotiations given the complexity of the matter, which may result in prolonged uncertainty, which could adversely affect our business. If a waiver covering COVID-19 treatments or prophylactics, such as sotrovimab and VIR-7229, is approved, our ability to successfully commercialize our COVID-19 product candidates and protect our related technology could be adversely affected. The current waiver is the result of public health concerns from the COVID-19 pandemic and an effort to make vaccines more widely available worldwide. This waiver may also lead to similar waivers of intellectual property rights in the future in connection with other public health pandemics or epidemics or other situations of public health concern, or to waivers for treatments or prophylactics in addition to vaccines. Given that our business is focused on treating and preventing infectious diseases and other serious conditions, there is a risk that our business and our ability to protect our technology could be adversely affected in situations beyond COVID-19. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking intellectual property protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Because we rely on third parties to help us discover, develop and manufacture our current and any future product candidates, or if we collaborate with third parties for the development, manufacturing or commercialization of our current or any future product candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development collaborations or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. We also enter into invention or patent assignment agreements with our employees, advisors and consultants. Despite our efforts to protect our trade secrets, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third-party illegally or unlawfully obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside of the United States are sometimes less willing to protect trade secrets. ~~In addition, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. 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 could have an adverse effect on our business, financial condition, results of operations and prospects.~~ We also seek to preserve~~

the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. Additionally, the risk of cyber- attacks or other privacy or data security incidents may be heightened as a result of our **utilization of work-from-home policies for most of our employees, which provides our employees the choice of working full time in the office, a hybrid approach, or full-time remote. A remote working environment** **environments for certain employees, which** may be less secure and more susceptible to hacking attacks. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time- consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business. We rely and expect to continue to rely on trademarks as one means to distinguish any of our products and product candidates that are approved for marketing from the products of our competitors. Additionally, the process of obtaining trademark protection is expensive and time- consuming, and we may not be able to prosecute all necessary or desirable trademark applications at a reasonable cost or in a timely manner or obtain trademark protection in all jurisdictions that we consider to be important to our business. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications in certain jurisdictions, as in **a** currently pending **oppositions— opposition** filed against **the Portuguese EU-wide** registration of our VIR Pharmaceuticals house mark and logo by Industria Quimica y Farmaceutica Vir. S. A., a Spanish company which claims exclusive rights in the term VIR in Spain and Portugal **—We also have a pending opposition of the Vir logo in Turkey by Ulkar Kimya Sanayii Ve Ticaret Anonim Sirketi, a Turkish company which claims exclusive rights in the term VIR in Turkey.** Third parties may also challenge our use of our trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks. In addition, any proprietary product name we propose to use with our current or any other product candidate 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 proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. **The potential exercise by the Gates Foundation of its licenses to certain of our intellectual property and its development and commercialization of products that we are also developing and commercializing could have an adverse impact on our market position.** We entered into **the Gates Agreement in January 2022, which amends an and amended and restated restates the original** letter agreement with the **Bill & Melinda Gates Foundation, or the Gates Agreement, in January 2022, which amends and restates the letter agreement with the Bill & Melinda Gates Foundation** that we entered into in December 2016. In connection with the **Gates original letter Agreement agreement**, the **Bill & Melinda Gates Foundation** purchased \$ 20. 0 million of shares of our convertible preferred stock which converted to shares of our common stock after our initial public offering and purchased \$ 40. 0 million of shares of our common stock. We are obligated to use the proceeds of the **Bill & Melinda Gates Foundation’s** investment in furtherance of its charitable purposes to perform certain activities set forth in the Gates Agreement. For additional information regarding our obligations under the Gates Agreement, see the section titled “**Business—Our Collaboration, License and Grant Agreements — Amended and Restated Letter Agreement with the Bill & Melinda Gates Foundation”** **in “ Part I, Item 1. Business ” in this Annual Report on Form 10- K**. If we fail to comply with (i) our obligations to use the proceeds of the **Bill & Melinda Gates Foundation’s** investment for the purposes described in the paragraph above and to not use such proceeds for specified prohibited uses, (ii) specified reporting requirements or (iii) specified applicable laws, or if we materially breach our specified global access commitments (any such failure or material breach, a specified default), we will be obligated to redeem or arrange for a third party to purchase all of our stock purchased by the **Bill & Melinda Gates Foundation** under the Gates Agreement, at the **Bill & Melinda Gates Foundation’s** request, at a price equal to the greater of (1) the original purchase price or (2) the fair market value, which amount may increase in the event of a sale of our company or all of our material assets relating to the Gates Agreement. Additionally, if a specified default occurs or if we are unable or unwilling to continue the HIV program, tuberculosis program, vaccinal antibody program or, if applicable, the mutually agreed additional program (except for scientific or technical reasons), or if we institute bankruptcy or insolvency proceedings, then the **Bill & Melinda Gates Foundation** will have the right to exercise a non-exclusive, fully- paid license (with the right to sublicense) under our intellectual property to the extent necessary to use, make and sell products arising from such programs, in each case solely to the extent necessary to benefit people in the developing countries in furtherance of the **Bill & Melinda Gates Foundation’s** charitable purpose. The exercise by the **Bill & Melinda Gates Foundation** of any of its non- exclusive licenses to certain of our intellectual property (or its right to obtain such licenses), and its development and commercialization of product candidates and products that we are also developing and commercializing, could have an adverse impact on our market position. **Risks Related to Our Business Operations, Employee Matters and Managing Growth** We are highly dependent on our management, **clinical and** scientific **and medical** personnel. Our key personnel may currently terminate their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. Additionally, we do not currently maintain “ key person ” life insurance on the lives of our executives or any of our employees. We **have recently** announced **several leadership changes, including** a **new** Chief Executive **Medical** Officer transition in January 2023 that became effective April 3, 2023 and

announced a Chief Financial Officer transition in February 2023-2024 that became effective March 27, 2023. Management transitions may create uncertainty and involve a diversion of resources and management attention, be disruptive to our daily operations or impact public or market perception, any of which could negatively impact our ability to operate effectively or execute our strategies. Recruiting, integrating and retaining other senior executives, qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. **Competition is intense for these skilled employee candidates, and we may be unable to retain or recruit such personnel with the expertise or experience necessary to achieve our business objectives, and such efforts may be further undermined by restructurings, changing office policies and other initiatives we may undertake improve operational efficiencies and operating costs, as well as shifting dynamics in the biotechnology labor market.** Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. **Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.** We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Macroeconomic conditions, specifically labor shortages, increased competition for employees and wage inflation, could also have a material impact on our ability to attract and retain talent, our turnover rate and the cost of operating our business. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited. Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations. We have in the past and may in the future acquire or invest in other companies or technologies, which could divert our management's attention, result in dilution to our stockholders and otherwise disrupt our operations and adversely affect our operating results. We have in the past and may in the future seek to acquire or invest in additional businesses and / or technologies that we believe complement or expand our product candidates, enhance our technical capabilities or otherwise offer growth opportunities in the United States and internationally. The pursuit of potential acquisitions and investments may divert the attention of management and cause us to incur various expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. In addition, we are exposed to market risks related to our investments, including changes in fair value of equity securities we hold, which is discussed in greater detail under in **" Part I, Item 7A-3. Quantitative and Qualitative Disclosures About Market Risk "** in this Annual Report on Form 10-K. For example, we acquired **numerous biotechnology companies between** ~~TomegaVax, Inc., or TomegaVax, in September 2016, Humabs BioMed SA, or Humabs, in August 2017, Agenovir Corporation, or Agenovir, in January 2018 and Statera Health, LLC, or Statera, in February 2018.~~ Realizing the benefits of these acquisitions will depend upon the successful integration of the acquired technology into our existing and future product candidates. We also may not realize the anticipated benefits from any acquired business. We face many risks in connection with acquisitions and investments, whether or not consummated. A significant portion of the purchase price of companies we acquire may be allocated to acquired goodwill and other intangible assets, which must be assessed for impairment at least annually. If our acquisitions do not yield expected returns, we may in the future be required to take charges to our operating results based on this impairment assessment process, which could adversely affect our business, financial condition, results of operations and prospects. Furthermore, acquisitions could also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our business, financial condition, results of operations and prospects may suffer. We cannot assure you that we will be successful in integrating the businesses or technologies we may acquire. The failure to successfully integrate these businesses could have a material adverse effect on our business, financial condition, results of operations and prospects. We have **in the past** experienced **significant, and expect to continue to experience,** growth in the **number of our employees and the scope of our operations in recent years at both our sites and remote locations,** particularly in the areas of research, development and regulatory affairs, **and we expect to continue to experience growth as the clinical development of our product candidates progresses.