Risk Factors Comparison 2025-03-11 to 2024-04-01 Form: 10-K

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The following information sets forth risk factors that could 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. You should carefully consider the risks described below, in addition to the other information contained in this Annual Report on Form 10- K and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations. Risks Related to Our Limited Operating History, Financial Position and Capital Requirements Our recurring losses from operations raise substantial doubt regarding our ability to continue as a going concern. If we are unable to raise sufficient additional capital in the near term, we **will** ~~may in the future~~ need to implement additional cost reduction strategies, which could include delaying, limiting, reducing or eliminating both internal and external costs related to our operations and research and development programs. As of December 31, ~~2023~~ **2024** , we had cash and cash equivalents of $ ~~44~~ **55** . ~~7~~ **3** million. Based on our current operating plans, we anticipate that our cash and cash equivalents as of December 31, ~~2023~~ **2024** , together with ~~(i)~~ the $ ~~30~~ **52** . 0 million **in** upfront ~~payment~~ **payments** ~~under~~ **received in** the ~~license~~ **first quarter of 2025 in connection with our collaboration** agreement with ~~Gilead Sciences~~ **AbbVie Group Holdings Limited** , ~~Inc., or Gilead, (ii) the approximately $ 13. 5 million in proceeds from the initial private placement with Gilead, which closed on March 28, 2024, and (iii) the approximately $ 11. 3 million in gross proceeds from our~~ **or AbbVie** ~~private placement, which is expected to close on April 2, 2024 (subject to customary closing conditions), and after giving effect to (a) one- time costs and anticipated future cost savings associated with our strategic portfolio reprioritization and workforce reduction announced in March 2024 and (b) the repayment in the first quarter of 2024 of the outstanding loan balance under our loan and security agreement with Pacific Western Bank~ , will be sufficient **to enable us** to fund our operating expenses and capital expenditure requirements into the ~~second~~ **first** quarter of ~~2025~~ **2026** . However, since these amounts ~~may~~ **are** not **expected to** be sufficient to fund our operations for at least twelve months from the date of issuance of the consolidated financial statements included elsewhere in this Annual Report on Form 10- K, ~~the~~ **there is** ~~report from our independent registered public accounting firm for the year ended December 31, 2023 includes an explanatory paragraph stating that our losses from operations and required additional funding to finance our operations raise~~ substantial doubt about our ability to continue as a going concern. Our future capital requirements and the period for which we expect our existing resources to support our operations may vary from what we expect ~~, and we may not achieve the expected savings that we anticipate as a result of our recent portfolio reprioritization and workforce reduction~~ . Our management has developed plans to continue to fund our operations, which primarily consist of raising additional capital through one or more of the following: additional equity or debt financings; additional collaborations, partnerships or licensing transactions; or other sources. However, there can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise, and we may be unable to obtain sufficient additional capital in the near term. If we are not able to secure sufficient additional capital, we **will** ~~may in the future~~ need to implement additional cost reduction strategies, which could include delaying, limiting, further reducing or eliminating both internal and external costs related to our operations and research and development programs. **If we are unsuccessful in our efforts in the near term to raise additional capital** ~~For~~ **or** ~~example,~~ in ~~March 2024, we announced that we would discontinue further investment in~~ the **future** ~~development of XTX202 as a monotherapy and would undergo a workforce reduction~~ to ~~further reduce~~ **engage in one** ~~our~~ **or** ~~expenses and streamline~~ **more other strategic alternatives, we could be required to liquidate, dissolve or otherwise wind down** our operations ~~, which workforce reduction we estimate will be substantially completed in the first half of 2024~~ . Furthermore, our cash forecasts are based on assumptions that may prove to be wrong, and we could use our available capital resources earlier than we currently expect ~~. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may exhaust our available capital sooner than planned~~ . Please see Note 1 to our consolidated financial statements appearing elsewhere in our Annual Report on Form 10- K for additional information on our assessment. We expect to continue to incur operating losses in connection with our ongoing research and development activities, particularly as we advance our product candidates through clinical trials, maintain the infrastructure necessary to support these activities and incur costs associated with operating as a public company. **We** ~~Our revenue, if any, will be derived from sales of products that we~~ do not expect to ~~be commercially available~~ **generate any revenue from the sale of products** for a number of years, if at all **, and any such revenue will not be realized unless and until we obtain marketing approval for and successfully launch and commercialize a product candidate** . If we obtain marketing approval for any current or future product candidates that we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Some of these expenses may be incurred in advance of marketing approval and could be substantial. Our future capital requirements, both short- term and long- term, will depend on many factors, including: ● our ability to implement and maintain further cost reduction strategies, as well as the timing of such cost reductions; ● the scope, progress, results and costs of research and development for our current and future product candidates, including our ongoing and planned clinical trials for our clinical- stage product candidates; ● the scope, prioritization and number of our research and development programs; ● the progress of the development efforts of parties with whom we have entered or may in the future enter into collaboration agreements; ● the timing and amount of payments we may receive or are obligated to pay under our collaboration agreements and license agreements; ● the scope, costs, timing and outcome of regulatory review of our product candidates; ● the costs of

expanding manufacturing capacity through third- party manufacturers and securing manufacturing materials for use in preclinical studies, clinical trials and, for any product candidates for which we receive regulatory approval, if any, use as commercial supply; ● the costs and timing of future commercialization activities for any of our product candidates for which we receive regulatory approval; ● the amount and timing of revenue, if any, received from commercial sales of any product candidates for which we receive regulatory approval; ● the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property- related claims; ● the extent to which we may acquire or in- license other products, product candidates, technologies or intellectual property, as well as the terms of any such arrangements; **45** ● our ability to maintain our current collaborations **and partnership** , including our clinical collaboration **with F. Hoffman- La Roche Ltd., or Roche,** to ~~further~~ develop **vilastobart (** XTX101 **)** , our **masked** ~~tumor- activated~~ , Fc- enhanced anti- CTLA- 4 **monoclonal antibody, or mAb** , in combination with atezolizumab, ~~including~~ **our license agreement with Gilead Sciences, Inc., or Gilead, to develop XTX301, our masked, engineered interleukin 12, or IL- 12, product candidate, and our collaboration agreement with AbbVie Group Holdings Limited, or AbbVie, to develop tumor- activated immunotherapies; ●** the **timing and amount of** cost- sharing ~~arrangements of such~~ **payments under our clinical** collaboration ~~,~~ **with Roche for vilastobart; ● the timing** and **amount of milestones, option- related fees and other contingent payments under** our ~~partnership~~ **license agreement** with Gilead for XTX301 ~~;●~~ ~~the timing~~ and ~~amount of milestones, equity investments and other contingent payments under~~ our ~~partnership~~ **collaboration agreement** with ~~Gilead~~ **AbbVie** for ~~XTX301~~ **tumor- activated immunotherapies** ; ● the costs of maintaining our operations and continuing to operate as a public company; and ● whether we are able to overcome the substantial doubt about our ability to continue as a going concern. We will require additional capital to sustain our operations. We currently do not have any committed external sources of funds and adequate additional capital may not be available to us on acceptable terms, or at all. In addition, our ability to raise additional capital may be adversely impacted by potential worsening economic conditions, both inside and outside the United States, including without limitation heightened inflation, capital market volatility, interest rate and currency rate fluctuations, any potential economic slowdown or recession, future pandemics, geopolitical tensions, including trade ~~50wars~~ -- **wars** or civil or political unrest, or wars or other armed conflicts. We can give no assurance that we will be able to secure additional capital to support our operations, or if such funds are available to us, that such additional funding will be sufficient to meet our needs. These factors raise substantial doubt about our ability to continue as a going concern, and our failure to raise capital, on attractive terms or at all, would have a material adverse effect on our business, results of operations and financial condition. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to product candidates or our technology. Unless and until we can generate a substantial amount of product revenue, we expect to seek additional capital through a combination of public or private equity offerings, debt, collaborations, licensing arrangements or other sources. Our issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our common stock to decline, and our stockholders may not agree with our plans for additional capital or the terms of such capital. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. For example, ~~(i)~~ when ~~we issue shares of common stock in connection with the March 2024 private placement, which private placement is expected to close on April 2, 2024 (subject to customary closing conditions), or if~~ we issue shares of common stock upon the exercise of ~~the~~ **our outstanding** prefunded warrants ~~to be issued in connection with the March 2024 private placement~~ , or ~~(ii)~~ if we issue **additional** shares of **our** common stock in **one** ~~connection with the sale of additional shares of our~~ - **or more " at-** ~~common stock or prefunded warrants to Gilead in up to three~~ -- **the** ~~potential private placements~~ **- market, " or ATM, offerings** , our existing stockholders will suffer dilution. In addition, as a condition to providing additional funds to us, Gilead **and AbbVie** received, and future investors may receive, rights superior to those of existing stockholders. To the extent that we incur additional indebtedness, we would become obligated to make payments to repay the loan balance with interest. The incurrence of any additional indebtedness would result in additional payment obligations and is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, would be repaid before holders of our equity securities received any distribution of our corporate assets. Additionally, in raising funds through our collaborations and licensing arrangements with third parties, we have had to, and may in the future need to, relinquish valuable rights, partially or fully, to our technologies, future revenue streams, research programs or product candidates and grant licenses on terms unfavorable to us. In addition, securing additional capital would require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day- to- day activities, which may adversely affect our management' s ability to oversee the development of our product candidates. ~~If~~ **46If in the future** we fail to **comply** ~~regain compliance~~ with the continued listing requirements of Nasdaq, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted. **We are required to comply with** ~~On January 19, 2024, we received a deficiency letter from~~ the **continued** ~~Listing~~ **listing requirements** ~~Qualifications Department, or the Nasdaq Staff,~~ of the Nasdaq Stock Market LLC, or Nasdaq, ~~notifying~~ **including, among other things, maintaining a minimum closing bid price of $ 1. 00 per share, referred to as the minimum bid price requirement, or shares of our common stock may be subject to delisting, which would have a material adverse effect on our business. In September 2024, we received a deficiency letter from the Listing Qualifications Department, or the Nasdaq Staff, informing** us that ~~,~~ ~~for~~ **we were not in compliance with** the ~~last 30 consecutive business days,~~ **continued listing requirements of the Nasdaq Global Select Market because** the bid price for our common stock had closed below $ 1. 00 per share **for 30 consecutive business days. In January 2025** , **we received written notification from** ~~which is the minimum bid price required to maintain continued listing on~~ the Nasdaq ~~Global Market, referred to as~~ **Staff informing us that we had regained compliance with** the minimum bid price requirement **as a result** ~~. In accordance with Nasdaq Listing Rules, we have an initial period~~ of **our common**

stock maintaining a closing bid price of $ 1. 00 per share or greater for at for at least ~~180~~ **10** ~~calendar~~ **consecutive business** days **. However** , ~~or until July 17, 2024,~~ **there can be no assurance that we will be able** to ~~regain~~ **continue to maintain** compliance with the minimum bid price requirement ~~. If, at any time before July 17, 2024, the closing bid price for~~ **or** ~~our common stock is at least $ 1. 00 per share for a minimum of 10 consecutive business days, the Nasdaq Staff will provide written notification to us that we are in compliance with the minimum bid price requirement, unless the Nasdaq Staff exercises its discretion to extend this 10- day period pursuant to the Nasdaq Listing Rules. If we do not regain compliance with the minimum bid price requirement by July 17, 2024, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would need to transfer the listing of our common stock to the Nasdaq Capital Market, provided that we meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards, with the exception of the minimum bid price requirement. To effect such a transfer, we would also need to pay an application fee to Nasdaq and would need to provide written notice to the Nasdaq Staff of our intention to cure the deficiency during the additional compliance period. 51If it appears to the Nasdaq Staff that we will not be able to cure the deficiency during the second compliance period or if we do not meet the other listing standards, the Nasdaq Staff will provide us with notice that our common stock may be delisted. At that time, we may appeal the Nasdaq Staff' s delisting determination to a Nasdaq Listing Qualifications Panel. We expect that our common stock would remain listed pending the panel' s decision. However, there can be no assurance that, even if we appeal the Nasdaq Staff' s delisting determination to the panel, such appeal would be successful. We intend to monitor the closing bid price of our common stock and may, if appropriate, consider available options to regain compliance with the minimum bid price requirement, which could include seeking to effect a reverse stock split. However, there can be no assurance that we will be able to regain compliance with the minimum bid price requirement, secure a second period of 180 days to regain compliance, or maintain compliance with** any of the other Nasdaq continued listing requirements. **Any potential** ~~If we are unable to comply with applicable Nasdaq listing~~ **delisting** ~~standards, shares~~ of our common stock ~~would be subject to delisting, which~~ could have a material adverse effect on the market for, and liquidity and price of, our common stock and would adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from Nasdaq could also have other negative results, including, without limitation, the potential loss of confidence by investors, customers and employees and fewer business development opportunities. Any delisting of our common stock from Nasdaq would also make it more difficult for our stockholders to sell their shares of our common stock in the public market. We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We have incurred significant operating losses since our inception and have not yet generated any revenue **from the sale of products** . If our product candidates are not successfully developed and approved, we may never generate any revenue **from product sales** . Our net losses were $ **58. 2 million and $** 76. 4 ~~million and $ 88. 2~~ 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 $ ~~325~~ **383** . ~~5~~ **8** million. To date, we have ~~funded~~ **financed** our operations primarily **from proceeds raised** through ~~proceeds from~~ **private placements of preferred units and convertible preferred stock, a debt financing,** our initial public offering, or IPO, ~~the sale~~ of **common** ~~preferred units and convertible preferred~~ stock **in October 2021, private placements of our common stock** and ~~a debt financing~~ **prefunded warrants, upfront payments under our license agreement with Gilead and collaboration agreement with AbbVie and our ATM offering program** . We have devoted substantially all of our financial resources and efforts to research and development. We are still in the early stages of development of our **tumor- activated, or masked,** product candidates, and we have not completed clinical development for our clinical- stage ~~, tumor- activated~~ product candidates, ~~XTX101~~ **vilastobart** (anti- CTLA- 4) ~~,~~ **and** XTX301 (IL- 12) ~~and XTX202 (IL- 2), and we have not commenced clinical development for any of our other product candidates. We have not generated any revenue from product sales to date~~ . We expect to continue to incur significant expenses and operating losses for the foreseeable future, particularly to the extent we: ● continue to advance our current research programs and conduct additional research programs; ● advance our current product candidates and any future product candidates we may develop into preclinical and clinical development; ● seek marketing approvals for any product candidates that successfully complete clinical trials; ● obtain, expand, maintain, defend and enforce our intellectual property; ● hire additional research, clinical, regulatory, quality, manufacturing and general and administrative personnel; ● establish a commercial and distribution infrastructure to commercialize any products for which we may obtain marketing approval; ● continue to discover, validate and develop additional product candidates; **47** ● continue to expand manufacturing capacity through third- party manufacturers and manufacture increasing quantities of our current or future product candidates for use in preclinical studies, clinical trials and for any potential commercialization; ~~52~~ ● acquire or in- license other product candidates, technologies or intellectual property; and ● incur additional costs associated with current and future research, development and commercialization efforts and operations as a public company. Even if we successfully complete clinical trials and obtain regulatory approval for one or more of our product candidates, our product candidates may not be commercially successful. In addition, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate revenue, we will not become profitable and may be unable to continue operations without continued funding. We have no products approved for commercial sale and have not generated any revenue from product sales. We may never generate any revenue **from product sales** or become profitable and, if we achieve profitability, we may not be able to sustain it. To date, we have not generated any revenue from ~~our product candidates or~~ product sales ~~, we~~ **. We** do not expect to generate any revenue from the sale of products for a number of years, and we may never generate revenue from the sale of products. Our ability to generate ~~product~~ revenue **from product sales** depends on a number of factors, including our ability to: ● successfully complete our ongoing and planned preclinical studies and clinical trials for any current or future product candidates; ● successfully receive U. S. Food and Drug Administration, or FDA, clearance for any investigational new

drug application, or IND, for any current or future product candidates; ● successfully initiate and complete clinical trials for our clinical- stage product candidates and any other current or future product candidates, including all safety and efficacy studies necessary to obtain U. S. and foreign regulatory approval for our product candidates; ● establish and maintain clinical and commercial manufacturing capabilities or make arrangements with third- party manufacturers for clinical supply and commercial manufacturing; ● launch commercial sales of our products, if and when approved, whether alone or in collaboration with others; ● obtain and maintain acceptance of the products, if and when approved, by patients, the medical community and third- party payors; ● effectively compete with other therapies; ● obtain and maintain healthcare coverage and adequate reimbursement for our products, if and when approved; ● maintain a continued acceptable safety profile of our products following approval; and ● enforce and defend intellectual property rights and claims. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of expenses we may incur in connection with these activities prior to generating ~~product~~ revenue **from product sales**. In addition, we may never succeed in these activities, and, even if we do, we may never ~~generate~~ **48generate** revenues that are significant enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment. ~~53Our~~ -- **Our** limited operating history may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability. We are a clinical- stage biotechnology company with a limited operating history upon which investors can evaluate our business and prospects. Since inception, we have devoted substantially all of our financial resources and efforts to performing research and development activities. Our approach to the discovery and development of tumor- activated product candidates using our proprietary platform technology ~~for tumor- activated molecules~~ is unproven, and we do not know whether we will be able to develop any approved products of commercial value. In addition, each of our product candidates is either in early clinical or preclinical development, and all of our other development programs are still in discovery stages. We have not yet demonstrated an ability to successfully complete any **late- stage** clinical trials, obtain regulatory approvals, manufacture a commercial- scale product, or arrange for a third party to do so on our behalf, or conduct the sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products. Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. We have incurred substantial losses during our history. As of December 31, ~~2023~~ **2024**, we had federal and state net operating loss, or NOL, carryforwards of $ ~~209~~ **245**. ~~3~~ **5** million and $ ~~180~~ **217**. ~~9~~ **5** million, respectively. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we do not know whether or when we will generate taxable income necessary to utilize our NOLs. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an " ownership change " (generally defined as a greater than 50 percentage point change (by value) in the ownership of its equity by certain stockholders over a three- year period), the corporation' s ability to use its pre- change **NOL** ~~net operating loss~~ carryforwards and other pre- change tax attributes to offset its post- change income is subject to limitations. **In the second quarter** ~~We have not yet completed a detailed study~~ of ~~our inception to date~~ **2024, we had an** ownership change ~~activity under~~ **as defined by** Sections 382 and 383 of the Code ~~. As a result of our prior private placements for preferred units and convertible preferred stock, our IPO or other transactions, we may have experienced such ownership changes in the past, and we may experience such ownership changes in the future as a result of changes in our stock ownership, some of which are outside our control~~. As a result, if we earn net taxable income, our ability to use our pre- change **NOL** ~~net operating loss~~ carryforwards and other pre- change tax attributes to offset such taxable income may be subject to limitations, which could result in increased future tax liability to us and could have an adverse effect on our future results of operations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise become unavailable to offset future income tax liabilities. As described below in " Risks Related to Ownership of Our Common Stock — Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition, " the Tax Cuts and Jobs Act of 2017, or the Tax Act, as amended by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, includes changes to U. S. federal tax rates and the rules governing NOL carryforwards that may significantly impact our ability to utilize our NOLs to offset taxable income in the future. In addition, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes. ~~Risks~~ **49Risks** Related to the Discovery and Development of Our Product CandidatesOur business is highly dependent on the success of our current product candidates, which are in the early stages of development and will require significant additional preclinical and clinical development before we can seek regulatory approval for and commercially launch a product. Our business and future success is highly dependent on our ability to obtain regulatory approval for, and if approved, successfully launch and commercialize, our current product candidates, including our clinical- stage, tumor- activated product candidates: **vilastobart and** ~~XTX101 (anti- CTLA- 4),~~ XTX301 ~~(IL- 12) and XTX202 (IL- 2)~~. We are currently evaluating ~~XTX101~~ **vilastobart** in combination with atezolizumab (Tecentriq ®) in Phase 1 combination dose escalation ~~and XTX301~~ in **patients with advanced solid tumors and** ~~a Phase 1 clinical 54trial. Additionally, we have been evaluating XTX202~~ in a Phase 2 clinical trial **evaluating the** ~~; however, as announced in March 2024, we plan to discontinue further investment in XTX202 as a monotherapy and plan to explore strategic opportunities to continue to develop XTX202 in~~ combination **in patients** with ~~other agents~~ **microsatellite stable colorectal cancer, or MSS CRC. We are currently evaluating XTX301 in a Phase 1 clinical trial**. We also have a portfolio of programs that are in even earlier stages of preclinical development and may never advance to clinical- stage development **,**

including XTX501, our masked PD- 1 / IL- 2 bispecific, which is designed to selectively stimulate PD- 1 positive antigen- experienced T cells and enhance their function and is currently advancing in initial IND- enabling activities, and our preclinical programs for masked T cell engagers targeting prostate- specific membrane antigen, or PSMA, claudin 18. 2, or CLDN18. 2, and six- transmembrane epithelial antigen of prostate 1, or STEAP1 . Commencing clinical trials in the United States is subject to acceptance by the FDA of an IND and finalizing the trial design based on discussions with the FDA and other regulatory authorities. In the event that the FDA requires us to complete additional preclinical studies, or we are required to satisfy other FDA requests prior to commencing clinical trials, the start of our clinical trials may be delayed. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect. There are equivalent processes and risks applicable to clinical trial applications in other countries, including countries in the European Union, or EU. To date, we have only had limited interactions with the FDA regarding our clinical development plans. We may experience issues surrounding preliminary trial execution, such as delays in FDA acceptance of any future INDs, revisions in trial design and finalization of trial protocols, difficulties with patient recruitment and enrollment, quality and provision of clinical supplies, or early safety signals. We are not permitted to market any biological product in the United States until we receive approval of a Biologics License Application, or BLA, from the FDA. We have not previously submitted a BLA to the FDA, or similar marketing application to comparable foreign regulatory authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent for each desired indication. A BLA must also include significant information regarding the chemistry, manufacturing and controls for the product, and the manufacturing facilities must complete a successful pre- license inspection. FDA approval of a BLA is not guaranteed, and the review and approval process is expensive, uncertain and may take several years. The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidate that we develop based on the completed clinical trials. Generally, public concern regarding the safety of biopharmaceutical products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling or require us to undertake other ~~activities~~ **50activities** that may entail additional costs. We have not obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for any current or future product candidates. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our current and any future product candidates, which may never occur. However, given our early stage of development, it will be years before we are able to demonstrate the safety and efficacy of a treatment sufficient to warrant approval for commercialization, and we may never be able to do so. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our current or any future product candidates, we may not be able to generate sufficient revenue to continue our business.