** In addition, if any of our product candidates receives marketing approval, we will need to build out our sales and marketing capabilities, either on our own or with others. To manage **any our anticipated** future growth, we must continue to implement and improve our managerial, operational and financial systems, **expand improve** our facilities, and continue to recruit and train additional qualified personnel. **As a result of the global pandemic resulting from COVID-19, the majority of our workforce began working from home in March 2020. In April 2022, we reopened our offices to allow employees to return to work, and we now offer all our employees the choice of working full-time in the office, a hybrid approach, or full-time remote. Despite this, we must continue to effectively integrate, develop and motivate a growing number of new employees, and maintain the beneficial aspects of our corporate culture.** The expansion of our operations may lead to significant costs and may divert our management and business development resources. We may not be able to effectively manage **the any further** expansion of our operations, recruit and train additional qualified personnel, or succeed at effectively integrating employees **into that joined during the global pandemic or our operations** otherwise joined us as remote workers. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations, and those of our CDMOs, **clinical trial sites,** CROs and other

contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, public health pandemics or epidemics (including, for example, the COVID-19 pandemic), geopolitical events, including civil or political unrest in any of our business locations, terrorism, insurrection or war (such as the ongoing war between Israel **conflicts in the Middle East** and **Eastern Europe** **Hamas and Ukraine and Russia**), and **as well as** other ~~natural or man-made disasters~~ or business interruptions, for which we are predominantly self-insured. 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 develop our product candidates could be disrupted if our operations or those of our suppliers are affected by **such** geopolitical events, ~~man-made or natural~~ disasters or other business interruptions. Our corporate headquarters are located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster. ~~Our business could be materially adversely affected by the effects of public health outbreaks, pandemics or epidemics, including the COVID-19 pandemic and future pandemics. Our business could be materially adversely affected by the effects of public health outbreaks, pandemics or epidemics, including the COVID-19 pandemic, the evolution of new and existing variants or subvariants of COVID-19 that are resistant to existing treatments or vaccinations and any future pandemics. Public health outbreaks, pandemics or epidemics pose the risk that we or our employees, contractors, suppliers, CDMOs or other partners may be prevented from conducting business activities for an indefinite period of time due to spread of the disease, or due to shutdowns that may be requested or mandated by federal, state and local governmental authorities. Business disruptions could include restrictions on our ability to travel, quarantine orders, temporary closures of our facilities or the facilities of our contractors, suppliers, CDMOs and other partners and other restrictions by governments to reduce the spread of the disease. The effects of these business disruptions may negatively impact productivity, limit our ability to obtain sufficient materials, raise the cost of materials (or otherwise disrupt our supply chain) and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of such business disruptions. For example, our clinical trials were affected by the COVID-19 pandemic. Site initiation and patient enrollment were delayed due to prioritization of hospital resources toward the COVID-19 pandemic, and, if there are future quarantines which impede patient movement or interrupt healthcare services, some patients may not be able or willing to comply with clinical trial protocols. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, was delayed or disrupted, which had adversely impacted our clinical trial operations. The public health emergency declarations related to COVID-19 ended on May 11, 2023. In addition, the FDA ended 22 COVID-19-related policies when the public health emergency ended on May 11, 2023, and the FDA allowed 22 related policies to continue for 180 days. The FDA plans to retain 24 COVID-19-related policies with appropriate changes and four policies whose duration is not tied to the end of the public health emergency. However, at this point, it is unclear how, if at all, these developments will impact our efforts to develop and commercialize our product candidates. We continue to monitor our operations and applicable government recommendations, and we have made lasting modifications to our normal operations because of the COVID-19 pandemic. We now offer all of our employees the choice of working full time in the office, a hybrid approach, or full-time remote. Coming into the office remains voluntary, unless a person's role requires them to be on site to do their job. As a result, we expect to continue to be subject to the challenges and risks of having a remote workforce, as well as new challenges and risks from operating with a hybrid workforce. For example, our employees are accessing our servers remotely through home or other networks to perform their job responsibilities. Such security systems may be less secure than those used in our offices, which may subject us to increased security risks, including cybersecurity-related events, and expose us to risks of data or financial loss and associated disruptions to our business operations. Additionally, employees who access company data and systems remotely may not have access to technology that is as robust as that in our offices, which could place