~~55Preclinical~~ -- **Preclinical** development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business. All our product candidates are still in the early clinical stage or preclinical stage of development, and their risk of failure is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the United States, or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies, and we cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our current or future preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin. Preclinical studies and clinical trials are expensive, time- consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials. The risk of failure for our current and any future product candidates is high. It is impossible to predict when or if any of our product candidates will successfully complete preclinical studies or clinical trials evaluating their safety and effectiveness in humans or will ultimately receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans for use in each target indication. Preclinical and clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the preclinical or clinical trial process. The outcome of preclinical testing and early clinical trials may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In particular, while we have conducted certain preclinical studies for each of our clinical stage product candidates, we do not know whether these product candidates will perform in our clinical trials as they have performed in these prior preclinical studies. ~~For example, in preclinical mouse models, we observed XTX101 had tumor- selective activity and tumor growth inhibition superior to that of an ipilimumab analog, and that XTX202 had comparable tumor growth inhibition to aldesleukin and non- masked IL- 2, with both XTX101 and XTX202 avoiding mortality~~

~~and body weight loss. However, there is no guarantee these preclinical results will be replicated in clinical trials.~~ Similarly, there can be no assurance that early, interim or preliminary clinical data or results will be predictive of or replicated in future clinical data or results, including without limitation, the ~~preliminary~~ **Phase 2 data for vilastobart in combination with atezolizumab and the** Phase 1 data ~~reported for XTX101, including the partial response observed in one patient treated with XTX101, the preliminary safety data into the third dose level reported~~ for XTX301 ~~, or the Phase 1 / 2 monotherapy data~~ reported ~~for XTX202~~ **to date**. Many companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in late- stage clinical trials after achieving positive results in early- stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events, or AEs. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to produce positive results in our planned and ongoing ~~preclinical~~ **51preclinical** studies or clinical trials, or if we experience material changes in clinical data or results from those we have previously reported, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business, financial condition and results of operations would be materially and adversely affected. ~~56We~~ **We** may encounter substantial delays in the commencement or completion, or termination or suspension, of our clinical trials, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate for its intended indications. We cannot guarantee that any clinical trials, including our Phase ~~1 combination dose escalation portion of our Phase 1 /~~2 clinical trial ~~for XTX101~~ **evaluating vilastobart** in combination with atezolizumab or our Phase 1 clinical trial ~~for~~ **evaluating** XTX301 **as a monotherapy**, will be conducted as planned or completed on schedule, if at all. For example, in ~~March~~ **the first quarter of** 2024, we announced ~~that we plan~~ **plans** to discontinue further investment in XTX202 **, our tumor- activated IL- 2,** as a monotherapy. We may experience numerous unforeseen events leading up to, during or as a result of clinical trials that could delay or prevent the initiation or completion of a clinical trial or our ability to receive marketing approval or commercialize our product candidates, including: ● we may be unable to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to obtain regulatory authorizations to commence a clinical trial; ● we may experience issues in reaching a consensus with regulatory authorities on trial design; ● regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; ● we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; ● clinical trial sites may deviate from a trial protocol or drop out of a trial or fail to conduct the trial in accordance with regulatory requirements; ● the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, or subjects may fail to enroll or remain in clinical trials at the rate we expect; ● subjects that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the subject from the trial, increase the needed enrollment size for the clinical trial or extend its duration; ● subjects may choose an alternative treatment for the indication for which we are developing our product candidates, or participate in competing clinical trials; ● subjects may experience severe or unexpected treatment- related adverse effects; ● clinical trials of our product candidates may produce unfavorable, inconclusive, or clinically insignificant results; ● we may decide to, or regulators, or IRBs, or ethics committees may require us to, make changes to a clinical trial protocol or conduct additional preclinical studies or clinical trials, or we may decide to abandon product development programs; ● we may need to add new or additional clinical trial sites; **52** ● our third- party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; ~~57~~ ● we may experience manufacturing delays, and any changes to manufacturing processes or third- party contractors that may be necessary or desired could result in other delays; ● we or our third- party contractors may experience delays due to complications resulting from the impact of public health crises, including epidemics and pandemics; ● the cost of preclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate or greater than our available financial resources; ● the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or we may not be able to obtain sufficient quantities of combination therapies for use in current or future clinical trials; ● reports may arise from preclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates; and ● regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate. If we are required to conduct additional clinical trials or other testing of our product candidates beyond the clinical trials and testing that we contemplate, if we are unable to successfully complete clinical trials or other testing of our product candidates, if the results of these clinical trials or tests are unfavorable or are only modestly favorable or if there are safety concerns associated with any of product candidates, we may: ● incur additional unplanned costs; ● be required to suspend or terminate ongoing clinical trials; ● be delayed in obtaining marketing approval, if 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 or other requirements; ● be required to perform additional clinical trials to support approval;

● have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS; ● be subject to the addition of labeling statements, such as warnings or contraindications; ● have the product removed from the market after obtaining marketing approval; ● be subject to lawsuits; or ● experience damage to our reputation. ~~Conducting~~ **53Conducting** clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative ~~58burdens~~ -- **burdens** associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates. In addition to the factors above, we may make formulation or manufacturing changes to our product candidates, in which case we may need to conduct additional preclinical studies or clinical trials to bridge our modified product candidates to earlier versions, which may be costly, time consuming and may not be successful at all. Our failure to successfully initiate and complete clinical trials of our product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of our product candidates would significantly harm our business. We cannot guarantee that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our clinical trials. Significant preclinical study or clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates. If we experience delays or difficulties in the enrollment of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including: ● clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating; ● the severity of the disease under investigation; ● the patient eligibility and the inclusion and exclusion criteria defined in the protocol; ● AEs in our clinical trials and in third- party clinical trials of agents similar to our product candidates; ● the size and health of the patient population required for analysis of the trial' s primary endpoints; ● the proximity of patients to trial sites; ● the design of the trial; ● our ability to recruit clinical trial investigators with the appropriate competencies and experience; **54** ● our ability to obtain and maintain patient consents; ~~59~~ ● our ability to monitor patients adequately during and after treatment; ● the risk that patients enrolled in clinical trials will drop out of the trials before completion; and ● factors we may not be able to control that may limit the availability of patients, principal investigators or staff or clinical sites, such as public health crises, including epidemics and pandemics. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial site. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, slow down or halt our product candidate development and approval process and jeopardize our ability to seek and obtain the marketing approval required to commence product sales and generate revenue, which would cause the value of our company to decline and limit our ability to obtain sufficient additional capital. Our product candidates may cause undesirable or unexpectedly severe side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any. Undesirable or unexpectedly severe side effects caused by our product candidates could cause us to interrupt, delay or halt preclinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Traditional cytokine therapies and checkpoint inhibitors have long been associated with severe toxicities, which can be life- threatening or fatal, that have resulted in the need to dose- reduce, dose- interrupt and discontinue many patients from treatment. As has been the case with traditional immuno- oncology, or I- O, treatments for cancer, it is possible that there may be **severe** side effects associated with the use of our current or future product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our clinical trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment- related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects

significantly. In addition, clinical trials rely on a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered when a significantly larger number of patients is exposed to the product candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates after such approval, a number of potentially significant negative consequences could result, including: ● regulatory authorities may require the addition of labeling statements, such as a " black box " warning or a contraindication; ● we may be required to create a medication guide outlining the risks of such side effects for distribution to patients; ● regulatory authorities may require a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools; ~~60~~ **55** ● we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates; ● we may be subject to regulatory investigations and government enforcement actions; ● regulatory authorities may withdraw or limit their approval of such product candidates; ● we may decide to remove such product candidates from the marketplace; ● we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and ● we may suffer reputational harm. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects. Interim top- line and preliminary data from our clinical trials 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. For example, ~~in 2023,~~ we **most recently** reported ~~preliminary monotherapy~~ **initial data from our Phase 2 clinical trial for vilastobart in combination with atezolizumab in January 2025, and we plan to report additional Phase 2 data in the middle of 2025, and we most recently reported safety** data from our Phase 1 clinical trial for ~~XTX101~~ **XTX301** ~~and from our Phase 1 / 2 clinical trial for XTX202, and~~ in ~~January~~ **December** 2024 ~~, we reported preliminary Phase 1 safety data into the third dose level for XTX301~~ . Preliminary and interim data from clinical trials 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 previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. We expect to develop certain of our product candidates in combination with third- party drugs and we will have limited or no control over the safety, supply, regulatory status or regulatory approval of such third- party drugs. We intend to develop our clinical- stage product candidates, and likely other future product candidates, in combination with third- party cancer drugs, which may be either approved or unapproved. For example, we are **currently** evaluating ~~XTX101~~ **vilastobart** in combination with atezolizumab (Tecentriq ®) in Phase 1 combination dose escalation ~~and plan to evaluate the combination~~ in **patients with advanced solid tumors and in a** Phase 2 **clinical trial evaluating the combination** in patients with **MSS CRC** ~~microsatellite stable colorectal cancer~~ . Our ability to develop and ultimately commercialize our current product candidates, and any future product candidates, used in combination with third- party drugs will depend on our ability to access such drugs on commercially reasonable terms for clinical trials and their availability for use with our commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs on commercially reasonable terms or at all. Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing such third- party drugs in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our current product candidates and any future product candidates as commercially viable therapies. If any of these occur, our business, financial condition, operating results or prospects may be materially harmed. Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. For example, our plans to evaluate current or future product candidates in combination with other agents may result in AEs based on the combination therapy that may negatively impact the reported safety profile of the monotherapy in clinical trials. In addition, the FDA or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of such trials could show that any positive previous trial results are attributable to the third- party drug and not our product candidate. Developments ~~61related~~ - **56related** to the third- party drug may also impact our clinical trials for the combination therapy as well as our commercial prospects should we receive regulatory approval. Such developments may include changes to the third- party drug' s safety or efficacy profile, changes to the availability of the third- party drug, quality, and manufacturing and supply issues with respect to the third- party drug. If we are able to obtain marketing approval, the FDA or comparable foreign regulatory authorities may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the third- party drug, this may require us to work with such third party to satisfy such a requirement. We would also continue to be subject to the risks that the FDA or comparable foreign regulatory authorities could revoke approval of the third- party drug used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with such drug. Similarly, if the third- party drugs we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially. We may not be successful in our efforts to use our platform technology to enable the development of a pipeline of tumor- activated product candidates. A key element of our strategy is to use our novel platform technology to engineer and develop tumor- activated molecules with the potential to trigger anti- tumor immunity with minimal systemic toxicity in order to ~~build~~ **advance** a pipeline of product