additional pressure on our user infrastructure and third parties that are not easily mitigated. We may also be exposed to risks associated with the locations of remote employees, including compliance with local laws and regulations or exposure to compromised internet infrastructure. Allowing our employees to work remotely may create intellectual property risk if employees create intellectual property on our behalf while residing in a jurisdiction with unenforced or uncertain intellectual property laws. Further, if employees fail to inform us of changes in their work location, we may be exposed to additional risks without our knowledge. Additionally, operating our business with both remote and in-person workers could have a negative impact on our corporate culture, decrease the ability of our workforce to collaborate and communicate effectively, decrease innovation and productivity, or negatively affect workforce morale. If we are unable to manage cybersecurity and other risks of a flexible first workforce model, and maintain our corporate culture and workforce morale, our business could be harmed or otherwise adversely impacted.~~ Our computer and information technology systems, cloud-based computing services and those of our current and any future collaborators, service providers and other parties upon whom we rely are potentially vulnerable to malware, computer viruses, denial-of-service attacks, ransomware attacks, user error or malfeasance, data corruption, cyber-based attacks, natural disasters, public health pandemics or epidemics, geopolitical events, including civil or political unrest, terrorism, war and telecommunication and electrical failures that may result in damage to or the interruption or impairment of key business processes, or the loss or corruption of our information, including intellectual property, proprietary business information and personal information. We may also experience server malfunction, software or hardware failures, supply-chain cyber-attacks, loss of data or other computer assets and other similar issues. We have experienced minor or inconsequential security breaches of our information technology systems, such as through attempted business email compromises. The techniques used to sabotage or to obtain unauthorized access to information systems, and networks in which cyber threat actors store data or through which they transmit data change frequently and we may be unable to implement adequate preventative measures. For example, attackers have used **AI artificial intelligence and machine learning** to

launch more automated, targeted and coordinated attacks against targets. Any significant system failure, accident or security breach could have a material adverse effect on our business, financial condition and operations. We may be required to expend significant resources, fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against security breaches and to detect, **investigate** (including performing required forensics), mitigate and remediate actual and potential vulnerabilities. Relevant laws, regulations, industry standards and contractual obligations may require us to implement specific security measures or use industry- standard or reasonable measures to protect against security breaches. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs, security breaches and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, data loss or corruption, delays, cessation of service and other harm to our business and our competitive position. If the information technology systems of our third- party vendors become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Although we maintain cybersecurity insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. Furthermore, if a security breach were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. In addition, such a breach may require notification to governmental agencies, supervisory bodies, credit reporting agencies, the media, individuals, collaborators or others pursuant to various federal, state and foreign data protection, privacy and security laws, regulations and guidelines, industry standards, our policies and our contracts, if applicable. In addition, the U. S. Securities and Exchange Commission adopted rules in 2023 requiring us to publicly disclose certain cybersecurity incidents. Such notices **may be costly and** could harm our reputation and our ability to compete. ~~Such disclosures are costly, and the our ultimate~~ disclosure ~~or the failure to comply with such requirements could lead to a material adverse effect on our reputation, business, or financial condition.~~ Additionally, federal, state and foreign laws and regulations can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail. We **and the third parties with whom we work** are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure **by us or the third parties with whom we work** to comply with such requirements could subject us to significant fines and penalties, **investigations and / or reputational harm**, which may have a material adverse effect on our business, financial condition or results of operations. We **and the third parties with whom we work** are subject to local, state, federal and international data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the United States, EU and the U. K. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Additionally, our use of AI and machine learning may be subject to laws and evolving regulations regarding the use of AI ~~or machine learning~~, controlling for data bias, and anti- discrimination. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. Failure **by us or any of the third parties with whom we work** to comply with any of these laws and regulations could result in **investigations or enforcement action against us, including fines, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.** If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, we could face civil and criminal penalties **, and claims that we failed to comply with privacy laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, result in adverse publicity and have a material adverse effect on our business, financial condition and results of operations.** Numerous ~~At least twelve~~ states in the U. S., including California, **Colorado, Oregon, Texas, Utah and Virginia, among others**, have passed comprehensive privacy laws. ~~These and other states are considering passing such~~ laws are either in effect or will go into effect sometime before the end of 2026. These laws create obligations related to the processing of personal information, as well as special obligations for the processing of “ sensitive ” data (which includes health data in some cases). ~~There are also states that are strongly considering or have already passed comprehensive~~ **At the federal level, HIPAA imposes specific requirements on certain types of individuals and entities relating to the** privacy laws during the 2023 legislative sessions that will go into effect in 2024 and beyond. ~~security including New York and New Jersey~~ **transmission of individually identifiable health information.** Congress has also ~~considered~~ ~~been debating~~ passing a federal privacy law. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe and other countries. The collection, use, disclosure, transfer or other processing of personal data, including personal health data, regarding individuals who are located in the ~~European Economic Area, or EEA~~, and the processing of personal data that takes place in the EEA, is regulated by the GDPR, ~~which went into effect in May 2018 and~~ which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross- border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our collaboration partners’ or service providers’ privacy or data

security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and / or fines of up to €20 million Euros or up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill. **In addition, we may be unable to transfer personal data from EEA countries and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Although there are various mechanisms that may be used in some cases to lawfully transfer personal data to the United States or other countries, these mechanisms are subject to legal challenges and may not be available to us. An inability or material limitation on our ability to transfer personal data to the United States or other countries could materially impact our business operations.** While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. **Any Failure failure to comply with U. S. federal and state and international laws and regulations regarding data protection-privacy would expose us to risk of enforcement actions taken by data protection authorities, in the EEA and elsewhere and carries with it them the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure failures to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, private lawsuits asserting claims for damages or other liabilities, regulatory investigations and potentially enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects. Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and, insider trading laws, or contractual obligations.** We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures, reckless and / or negligent conduct or unauthorized activities that violates (i) the laws and regulations of FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad, (iv) laws that require the true, complete and accurate reporting of financial information or data and, (v) insider trading laws that restrict the buying and selling of shares of securities our common stock while in possession of material non-public information, (vi) **federal and state data privacy laws and regulations and (vii) contractual obligations of VirBio or such parties.** In particular, sales, marketing and 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. Such misconduct also could involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials studies, creating fraudulent data in our preclinical **lor clinical studies or clinical trials** or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. **In addition, during the course of our operations, our directors, executives and employees may have access to material non-public information regarding our business, our results of operations or potential transactions we are considering. We may not be able to prevent a director, executive or employee from violating our insider trading policies and buying or selling, or “tipping” others who might buy or sell, shares of our common stock on the basis of, or while having access to, material non-public information. If a director, executive or employee was to be investigated, or an enforcement action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and our stock price.** It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these **contractual provisions, laws or regulations.** Additionally, we are subject to the risk that a person or government could allege such fraud, **violations** 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 result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects. Our ability to use our net operating losses, or NOLs, to offset future taxable income may be subject to certain limitations. As of December 31, **2023-2024**, we had net operating loss carryforwards of \$ **487-645.0-3** million for federal tax purposes and \$ **415-450.4-2** million for state tax purposes. If not utilized, federal carryforwards will begin expiring in 2036 and state carryforwards will begin expiring in 2031. Our ability to use our federal and state NOLs to offset potential future taxable income is dependent upon our generation of future taxable income before any expiration dates of the NOLs, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs. Beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures currently and requires taxpayers to capitalize and amortize them over five or fifteen years pursuant to Section 174 of the Internal Revenue Code of 1986, as amended, or the Code. Although Congress is considering legislation that could repeal such requirement or

defer the amortization requirement to later years, it is not certain that the provision will be repealed or otherwise modified. If the requirement is not modified, it will continue to reduce our anticipated net operating losses over the next several years.