candidates. We may not be able to continue to identify and develop novel I- O therapies. Even if we are successful in continuing to ~~build~~ **advance** our pipeline, the potential product candidates that we identify may not be suitable for clinical development. For example, potential product candidates may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to or will not be drugs that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our platform approach or take longer to do so than anticipated, we will not or may not be able to obtain drug revenues in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price. We may not be successful in our efforts to identify or discover additional product candidates. Although we intend to explore other therapeutic opportunities in addition to the product candidates that we are currently developing, we may fail to identify or discover viable new product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed. Research programs to pursue the development of our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. We may in the future rely on third parties for certain research, and we will not have complete control over their performance and ability to successfully develop product candidates. Our research programs may initially show promise in identifying potential indications and / or product candidates, yet fail to yield results for clinical development for a number of reasons, including: ● the research methodology used may not be successful in identifying potential indications and / or product candidates; ● potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; and ● it may take greater human and financial resources than we will possess to identify and advance additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio. Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our current product candidates or to develop suitable additional product candidates through internal research programs, which could materially adversely affect our future growth and prospects. ~~62Our~~ **57Our** approach to the discovery and development of product candidates based on our technological approaches is unproven, and we do not know whether we will be able to develop any products of commercial value. The success of our business depends primarily upon our ability to discover, develop and commercialize products based on our technological approaches. While we have had favorable preclinical ~~study~~ **and early clinical** results related to our clinical **-** stage product candidates **, vilastobart and XTX301** , we have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in current or future clinical trials or in obtaining marketing approval thereafter. We rely on matrix metalloproteases, or MMPs, to activate our molecules within the tumor microenvironment. If MMP activity in human tumors is not sufficient to cleave the masking protein domain, the potential efficacy of our product candidates would be limited. We have no assurance that our product candidates will successfully progress through clinical development and ultimately marketing approval. We have invested substantially all of our efforts and financial resources in developing our initial product candidates and our future success is highly dependent on the outcome of our ongoing clinical trials and the successful development of our technology and product candidates. In addition, the clinical trial requirements of the FDA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate may vary according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. As a result, we may face a greater regulatory burden to initiate clinical trials or to obtain regulatory approval of our product candidates as compared to product candidates based on more established technology. In addition, any product candidates for which we may be able to obtain marketing approval may be subject to extensive post- approval regulatory requirements, including requirements pertaining to manufacturing, distribution and promotion. We may need to devote significant time and resources to comply with these requirements. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. We have chosen to initially develop each of our clinical- stage product candidates for the treatment of various solid tumor types. Nevertheless, our development efforts will be limited to a small number of cancer types, and we may forego or delay pursuit of opportunities in other cancer types that may prove to have greater potential. Likewise, we may forego or delay the pursuit of opportunities with other potential product candidates that may prove to have greater commercial potential. In addition, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any viable product candidates. Similarly, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate. We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or following commercial sale, and any product liability insurance we may obtain may not cover all damages from such claims. We are exposed to potential product liability risks that are inherent in the research, development, manufacturing, marketing and use of biopharmaceutical products. The use of product candidates by us in clinical trials, and any sale of approved products in the future, may expose us to liability claims. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any

of our product candidates were to cause adverse ~~63side~~ **58side** effects during clinical trials or after approval thereof, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the development or commercialization of our product candidates or any products for which we may have received marketing approval. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: ● delay or termination of clinical trials; ● decreased demand for any product candidates or products that we may develop; ● injury to our reputation and significant negative media and social media attention; ● withdrawal of clinical trial participants or difficulties in recruiting new trial participants; ● initiation of investigations by regulators; ● costs to defend or settle the related litigation; ● a diversion of management' s time and our resources; ● substantial monetary awards to trial participants or patients; ● product recalls, withdrawals or labeling, marketing or promotional restrictions; ● significant negative financial impact; and ● the inability to commercialize any of our product candidates, if approved. Although we will seek to procure and maintain sufficient product liability insurance coverage, our current insurance coverage and any insurance coverage we obtain in the future may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be materially harmed. Risks Relating to Manufacturing and SupplyManufacturing biologics is complex, and we may experience manufacturing problems that result in delays in our development or commercialization programs. The manufacturing of biologics is complex and difficult and we may experience production issues or interruptions in supply for our product candidates, including variability of raw material, consumable or starting material quality, cell line viability, productivity or stability issues, shortages of any kind, shipping, distribution, storage and supply chain failures, media contamination, equipment malfunctions or failures, operator errors, facility contamination, labor problems, quality system and regulatory inspection failures, natural disasters, disruption in utility services, terrorist activities, or acts of god that are beyond our control or the control of our third- party contract development and manufacturing organizations, or CDMOs. Given the nature of biologics manufacturing, there is a risk of contamination during manufacturing. Any contamination could materially harm our ability to produce product candidates on schedule and could harm our results of operations and ~~64cause~~ **59cause** reputational damage. In the event that raw materials required in our manufacturing process need to be derived from biologic sources, they may be difficult to procure and may be subject to contamination or recall. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects, out- of- specification analytical results or manufacturing failures that result in lot failures, product recalls, product liability claims, insufficient inventory or potentially delay progression of our preclinical or clinical development of any product candidates we may develop. If we successfully develop product candidates, we may encounter problems achieving adequate quantities and quality that meet FDA, European Medicines Agency, or EMA, or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs. The ability to scale our manufacturing and maintain the manufacturing process at the same levels of quality and efficiency that we are currently manufacturing is yet to be tested. If we or our third- party CDMO is unable to scale our manufacturing and meet the same levels of quality and efficiency, or provide sufficient manufacturing campaign slots to generate materials, we may not be able to supply the required number of doses for clinical trials or commercial supply. A material shortage, contamination event or manufacturing failure in the manufacture of any product candidate we may develop or other adverse impact or disruption in the commercial manufacturing or the production of clinical material could materially harm our development timelines and our business, financial condition, results of operations and prospects. We face risks related to our reliance on our current and any future CDMOs. For example, we and our CDMO are subject to significant regulation with respect to manufacturing our products. The manufacturing facilities of the CDMO on which we rely may not continue to meet regulatory requirements, may have limited capacity or may experience interruptions in supply, any of which could adversely affect our development and commercialization plans for our product candidates. All entities involved in the preparation and storage of therapeutics for clinical trials or commercial sale, including any CDMOs of any product candidates we may develop, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with current Good Manufacturing Practices, or cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, in partnership with our CDMO, must supply all necessary documentation in support of an IND for clinical product, and later in support of a BLA for any potential commercial product, on a timely basis and must adhere to the FDA' s and EMA' s current Good Laboratory Practices and cGMP regulations enforced through the applicable regulatory authority' s facilities inspection program. Our facilities and quality systems and the facilities and quality systems of our CDMO must pass a pre- approval inspection, or PAI, to confirm validity of the information presented in the BLA and to confirm the capability of the facility to manufacture our product in compliance with the applicable regulations. The PAI is a condition of regulatory approval of any product candidates we may develop or any of our other potential products. If our or our CDMO' s quality systems or facilities involved with the preparation of our product candidates do not pass the PAI, FDA approval of such product candidates will not be granted. In addition, the regulatory authorities may, at any time, conduct a routine or for- cause inspection of a manufacturing facility involved with the preparation of our product candidates, which inspection is related to other products manufactured at

the site or the associated quality systems, for compliance with the regulations applicable to the activities being conducted. The regulatory authorities also may, at any time following approval of a product for sale, inspect our facilities or the manufacturing facilities of our CDMOs. If any such inspection identifies a failure to comply with applicable regulations, or if a violation of our product specifications or applicable regulations occurs independent of such an inspection, we or the relevant regulatory authority may require remedial measures that may be costly and / or time- consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales, the temporary or permanent closure of a facility, or other remedial measures that may delay or disrupt the manufacture or release of our product candidates or other potential products. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. ~~If~~ **60If** we or any CDMO with which we contract for manufacturing and supply fails to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, a clinical hold, refusal to approve a pending application for a new drug product or biologic product, revocation of a pre- existing approval, or an import alert. As a result, our business, financial condition and results of operations may be materially harmed. ~~65Currently~~ -- **Currently** , we depend on ~~a single manufacturer~~ **WuXi Biologics (Hong Kong) Limited, or WuXi Biologics,** for developing the manufacturing processes required to supply our product candidates. We cannot ensure that this manufacturer will remain in business or have sufficient capacity or supply to meet our needs. Our use of a single manufacturer exposes us to several risks, including price increases or manufacturing delays beyond our control. ~~This CDMO~~ **WuXi Biologics** is based in and has significant operations in China, where our product candidates are manufactured, which subjects us to additional risks including those related to U. S. export control laws, potential sanctions or other trade restrictions imposed by the U. S. government. Moreover, reliance on third- party manufacturers generally entails risks to which we would not be subject if we manufactured the product candidates ourselves, including: ● the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms or at all, particularly if they are affiliated with our competitors; ● reduced control as a result of using third- party manufacturers for all aspects of manufacturing activities, particularly if they are under contract with our competitors; ● termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; ● disruptions to the operations of our third- party manufacturers or suppliers caused by conditions unrelated to our business or operations, including geopolitical tensions or restrictions, such as export controls or sanctions, or the bankruptcy of the manufacturer or supplier; ● the inability to import or obtain components or materials from alternate sources at acceptable prices or with acceptable quality in a timely manner; and ● substantial delays or difficulties related to the establishment of replacement manufacturers who meet regulatory requirements. Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize future products. Some of these events could be the basis for FDA action, including injunction, recall, seizure, import alert, or total or partial suspension of production. Additionally, if supply from one approved manufacturer is interrupted, such as could be the case with our current CDMO, **WuXi Biologics,** there could be a significant disruption in supply. While we believe there are alternate manufacturers who can provide the manufacturing processes required to develop and manufacture our product candidates, if we have to switch to a replacement manufacturer, the manufacture and delivery of our product candidates could be interrupted for an extended period, which could adversely affect our business. Furthermore, an alternative manufacturer must be able to demonstrate successful technology transfer of the manufacturing process and associated assays, and, to do so, may need to modify the manufacturing process required to develop our product candidates, and the alternative manufacturer would need to be qualified through additional regulatory filings, all of which could result in further delay and significant costs. The regulatory agencies may also require additional studies or trials if a new manufacturer is relied upon for clinical or commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement ~~suppliers~~ **61suppliers** capable of production at a substantially equivalent cost, our clinical trials may be delayed, or we could lose potential revenue or market share with respect to any product that has received marketing approval. ~~66If~~ Certain of our research and development and manufacturing activities take place in China through **WuXi Biologics** ~~a third- party CDMO~~ .A significant disruption in our ability to rely on ~~this CDMO~~ **WuXi Biologics** could materially adversely affect our business,financial condition and results of operations.We have relied on **WuXi Biologics** ~~a third party located~~ in China to manufacture and supply certain raw materials used in our product candidates,and we expect to continue to use ~~such third- party~~ **WuXi Biologics as our** CDMO for such purposes.A natural disaster,epidemic or pandemic,such as the COVID- 19 pandemic,trade war,political unrest,economic conditions,changes in legislation,including the passage of the People' s Republic of China Biosecurity law,which became effective on April 15,2021,and subsequent legislation that China or the United States may adopt in the future,or other events in China could disrupt our ability to continue to rely upon CROs **,CDMOs** ,collaborators,manufacturers or other third parties with whom we conduct business now or in the future.Any disruption in China or the United States that significantly impacts such third parties,including services provided by CROs for our research and development programs,or our manufacturers' ability to produce and export raw or manufactured materials in adequate quantities to meet our needs,could impair our ability to operate our business on a day- to- day basis and impede,delay,limit or prevent the research,development or commercialization of our current and future products or product candidates.In addition,for any activities conducted in China,we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the U.S.or Chinese governments,political unrest or unstable economic or geopolitical conditions,including sanctions in China or against certain Chinese companies;changes in U.S.export laws or the imposition by the United States of trade barriers;sanctions;limitations on uses of U.S.government executive agency contract,grant or loan funds;or other restrictions on doing business with certain Chinese companies,including ~~our CDMO~~ **WuXi Biologics** ,which