Risks Related to Ownership of Our Common Stock Our financial condition and results of operations may fluctuate from quarter to quarter and year to year, which makes them difficult to predict. We expect our financial condition and results of operations to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance. Factors that may cause fluctuations in our financial condition and results of operations include, without limitation, those listed elsewhere in this “ Risk Factors ” section and those listed below: • the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which will change from time to time; • the cost of manufacturing our product candidates and any future product candidates, which may vary depending on FDA, EMA or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers; • expenditures that we will or may incur to acquire or develop additional product candidates and technologies or other assets; • the timing and outcomes of preclinical studies and clinical trials for our product candidates; • the need to conduct unanticipated clinical trials or clinical trials that are larger or more complex than anticipated; • competition from existing and potential future products that compete with our product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners; • any delays in regulatory review or approval of our product candidates; • the level of demand for any of our product candidates, if approved, which may fluctuate significantly and be difficult to predict; • the risk / benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with our product candidates; • our ability to commercialize our product candidates, if approved, inside and outside of the U. S., either independently or working with third parties; • our ability to adequately support future growth; • potential unforeseen business disruptions that increase our costs or expenses; • future accounting pronouncements or changes in our accounting policies; and • the changing and volatile global economic and political environment both inside and outside the U. S., including heightened inflation, capital market volatility, interest rate and currency rate fluctuations, and economic slowdown or recession.

In addition, our collaboration revenue and certain assets and liabilities are subject to foreign currency exchange rate fluctuations due to the global nature of our operations. As a result, currency fluctuations among our reporting currency, the U. S. dollar, and other currencies in which we do business will affect our operating results, often in unpredictable ways. Currency exchange rates have been especially volatile in the recent past, and these currency fluctuations have affected, and may continue to affect, our assets and liabilities denominated in foreign currency. We are also exposed to market risks related to our investments, including changes in fair value of equity securities we hold which may fluctuate from quarter to quarter and year to year. For additional information, see “ Part II, Item 7A. Quantitative and Qualitative Disclosures About Market Risk ” in this Annual Report on Form 10- K. Our stock price has been, and in the future, may be, subject to substantial volatility. Accordingly From October 11, 2019, our first day of trading on The Nasdaq Global Select Market, or Nasdaq, through February 16, 2024, the closing price of our stock ranged from \$ 7. 76 per share to \$ 83. 07 per share. As a result of the volatility in our stock price, our stockholders could incur substantial losses. The stock market in general and the market for biopharmaceutical and pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The COVID-19 pandemic Investor concerns regarding financial systems and general economic conditions, both inside and outside for example, negatively affected some sectors of the stock U. S., including capital market markets and investor sentiment and resulted in significant volatility. In addition, economic trends and other external factors including, but not limited to, heightened inflation, interest rate and currency rate fluctuations, and economic slowdown or recession, capital markets volatility as well as geopolitical events, man- made or natural foreign market trends, national crisis, and disasters, or public health pandemics or epidemics, may impact the market price of our common stock and result in volatility. As a result of this volatility, you may not be able to sell your common stock at or above the price you paid for your shares. Market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock. Moreover, sales of a substantial number of shares of our common stock by our stockholders in the public market or the perception that these sales might occur, have in the past, and may in the future depress the market price of our common stock. Information related to our research, development, manufacturing, regulatory and commercialization efforts with respect to any of our product candidates or information regarding such efforts by competitors with respect to their potential therapies, may also meaningfully impact our stock price. Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time- consuming and could divert our management’ s attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock. Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions. Our executive officers, directors and stockholders who own more than 5 % of our outstanding common stock beneficially own a significant percentage of our outstanding common stock. If these persons acted together, they may be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. The concentration of voting power and transfer restrictions could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in the management of our company in ways