could have a material adverse effect on our business.Additionally,we may be exposed to fluctuations in the value of the local currency in China for goods and services.Our costs for any of these services or activities could also increase as a result of future appreciation of the local currency in China or increased labor costs if the demand for skilled laborers increases and / or the availability of skilled labor declines in **China.If** we or any CDMOs and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We and any CDMOs and suppliers we engage are subject to numerous federal, state and local environmental, health, and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of biological or hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at third- party facilities. We also could incur significant costs associated with civil or criminal fines and penalties. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations and prospects. ~~In~~ **62In** addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws, regulations and permitting requirements. These current or future laws, regulations and permitting requirements may impair our research, development or production efforts. Failure to comply with these laws, regulations and permitting requirements also may result in substantial fines, penalties or other sanctions or business disruption, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Any third- party CDMOs and suppliers we engage will also be subject to these and other environmental, health and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Risks Related to our Dependence on Third PartiesWe expect to rely on third parties to conduct, supervise and monitor IND- enabling studies and clinical trials, and if these third parties perform in an unsatisfactory manner, it may harm our business, reputation and results of operations. We expect to rely on CROs and research and clinical trial sites to ensure our IND-enabling studies and clinical trials are conducted properly and on time, and we expect to rely in the future on CROs for additional research programs. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of these studies 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 will be required to comply with the FDA' s Good Clinical Practices, or GCPs, for conducting, recording and reporting the results of IND-enabling studies and clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces these GCPs through periodic inspections of study sponsors, principal investigators and clinical trial sites. If we or our ~~67CROs~~ -- **CROs** fail to comply with applicable GCPs, the preclinical and clinical data generated in our studies may be deemed unreliable and the FDA may require us to perform additional studies before approving any marketing applications. Upon inspection, the FDA may determine that our studies did not comply with GCPs. Our CROs are not our employees, and we are therefore unable to directly monitor whether or not they devote sufficient time and resources to our clinical and nonclinical 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 drug development activities that could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements, or for any other reasons, our studies may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidates we may develop. As a result, our financial results and commercial prospects would be harmed, our costs could increase, and our ability to generate revenues could be delayed. We have entered into, and may in the future seek to enter into, licenses, collaborations or similar arrangements with third parties for the research, development and commercialization of certain of our current or future product candidates. If any such arrangements are not successful, we may not be able to capitalize on the market potential of those product candidates. In March 2024, our wholly- owned subsidiary, Xilio Development, Inc., or Xilio Development, entered into ~~the~~ **a** license agreement with Gilead, pursuant to which Gilead was granted an exclusive global license to develop and commercialize XTX301, our tumor activated IL- 12, and other specified molecules directed toward IL- 12 **. In February 2025** , **Xilio Development entered into a collaboration, license and option agreement with AbbVie, pursuant to** which **AbbVie** ~~we refer to as~~ **was** ~~our IL~~ **granted (i) an exclusive option for (a) an initial program to discover, develop and commercialize masked T cell engager molecules for an agreed upon initial target and backup target and (b)**

subject to the terms of the agreement, up to two additional programs to discover, develop, and commercialize masked T cell engager molecules for an initial target and backup target determined at the time of program initiation and (ii) an exclusive license to develop and commercialize a 63masked antibody ~~- 12 program~~ **based immunotherapy** . We may in the future seek third- party collaborators or licensors for the research, development and commercialization of other current or future product candidates. With respect to our ~~license agreement~~ **agreements** with Gilead **and AbbVie** , and what we expect will be the case with any future collaboration agreements we enter into, we have and would likely have limited control over whether such collaborators pursue the development of our product candidates or the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates that we seek to develop with them. For example, under the license agreement with Gilead, if Gilead exercises its right to transition responsibilities for the development and commercialization of XTX301 and the rest of our IL- 12 program, it will have sole decision **-** making authority with respect to the continued development and future commercialization of our IL- 12 program and may elect to prioritize other assets that it believes are more competitive, or it may exercise its right to terminate the license and return the licensed IL- 12 program assets to us. **Similarly, subject to limited exceptions, AbbVie has sole decision- making authority with respect to the development and commercialization of the masked antibody- based immunotherapy program. With respect to any T cell engager program for which AbbVie exercises its option, AbbVie will have sole decision- making authority with respect to the continued development and future commercialization of such option program and may elect to prioritize other assets that it believes are more competitive, or it may exercise its right to terminate the license and return the licensed T cell engager program assets to us.** As a result, there can be no assurances that any of the programs covered by our existing or future collaborations or licenses will be developed further or reach commercialization. Further, our ability to generate revenues from these existing and future arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into. Collaborations, licenses or similar arrangements involving our research programs or any product candidates currently pose, and will continue to pose, numerous risks to us, including the following: ● collaborators or licensors have significant discretion in determining the efforts and resources that they will apply to these arrangements; ● collaborators or licensors may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in such third party' s strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities; ● collaborators or licensors may delay programs, preclinical studies or clinical trials, provide insufficient funding for programs, preclinical studies or clinical trials, stop a preclinical study or clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; ~~68~~ ● collaborators or licensors could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; ● collaborators or licenses may be acquired by a third party having competitive products or different priorities; ● collaborators or licensors with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidate (s); ● collaborators or licensors may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation; ● disputes may arise between the collaborators or licensors and us that result in the delay or termination of the research, development, or commercialization of our product candidates or any of our product candidates or that ~~result~~ **64result** in costly litigation or arbitration that diverts management attention and resources or that jeopardize or invalidate our intellectual property or proprietary information; ● we may lose certain valuable rights under certain circumstances, including if we undergo a change of control; ● collaborations or licenses may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and ● collaborations or license agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator or licensor of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated. If our current or future collaborations, licenses or similar transactions do not result in the successful development and commercialization of product candidates, ~~or~~ **including** if one of our **current or future** collaborators or licensors terminates its agreement with us, we may not receive any future ~~research funding or milestone or royalty~~ payments **for which we might otherwise be eligible** under such agreement ~~, we may lose valuable rights to our intellectual property,~~ or we may incur significant costs in **re-** ~~reestablishing~~ -- **establishing** the development and manufacturing of such product candidates. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop **such** product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or licensor or for us to attract new collaborators or licensors, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10- K apply to the activities of our collaborators or licensors. These relationships, or those like them, may require us to incur non- recurring and other charges, increase our near- and long- term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time- consuming and complex. Our ability to reach a definitive collaboration or license agreement with future partners will depend, among other things, upon our assessment of the resources and expertise of such third- party collaborator or licensor and the terms and conditions of the proposed collaboration or license. Further, if we license rights for use in any product candidates we or our

collaborators may develop, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. ~~69If~~ **If** we are not able to establish collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans. Our product development and research programs and the potential commercialization of any product candidates we may develop will require substantial additional cash to fund expenses. For some of the product candidates we may develop, we have decided and may in the future decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, the EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us. ~~Collaborations~~ **65Collaborations** are complex and time- consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate future collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidates for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay their potential commercialization, reduce the scope of any sales or marketing activities, or increase our own expenditures on the development of the applicable product candidate. Certain of our research and development and..... skilled labor declines in China. 70Risks -- **Risks** Related to CommercializationWe have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any products that receive regulatory approval, either on our own or together with collaborators. We have never commercialized a product candidate. We currently have no sales force or marketing or distribution capabilities. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own sales, marketing and supply capabilities or outsource these activities to one or more third parties. Factors that may affect our ability to commercialize our product candidates on our own include our ability to recruit and retain adequate numbers of effective sales and marketing personnel and obtain access to or persuade adequate numbers of physicians to prescribe our product candidates, as well as any unforeseen costs we may incur in connection with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment and substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day- to- day activities, which could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States, the EU or other key global markets. To the extent we need to rely upon one or more third parties, we may have little or no control over the marketing and sales efforts of those third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We will also face competition in any search for third parties to assist us with sales and marketing efforts for our product candidates. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them. We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. The development and commercialization of new products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer. There are other companies working to develop immunotherapies for the treatment of cancer including divisions of pharmaceutical and biotechnology companies of various sizes. Some of these competitive therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. We are developing our ~~current~~ **most advanced clinical- stage, tumor- activated** product candidates for the treatment of cancer and have not completed clinical development ~~for our clinical- stage, tumor- activated product candidates, XTX101 (anti- CTLA- 4), XTX301 (IL- 12) or XTX202 (IL- 2), and we have not commenced clinical development for any of our other product candidates~~ or received marketing approval for ~~any of~~ **either vilastobart** ~~our~~ **or XTX301** ~~product candidates~~. There are already a variety of available therapies marketed for cancer and some of the currently approved therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved therapies are well- established and widely accepted by physicians, patients and third- party payors. Insurers and other third- party payors may also encourage the use of generic products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product ~~candidates~~ **66candidates**. Competition may further increase with advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. ~~XTX101~~ **Vilastobart**, if approved, may face competition from other anti- CTLA- 4 based therapies. For example, Yervoy (ipilimumab), an anti- CTLA- 4, is approved to treat melanoma, renal cell carcinoma and certain cancers of the large intestine, and Imjudo