with which other stockholders disagree. If research analysts ~~do not publish research or reports, or~~ publish unfavorable research or reports about us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock ~~will~~ **may** be influenced by ~~the~~ research and reports that industry or financial analysts publish about us ~~or~~, our business **or the potential markets for our products or product candidates**. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance **(including changes in analyst recommendations or price targets for our stock)**, or if the clinical ~~trials~~ **studies** and operating results fail to meet the expectations of analysts, our stock could decline. ~~If~~ **In addition, if** analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. You should not rely on an investment in our common stock to provide dividend income. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain in the foreseeable future. We have incurred and we will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives. As a public company, we ~~are subject~~ **have incurred and we will continue to incur significant legal, accounting, investor relations and other** ~~the~~ **expenses. In addition reporting requirements of the Exchange Act, the listing standards of Nasdaq**, the Sarbanes-Oxley Act and **other applicable securities** rules subsequently implemented by SEC and Nasdaq **regulations. We have incurred** imposed various requirements on public companies, including establishment and **will continue to incur significant legal** maintenance of effective disclosure and financial controls and corporate governance practices. Further, **accounting** in July 2010, **investor relations and the other expenses** Dodd-Frank Wall Street Reform and Consumer Protection Act was enacted, pursuant to which **comply with the these** SEC adopted rules and regulations related to corporate governance and executive compensation, such as “say on pay” and proxy access. Stockholder activism, the current political environment and the current high level of U. S. government intervention and regulatory reform may also lead to substantial new regulations and disclosure obligations, which may in turn lead to additional compliance costs and impact the manner in which we operate our business in ways we do not currently anticipate. Our management and other personnel will need to devote a substantial amount of time to comply with these requirements. Moreover, these requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. ~~As a public company, we may also be subject to more stringent state law requirements, such as California Senate Bill 826, which generally requires public companies with principal executive offices in California to have a minimum number of females on the company’s board of directors, and California Assembly Bill 979, which generally requires public companies with principal executive offices in California to include specified numbers of directors from “underrepresented communities.” We are currently compliant with the requirements, but there are no assurances that we will be compliant in the future. Both Senate Bill 826 and Assembly Bill 979 have been challenged in legal proceedings and there is uncertainty whether the courts will uphold Senate Bill 826 or Assembly Bill 979. If we fail to comply with either Senate Bill 826 or Assembly Bill 979, we could be fined by the California Secretary of State, with a \$ 100, 000 fine for the first violation and a \$ 300, 000 for each subsequent violation, and our reputation may be adversely affected.~~ If we fail to develop or maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in us and the trading price of our common stock may decline. Effective internal control over financial reporting are necessary for us to provide reliable financial reports and effectively prevent fraud and operate successfully as a public company. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If our internal control over financial reporting is not effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting could also restrict our future access to the capital markets. A material weakness in internal control over financial reporting has in the past and could in the future lead to deficiencies in the preparation of financial statements. Deficiencies in the preparation of financial statements, could lead to litigation claims against us. The defense of any such claims may cause the diversion of management’s attention and resources, and we may be required to pay damages if any such claims or proceedings are not resolved in our favor. Any litigation, even if resolved in our favor, could cause us to incur significant legal and other expenses. Such events could also affect our ability to raise capital to fund future business initiatives. Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the Sarbanes-Oxley Act, the requirements of being a reporting company under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and any complex accounting rules in the future, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the United States. Generally accepted accounting principles in the United States are subject to interpretation by the Financial Accounting Standards Board or the SEC, and various bodies formed to promulgate and interpret appropriate accounting principles. A change in these principles or interpretations could have a

significant effect on our reported financial results, may retroactively affect previously reported results, could cause unexpected financial reporting fluctuations and may require us to make costly changes to our operational processes and accounting systems. Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our corporate charter and our **amended and restated** bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. ~~For a summary of these provisions, see the section titled “Anti-Takeover Provisions of Delaware Law and Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws — Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws” in Exhibit 4.3 Description of Capital Stock, as updated by our Amended and Restated Bylaws filed herewith as Exhibit 3.2.~~ Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: • any derivative action or proceeding brought on our behalf; • any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; • any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws; • any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and • any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U. S. federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act of 1933, as amended ~~(, or the Securities Act ,)~~ creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, unless we consent in writing to the selection of an alternative forum. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions ~~. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation.~~ This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. These exclusive- forum provisions may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies’ certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the exclusive- forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could harm our business.