(tremelimumab) is approved as a combination therapy to treat unresectable hepatocellular carcinoma. In addition, we are aware that several companies have anti- CTLA- 4 programs in development, including Adagene, Inc., Agenus Inc., AstraZeneca plc, BioAtla, Inc., CytomX Therapeutics, Inc., MacroGenics, Inc. and OncoC4, Inc. ~~71With --~~ **With** respect to XTX301, **currently** there are no ~~approved~~ IL- 12 therapies **approved** ~~currently on the market~~ for the treatment of cancer ~~;. however~~ **However** , we are aware of several other companies that have modified IL- 12 ~~or intra- tumoral IL- 12~~ delivery programs ~~for the treatment of cancer~~ in development, including ~~Amunix Pharmaceuticals, Inc., AstraZeneca plc / Moderna, Inc.,~~ Cullinan Management Inc., Dragonfly Therapeutics, Inc., ImmunityBio, Inc., PDS Biotechnology Corporation, Philogen S. p. A., Sonnet BioTherapeutics, Werewolf Therapeutics, Inc., Xencor Inc. and Zymeworks Inc. ~~XTX202~~ **With respect to our most advanced research- stage product candidate** , **XTX501** ~~if approved~~ , **currently,** ~~may face competition from other --~~ **there are no bispecific PD- 1 targeted** IL- 2 ~~- based~~ **therapies approved for the treatment of** cancer ~~therapies~~ . **However** ~~For example~~ , **if we continue to advance development** ~~Proleukin (aldesleukin), a human recombinant interleukin- 2 product, is approved and marketed for the treatment~~ of **XTX501** ~~metastatic renal cell carcinoma and melanoma. In addition~~ , we are aware ~~that a number~~ of **several** other companies **that** have modified **PD** ~~or low -~~ ~~dose~~ **1 targeted** IL- 2 **bispecific antibodies in development, including Anaveon AG, Innovent Biologics, Inc., Regeneron Pharmaceuticals, Inc. and Roche. With respect to our masked T cell engager programs, currently there are no T cell engager therapies targeting PSMA, CLDN18. 2 or STEAP1 approved for the treatment of cancer. We are aware of several other companies that have masked T cell engager** programs in development for **PSMA** ~~the treatment of cancer~~ , including **Janux** ~~Alkermes plc, Anaveon AG, Ascendis Pharma A / S, Asher Biotherapeutics~~ **Therapeutics** , Inc. ~~, Aulos Bioscience~~ **and Vir Biotechnology** , Inc. **To our knowledge** , ~~Bright Peak~~ **there are no companies currently developing masked T cell engager programs for CLDN18. 2 or STEAP1. However, we are aware of several companies developing non- masked T cell engager programs for CLDN18. 2, including Amgen Inc., Innovent Biologics, Inc., Transcenta Holding Ltd. and Zai Lab Limited, and for STEAP1, including Amgen Inc., Nutcracker** Therapeutics **and Xencor** ~~, Cue Biopharma,~~ Inc ~~., Cugene Inc., Cullinan Management Inc., Egle Therapeutics SAS, GI Innovation, Iovance Biotherapeutics, Inc., Kymab Ltd., Medicenna Therapeutics Corp., Medikine, Inc., Modulate Therapeutics, Inc., Neoleukin Therapeutics, Inc., Philogen S. p. A., Proviva Therapeutics, Inc., Roche AG, Sanofi, Seleexine, Synthekine, Inc., Trutino Biosciences Inc., Werewolf Therapeutics, Inc., XOMA Corporation and Zydus Cadila~~ . Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. We also compete with these organizations in establishing clinical trial sites and patient registration for clinical trials, as well as in recruiting and retaining qualified scientific and management personnel, which could negatively affect our level of expertise and our ability to execute our business plan. Many of our competitors, either alone or with their collaborators, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel product candidates or to in- license novel product candidates that could make our product candidates less competitive or obsolete. Smaller or early- stage companies may also prove to be significant competitors, including through collaborative arrangements with large and established companies. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. The availability of competing products could limit the demand and the price we are able to charge for product candidates we commercialize, if any. The inability to compete with existing or subsequently introduced products would harm our business, financial condition and results of operations. If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of any of our product candidates may be delayed, and our business could be harmed. For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the release of clinical trial data, the completion of an ongoing clinical trial, the initiation of other clinical trials, receipt of regulatory approval or the commercial launch of a product. The achievement of many of these milestones may be outside of our ~~control~~ **67control** . All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including: ● our available capital resources or capital constraints we experience; ● the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators; ● our ability to identify and enroll patients who meet clinical trial eligibility criteria; ~~72~~ ● our receipt of approvals by the FDA, EMA and comparable regulatory authorities in other jurisdictions, and the timing thereof; ● other actions, decisions or rules issued by regulators; ● our ability to access sufficient, reliable and affordable supplies of materials used in the manufacture of our product candidates; ● our ability to manufacture and supply clinical trial materials to our clinical trial sites on a timely basis; ● the efforts of our collaborators with respect to the development of our product candidates or the potential commercialization of any of our product candidates, if approved; and ● the securing of, costs related to, and timing issues associated with, commercial product manufacturing as well as sales and marketing activities. If we fail to achieve announced milestones in the timeframes we expect, the commercialization of any of our product candidates may be delayed, and our business, results of operations, financial condition and prospects may be adversely affected. If approved, our product candidates that are licensed and regulated as biological products, or biologics, may face competition from biosimilars approved through an abbreviated regulatory pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, to establish an abbreviated pathway for the

approval of biosimilar and interchangeable with an FDA- licensed reference biologic product. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as " interchangeable " based on its similarity to an approved biologic. Under the BPCIA, reference biological product is granted 12 years of non- patent data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the licensure of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12- year period of exclusivity, another company may still develop and receive licensure of a competing biologic, so long as their BLA does not rely on the reference product or sponsor' s data or submit the application as a biosimilar application. We believe that any of the product candidates we develop that is licensed in the United States as a biological product under a BLA should qualify for the 12- year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidate to be a reference product for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a ~~way~~ **68way** that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. The approval of a biosimilar of our product candidates could have a material adverse impact on our business due to increased competition and pricing pressure. If competitors are able to obtain regulatory approval for biosimilars referencing our product candidates, our product candidates may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. ~~73The~~ -- **The** sizes of the potential markets for our product candidates are difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates. The potential market opportunities for our product candidates are difficult to estimate and, if our product candidates are approved, will ultimately depend on, among other things, the indications for which our product candidates are approved for sale, any products with which our product candidates are co- administered, the success of competing therapies and therapeutic approaches, acceptance by the medical community, patient access, product pricing, reimbursement and our ability to create meaningful value propositions for patients, prescribers and payors. Our estimates of the potential market opportunities for our product candidates are predicated on many assumptions, which may include industry knowledge and publications, third- party research reports and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions prove to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities. The successful commercialization of our product candidates will depend in part on the extent to which we obtain and maintain favorable insurance coverage, adequate reimbursement levels and cost- effective pricing policies with third- party payors. The availability and adequacy of coverage and reimbursement by third- party payors, including governmental healthcare programs such as Medicare and Medicaid, managed care organizations, and private health insurers, are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by third- party payors will have an effect on our ability to successfully commercialize our product candidates. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for our product candidates, if approved, or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. Third- party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third- party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third- party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third- party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates, if approved. Even if our product candidates are approved and we obtain coverage for our product candidates by a third- party payor, such products may not be considered cost- effective and / or the resulting reimbursement payment rates may be insufficient or may require co- payments that patients find unacceptably high. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, if approved, and may not be able to obtain a satisfactory financial return on our product candidates. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. The regulations that govern marketing approvals, pricing and reimbursement for new medicines vary widely from country to ~~country~~ **69country** . In the United States, third- party payors play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how third- party payors develop their coverage and reimbursement policies for drugs and biologics. Some third- party payors may require pre- approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third- party payors will decide with respect to the coverage and reimbursement for our product candidates, if approved. ~~74No~~ **No** uniform policy for coverage and reimbursement for products exists among third- party payors in the United States and coverage and reimbursement for products can therefore differ significantly from payor to payor and

coverage and reimbursement by one payor does not guarantee coverage and reimbursement by another payor. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our ability to demonstrate to these third- party payors that any of our approved product candidates creates a meaningful value proposition for patients, prescribers and payors will be important to gaining market access and reimbursement and there is no guarantee that we will be successful in doing so. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely. Even if a product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, third- party payors and others in the medical community necessary for commercial success. If any product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, hospitals, cancer treatment centers, third- party payors, and others in the medical community. For example, cancer treatments like chemotherapy, radiation therapy and certain existing immunotherapies are well established in the medical community, and doctors may continue to rely on these therapies. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product, if approved for commercial sale, will depend on a number of factors, including: ● the product' s efficacy, safety and potential advantages compared to alternative treatments; ● the prevalence and severity of any side effects; ● the product' s convenience and ease of administration compared to alternative treatments; ● the clinical indications for which the product is approved; ● the willingness of the target patient population to try a novel treatment and of physicians to prescribe such treatments; ● the recommendations with respect to the product in guidelines published by scientific organizations; ● the ability to obtain sufficient third- party insurance coverage and adequate reimbursement, including, if applicable, with respect to the use of the product as a combination therapy; ● the strength of marketing, sales and distribution support; ● the effectiveness of our sales and marketing efforts; ● the approval of other new products for the same indications; ~~and~~ **and70** ● our ability to offer the product for sale at competitive prices. If we obtain marketing approval for a product but such product does not achieve an adequate level of market acceptance, we may not generate or derive significant revenue from that product and our business, financial condition and results of operations may be adversely affected. ~~75Risks~~ -- **Risks** Related to Our Intellectual Property If we are unable to obtain and maintain patent protection for any product candidates we develop or for other proprietary technologies we may develop, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize product candidates and technology similar or identical to our product candidates and technology, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected. 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, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment and development that are important to our business. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our product candidates that are important to our business; we also license and may in the future license or purchase additional patents and patent applications filed by others. If we are unable to secure or maintain patent protection with respect to our product candidates and any proprietary products and technology we develop, our business, financial condition, results of operations and prospects could be materially harmed. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. Specifically, our patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non- infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a different masking moiety that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or have licensed with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. The U. S. Patent and Trademark Office, or the USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. Our or our licensor' s failure to comply with all such provisions during the patent process could result in abandonment or lapse of a patent or patent application that we own or license, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market and compete with us earlier than would otherwise have been the case. Moreover, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. In addition, to the extent that we license intellectual property in the future, we cannot guarantee that those licenses will remain in force. Patent positions of life sciences companies can be uncertain and involve complex factual and legal questions and have in recent years been the subject of much litigation. No consistent policy governing the scope of claims allowable in the field of engineered therapeutic proteins has emerged in the United States. The scope of patent protection in jurisdictions outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the

scope of our patents and any that we may license. Under the Leahy- Smith America Invents Act enacted in 2011, or the AIA, the United ~~States~~ **71States** moved to a first- to- file system in early 2013 (whereby, assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent), from the previous system under which the first to make a claimed invention was entitled to the patent. Publications of discoveries in the scientific and academic literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to file for patent protection on the inventions claimed in our patents or pending patent applications. Furthermore, for U. S. ~~76applications~~ **applications** in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third- party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. The patent prosecution process is complex, expensive, time- consuming and inconsistent across jurisdictions. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is possible that we will fail to identify important patentable aspects of our research and development efforts in time to obtain appropriate or any patent protection. While we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development efforts, including for example, our employees, external academic scientific collaborators, CROs, CDMOs, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose our confidential or proprietary information before a patent application is filed, thereby endangering our ability to seek patent protection. The issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Pending patent applications cannot be enforced against third parties unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or any patent applications that we may license in the future will result in patents being issued. Further, the scope of the invention claimed in a patent application can be significantly reduced before the patent is issued, and this scope can be reinterpreted after issuance. Even if patent applications we currently own or that we may license in the future issue as patents, they may not issue in a form that will provide us with adequate protection to prevent competitors or other third parties from competing with us, or otherwise provide us with a competitive advantage. Any patents that eventually issue may be challenged, narrowed or invalidated by third parties. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by valid and enforceable patent rights. Our competitors or other third parties may be able to evade our patent rights by developing new products that are similar to our product candidates, biosimilars of our product candidates, or alternative technologies or products in a non- infringing manner. The issuance or grant of a patent is not irrefutable 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. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. We may in the future, become subject to a third- party pre- issuance submission of prior art, pre- or post- issuance opposition, derivation, revocation, re- examination, post- grant and inter partes review, or interference proceeding and other similar proceedings challenging our patent rights or the patent rights of others in the USPTO or other foreign patent office. An unfavorable determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. 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. Moreover, third parties may have certain ownership interest in some of our owned and in- licensed patents and patent applications. If we are unable to obtain an exclusive license to any such third- party co- owners' interest in such patents or patent applications, such co- owners may be able to license their rights to other third parties, including our ~~competitors~~ **72competitors**, and our competitors could market competing products and technology. In addition, we or our licensors may need the cooperation of any such co- owners of our owned and in- licensed patents in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. ~~77Obtaining~~ **Obtaining** and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Some of our patent applications have been granted or may be granted or allowed in the future. We cannot be certain that an allowed patent application will become an issued patent. There may be events that can cause the allowance of a patent application to be withdrawn. For example, after a patent application has been allowed, but prior to being issued, material that could be relevant to patentability may be identified. In such circumstances, the sponsor may pull the application from allowance in order for the USPTO to review the application in view of the new material. We cannot be certain that the USPTO will re- allow the application in view of the new material. Further, periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and following the issuance of a patent. **Recently, the USPTO**

implemented new fee rules including Continuing Application Fee, which would increase our cost for obtaining and maintaining patent protection in the U. S. and potentially limit our ability of seeking additional patents in our existing patent families especially those early filed platform families that have been pending for close to or more than six years. We rely on our outside counsel and other professionals or our licensing partners to pay these fees due to the USPTO and non- U. S. government patent agencies and to help us comply with other procedural, documentary and other similar requirements 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. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business. Issued patents covering our product candidates or technology could be found invalid or unenforceable if challenged in court or the USPTO. Despite the measures we take to obtain and maintain patent and other intellectual property rights with respect to our product candidates, our intellectual property rights could be challenged or invalidated. If we or one of our licensors initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or our technology, the defendant could counterclaim that the patent covering our product candidate or technology, as applicable, is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, inter partes review, post- grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates or technology. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates or technology. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates. ~~Changes~~ **73Changes** to patent law in the United States and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time- consuming and inherently uncertain. In addition, the United States continues to adapt to wide- ranging patent reform legislation that became effective starting in 2012. Moreover, recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty regarding our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on new ~~78legislation~~ **legislation** and decisions by the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, the U. S. Supreme Court, in the case Amgen v. Sanofi, held that broad functional antibody claims are invalid for lack of enablement. In addition, in Juno v. Kite, the Federal Circuit held claims reciting broad antibody genus based on function invalid for lack of written description. Recently, the Federal Circuit issued ~~a~~ precedential ~~decision~~ **decisions** in In re Cellect ~~(No~~ **and Allergan v** . **MSN** ~~22- 1293)~~ that could shorten or eliminate an extended patent term awarded under patent term adjustment **in certain patent family members** if challenged on the basis of obviousness- type double patenting. While we do not believe that any of the patents owned or licensed by us will be found invalid based on these decisions, we cannot predict how future decisions by the courts, Congress or the USPTO may impact the value of our patents. Similarly, changes in the patent laws of other jurisdictions could adversely affect our ability to obtain and effectively enforce our patent rights, which would have a material adverse effect on our business and financial condition. We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world. We have obtained allowed patents in the United States that we consider to be important for certain of our product candidates, however, we may have less robust intellectual property rights outside the United States, and, in particular, we may not be able to pursue generic coverage of our product candidates outside of the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Most of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign

jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. In addition, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Many countries also limit the enforceability of patents against government agencies or government ~~contractors~~ **74contractors**. 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 and financial condition may be adversely affected. ~~79We~~ **We** rely on in-license agreements for patent rights with respect to our product candidates and may in the future acquire or in- license additional third- party intellectual property rights on which we may similarly rely. We face risks with respect to such reliance, including the risk that we could lose these rights that are important to our business if we fail to comply with our obligations under these licenses or that we may be unable to acquire or in- license third- party intellectual property that may be necessary or important to our business operations. We rely on third- party license agreements pursuant to which we have non- exclusive and exclusive rights to technology that is incorporated into our development programs and product candidates. For example, under our ~~cross-license agreement with AskGene, we have exclusively in- licensed patent rights relating to our IL- 2 program. In addition, under our~~ license agreement with City of Hope, we have exclusively in- licensed certain patent rights that cover our anti- CTLA- 4 antibody. We also have a license agreement with WuXi Biologics ~~(Hong Kong) Limited, or WuXi Biologics,~~ pursuant to which we received an exclusive worldwide license to specified ~~monoclonal antibodies, or~~ mAbs ~~,~~ and patent rights and know- how controlled by WuXi Biologics, including certain patent rights related to our anti- CTLA- 4 mAb program. These license agreements impose diligence, milestone payment, royalty payment and other obligations on us. Moreover, the growth of our business may depend in part on our ability to acquire, in- license or use additional third- party intellectual property rights. The licensing and acquisition of third- party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third- party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Licenses to additional third- party intellectual property, technology, processes, and materials that may be required for the development and commercialization of our product candidates or technology may not be available at all or on commercially reasonable terms. In that event, we may be required to expend significant time and resources to redesign our product candidates or manufacturing processes, or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize our future product candidates or technologies, which could materially harm our business, financial condition, results of operations and growth prospects. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, in the event we do in- license third- party intellectual property rights, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability. Under our agreement with City of Hope, we are responsible for the achievement of certain diligence milestones, and our failure to timely achieve such milestones could result in City of Hope' s termination of the agreement or conversion of our exclusive licenses under the licensed patents to non- exclusive licenses. If City of Hope terminates the agreement or converts our licenses to non- exclusive licenses as a result of our failure to meet these diligence milestones, then our ability to commercialize products comprising our anti- CTLA- 4 antibody may be impaired or we may face increased competition in the commercialization of anti- CTLA- 4 antibody products. Furthermore, our agreement with City of Hope is subject to, and we expect our future license agreements may also be subject to, a reservation of rights by one or more third parties, including the licensor. ~~Under our agreement with AskGene, AskGene retained co- exclusive rights to exploit antigen- binding IL- 2 products. Therefore, AskGene could develop and commercialize one or more antigen- binding IL- 2 products on a more timely basis than us, if we ever develop such a product, or that are more effective or have more commercial success than products that we may develop. Additionally, AskGene is responsible for prosecution and maintenance of the licensed patents under the agreement and any future third party from whom we may license patent rights may similarly be responsible for prosecution and maintenance of such patents. We have limited control over the activities that are the responsibility of AskGene and would have limited control over the activities that are the responsibility of any future licensor, and it is possible that prosecution and maintenance of licensed patents by AskGene or any future licensor may be less vigorous than had we conducted such activities ourselves.~~ Disputes may arise regarding intellectual property subject to our current or any future license agreements, including: ~~80~~ ● the scope of rights granted under the license agreement and other interpretation- related issues; ● the amount and timing of payments owed under the license agreements; **75** ● our or our licensor' s ability to defend intellectual property and to enforce intellectual property rights against third parties; ● the extent to which our technology, product candidates and processes infringe, misappropriate or otherwise violate any intellectual property of the licensor that is not subject to the licensing agreement; ● the sublicensing of patent and other rights under the license agreement; ● our diligence obligations under the license agreement and what activities satisfy

those diligence obligations; ● the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and any partners of ours; and ● the priority of invention of patented technology. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks described in this Annual Report on Form 10- K with respect to protection of intellectual property that we license as we are for intellectual property that we own. If we or our licensors fail to adequately obtain or protect this intellectual property, our ability to commercialize products could suffer. Our current and any potential future licensors might conclude that we have materially breached our license agreements and might therefore terminate the relevant license agreements, thereby removing our ability to develop and commercialize products and technology covered by such license agreements. If any of our current or future inbound license agreements are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products that are covered by such license agreements and underlying patents, which might be identical or similar to our products or product candidates. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and growth prospects. Our business also would suffer if any current or future licensors fail to abide by the terms of the license or fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor' s rights. Any licensor of ours may have relied on third- party consultants or collaborators or on funds from third parties, such as the United States government, such that such licensor is not the sole and exclusive owners of the patents we in- licensed. If other third parties have ownership rights or other rights to our in- licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. If our efforts to protect the proprietary nature of the intellectual property related to our technologies and product candidates are not adequate, we may not be able to compete effectively in our market. Biotechnology and pharmaceutical companies generally, and we in particular, compete in a crowded competitive space characterized by rapidly evolving technologies and aggressive development of intellectual property. We rely upon a combination of patents, confidentiality agreements, trade secret protection and license agreements to protect the intellectual property related to our technologies and our product candidates. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate ~~81or~~ **or** surpass our technological achievements and product candidates, thus eroding our competitive position in our market. We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. ~~It~~ **76It** is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, licensees or licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees or licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and / or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. We cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries. Third parties may challenge the validity, enforceability or scope thereof. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, a competitor' s technology or product would be found by a court to infringe our patents. Various post- grant review proceedings, such as inter partes review, post- grant review and derivation proceedings, are available and may be pursued by any interested third party in the USPTO to challenge the patentability of claims issued in patents to us or our licensors. No assurance can be given as to the outcome of any such post- grant review proceedings. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates or technology is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. On the other hand, the possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our products. Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, the AIA implemented in March 2013, moved the United States from a " first to invent " to a " first- to- file " system. Under a " first- to- file " system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The AIA includes a number of other significant changes to U. S. patent law, including provisions that affect the way patent applications are prosecuted,

redefine prior art and establish a USPTO- administered post- grant review system that has affected patent litigation. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example: ● others may be able to make or use polypeptides or nucleic acids that are similar to our product candidates or components of our product candidates but that are not covered by the claims of our patents; ~~82~~ ● the active biological ingredients in our current product candidates will eventually become commercially available in biosimilar drug products, and no patent protection may be available with regard to formulation or method of use; ● we or our licensors, as the case may be, may fail to meet our obligations to the U. S. government in regard to any patents and patent applications funded by U. S. government grants, leading to the loss of patent rights; **77** ● we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions; ● others may independently develop similar or alternative technologies or duplicate any of our technologies; ● it is possible that our pending patent applications will not result in issued patents; ● it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents; ● it is possible that others may circumvent our owned or in- licensed patents; ● it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours; ● the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States; ● the claims of our owned or in- licensed issued patents or patent applications, if and when issued, may not cover our product candidates or technology; ● our owned or in- licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties; ● the inventors of our owned or in- licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors; ● it is possible that our owned or in- licensed patents or patent applications omit individual (s) that should be listed as inventor (s) or include individual (s) that should not be listed as inventor (s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable; ● we have engaged in scientific collaborations in the past and will continue to do so in the future, and such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents; ● we may not develop additional proprietary technologies for which we can obtain patent protection; ● it is possible that product candidates or technology we develop may be covered by third parties' patents or other exclusive rights; or ● the patents of others may have an adverse effect on our business. ~~83Our~~ -- **Our** proprietary position depends upon patents that are manufacturing, formulation or method- of- use patents, which may not prevent a competitor or other third party from designing around or using the same product candidate for another use. Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of making or method of use. We cannot be certain, however, that the claims in our pending patent applications, including those claims covering the composition of matter of our product candidates, will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our patents that have issued or may issue will be considered valid and enforceable by courts in the United States or foreign countries. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions of matter relating to our product candidates, and instead ~~may~~ **78may** need to rely on secondary intellectual property, including patents or patent applications with claims covering formulations, methods of use and / or methods of manufacture. Method of use patents protect a specified method of using a product, such as a method of treating a particular medical indication. This type of patent may only be enforced against a competitor through indirect infringement, i. e., inducement or contributory infringement, which is more difficult to prove than direct infringement. A competitor may be able to circumvent this type of patent by skinny labelling. Furthermore, this type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their products for our targeted indications, physicians may prescribe these products " off- label " for those uses that are covered by our method of use patents. Although off- label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent by enforcing patent rights or otherwise. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to the protection afforded by patents, we seek to rely on trade secret protection, confidentiality agreements, and license and other agreements to protect proprietary know- how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know- how, information, or technology that is not covered by patents. For example, significant elements of our product candidates, including aspects of sample preparation, methods of manufacturing, cell culturing conditions and related processes are based on unpatented trade secrets that are not publicly disclosed. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party' s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best

practices, in protecting our trade secrets. However, we cannot provide assurance that these agreements and policies will not be breached by our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors and that our trade secrets and other proprietary and confidential information will not be disclosed to publicly or to competitors. We cannot be certain that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our trade secrets and other confidential proprietary know- how, information, or technology both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our trade secrets and other confidential information to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition. ~~84If~~ **If** we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Third- party claims of intellectual property infringement or violations may prevent or delay our discovery and development efforts. Our commercial success depends in part on our avoiding infringement of the patents and violation of other proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, reexamination, and post- grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation or other adversarial proceedings by third parties having patent or other intellectual property rights alleging that our product candidates and / or ~~proprietary~~ **79proprietary** technologies infringe their intellectual property rights. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents may ultimately issue because many patent filings cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods. If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to: ● infringement and other intellectual property claims, which, regardless of merit, may be expensive and time- consuming to litigate and may divert our management' s attention from our core business; ● substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party' s rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner' s attorneys' fees; ● a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do; ● if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts ~~,~~ and / or grant cross- licenses to intellectual property rights for our products; and ● redesigning our product candidates or processes so they do not infringe third- party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting preclinical and clinical trials and other development activities in the United States is not considered an act of infringement. If any of our product candidates is approved by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we do not believe that any claims that could otherwise have a materially adverse effect on the commercialization of our product candidates are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is " clear and convincing, " a heightened standard of proof. There may be issued third- party patents of which we are currently unaware with claims to compositions, formulations, methods ~~85of~~ **of** manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents or patent applications, the scope of pending or issued patent claims, or the expiration of relevant patents are complete, nor can we be certain that we have identified each and every third- party patent and pending application in the United States and abroad that is relevant to or necessary to commercialization of our product candidates in any jurisdiction. There may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant third- party patents or incorrectly interpret the relevance, scope, or expiration of a third- party patent or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third- party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the ~~holders~~ **80holders** of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third- party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we

obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available on commercially reasonable terms or at all. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in- licenses. Currently, we have certain intellectual property rights under patents and patent applications that we own or have rights to under our inbound license agreements related to our product candidates. Our development of additional product candidates may require the use of proprietary rights held by third parties, and the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. Our product candidates may also require specific formulations to work effectively and efficiently, and rights to such formulation technology may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. Moreover, the specific components, such as linkers and antibody fragments, that will be used with our product candidates may be covered by the intellectual property rights of others. We may be unable to acquire or in- license any compositions, methods of use, formulations, processes or other third- party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by ~~86such --~~ **such** third- party intellectual property rights and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Additionally, we may collaborate with or sponsor research at academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions may provide us with an option to negotiate a license to any of the institution' s rights in technology resulting from the collaboration or sponsorship. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third- party ~~intellectual~~ **81intellectual** property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer. The licensing and acquisition of third- party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time- consuming and unsuccessful. Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file lawsuits with infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Third parties may initiate post- grant proceedings and the Patent Trial and Appeal Board of the USPTO may institute such proceedings to determine the validity or priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Litigation or post- grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, infringement of our

patents or misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. ~~87We~~ **We** may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own. ~~We~~ **82We** may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed confidential information of our competitors or are in breach of non- competition or non- solicitation agreements with our competitors. Many of our employees, consultants and advisers were previously employed at other pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. Some of these employees, consultants, advisers, and members of management executed proprietary rights, non- disclosure and non- competition agreements in connection with such previous employment. Although we take steps to ensure that our employees do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, consultants, advisers, and members of management have inadvertently or otherwise used or disclosed trade secrets or other confidential information of these former employers or competitors. In addition, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non- competition or non- solicitation agreement. 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 these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition. In the future, we may in- license intellectual property that may have been discovered through government funded programs and thus may be subject to federal regulations and a preference for U. S.- based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non- U. S. manufacturers. Any of the intellectual property rights that we have licensed or may license in the future and that have been generated through the use of U. S. government funding are subject to certain federal regulations. As a result, the U. S. government may have certain rights to intellectual property embodied in our product candidates pursuant to the Bayh- Dole Act of 1980, or the Bayh- Dole Act. These U. S. government rights in certain inventions developed under a government- funded program include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose, generally referred to as " march- in rights. " To our knowledge, none of our current product candidates are subject to march- in rights. However, intellectual property rights that we license in the future could be subject to such limitations. The U. S. government also has the right to take title to such intellectual property rights if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. We cannot be certain that our current or future licensors will comply with the disclosure or reporting requirements of the Bayh- Dole Act at all times or be able to rectify any lapse in compliance with these requirements. In addition, the U. S. government requires that any products embodying the subject invention or produced using the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible. This preference for U. S. manufacturers may limit ~~88our~~ -- **our** ability to contract with non- U. S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U. S. government funding, the provisions of the Bayh- Dole Act may similarly apply. If we do not obtain patent term extension for any of our current or future product candidates, our business may be materially harmed. Depending upon the timing, duration and specifics of any FDA marketing approval of any of our current or future product candidates, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch- Waxman Act. The Hatch- Waxman Act permits a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. ~~A~~ **83A** patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended for each marketing approval and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If

we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our marks of interest and our business may be adversely affected. Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and / or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. Numerous factors may limit any potential competitive advantage provided by our intellectual property rights. The degree of future protection afforded by our intellectual property rights, whether owned or in- licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The factors that may limit any potential competitive advantage provided by our intellectual property rights include: ● pending patent applications that we own or license may not lead to issued patents; ● patents, should they issue, that we own or license, may not provide us with any competitive advantages, or may be challenged and held invalid or unenforceable; ● others may be able to develop and / or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any of our owned or in- licensed patents, should any such patents issue; ~~89~~ ● third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection; ● we (or our licensors) might not have been the first to make the inventions covered by a pending patent application that we own or license; ● we (or our licensors) might not have been the first to file patent applications covering a particular invention; ● others may independently develop similar or alternative technologies without infringing our intellectual property rights; **84** ● we may not be able to obtain and / or maintain necessary licenses on reasonable terms or at all; ● third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property; ● we may not be able to maintain the confidentiality of our trade secrets or other proprietary information; ● we may not develop or in- license additional proprietary technologies that are patentable; and ● the patents of others may have an adverse effect on our business. Should any of these events occur, they could significantly harm our business and results of operation. Risks Related to Regulatory Approval and Other Legal Compliance Matters Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we will obtain marketing approval to commercialize a product candidate. The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of drug and biologic products are subject to extensive regulation by the FDA and comparable foreign regulatory authorities. We are not permitted to market our product candidates in the United States or in other countries until we receive approval of **a** ~~an NDA or~~ BLA from the FDA or marketing approval from applicable regulatory authorities outside the United States. Our product candidates are in various stages of development and are subject to the risks of failure inherent in development. We have not submitted an application for or received marketing approval for any of our product candidates in the United States or in any other jurisdiction. We have no experience as a company in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third- party CROs to assist us in this process. The process of obtaining marketing approvals, both in the United States and abroad, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy. The FDA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. Further, **the FDA may determine that we must provide additional evidence and data before approving a BLA for our product candidates. For example, the FDA reviews an application to determine whether there is " substantial evidence " to support a finding of effectiveness for the proposed product for its intended use (s). The FDA has interpreted this evidentiary standard to generally require at least two adequate and well- controlled clinical trials to establish effectiveness of a new product. Under certain circumstances, however, the FDA has indicated that a single trial with certain characteristics and additional confirmatory evidence may satisfy this standard. The FDA issued draft guidance in September 2023 that outlines considerations for relying on confirmatory evidence in lieu of a second clinical trial to demonstrate effectiveness. In the event that we submit a BLA on the basis of one clinical trial and confirmatory evidence, the FDA could determine that such information is not sufficient to support approval of the application and the agency could require us to conduct an additional trial in support of the BLA. Further,** under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA ~~, or NDA or supplement to an NDA,~~ for certain biological products ~~and drug products, respectively,~~ must contain data to assess the safety and effectiveness of the biological

product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a ~~finding~~ **85finding** that the product or therapeutic candidate ~~90is~~ **is** ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The applicable legislation in the EU also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our product candidates for which we are seeking regulatory approval in the United States or the EU, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action. In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable **. Moreover, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA, or a comparable foreign regulatory authority, may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA, or comparable foreign regulatory authority, may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA, or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates** . For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act, or FDORA, 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 of FDA- regulated products **. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for diversity action plans, or DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance, when finalized, will have the force of law, because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance** . Further, in January 2022, the new Clinical Trials Regulation (EU) No 536 / 2014 became effective in the EU and replaced the prior Clinical Trials Directive 2001 / 20 / EC. This regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the EU. Under the coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one EU Member State will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a clinical trials portal overseen by the EMA and available to clinical trial sponsors, competent authorities of the EU Member States and the public. Accordingly, any delay in obtaining or failure to obtain required approvals could negatively affect our ability or that of any future collaborators to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price. Disruptions in the FDA and other government agencies ~~caused by funding shortages or~~ **for any reason** ~~global health concerns~~ could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes and other events that may otherwise affect the FDA' s ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other ~~government~~ **86government** agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA, EMA and other agencies may also slow the time necessary for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U. S. government shut down several times and certain regulatory agencies, such as the FDA and the Securities and Exchange Commission, or the SEC, had to furlough critical employees and stop critical activities. In addition, disruptions may result from events similar to the COVID- 19 pandemic. During the COVID- 19 pandemic, a number of companies announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the United States facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities. ~~91If~~ **Further, with the change in U. S. presidential administrations in 2025, there is substantial uncertainty as to how, if at all, the new presidential administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. There is also uncertainty as to how other measures being implemented by the Trump Administration across the government will impact our activities and those of the FDA and its operations. For example, the potential loss of FDA personnel could lead to further disruptions and delays in FDA review of our product candidates. Similarly, efforts by the new presidential administration to substantially reduce research funding by the U. S. National Institutes of Health of medical research could have substantial direct or indirect impacts on our research activities. If** a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our

regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets. Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad. Any approval we may be granted for our product candidates in the United States would not assure approval of our product candidates in foreign jurisdictions and any of our product candidates that may be approved for marketing in a foreign jurisdiction will be subject to risks associated with foreign operations. In order to market and sell our products in the EU and other foreign jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may file for marketing approvals but not receive necessary approvals to commercialize our products in any market. In many countries outside the United States, a product candidate must also be approved for reimbursement before it can be sold in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. Obtaining non- U. S. regulatory approvals and compliance with non- U. S. regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. In addition, if we fail to obtain the non- U. S. approvals required to market our product candidates outside the United States or if we fail to comply with applicable non- U. S. regulatory requirements, our target markets will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects may be adversely affected. ~~Additionally~~ **87Additionally** , we could face heightened risks with respect to obtaining marketing authorization in the United Kingdom **, or the U. K.,** as a result of the withdrawal of the ~~United Kingdom~~ **U. K.** from the EU, commonly referred to as Brexit. The ~~United Kingdom~~ **U. K.** is no longer part of the European Single Market and EU Customs Union. As of January 1, ~~2021~~ **2025** , the Medicines and Healthcare ~~products~~ **Products** Regulatory Agency, or MHRA, ~~became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas under the terms of the Northern Ireland Protocol, Northern Ireland~~ is ~~currently subject to EU rules. The United Kingdom and EU have however agreed to the Windsor Framework which fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the United Kingdom Once implemented, the changes introduced by the Windsor Framework will see the MHRA be~~ responsible for approving all medicinal products destined for the ~~UK~~ **U. K.** market (i. e., Great Britain and Northern Ireland) **. At the same time** , **a new international recognition procedure, or IRP, will apply, which intends to facilitate approval of pharmaceutical products in the U. K. The IRP is open to applicants that have already received** ~~and~~ **an authorization for** the **same product from one of the MHRA' s specified Reference Regulators. The Reference Regulators notably include** EMA **and regulators** ~~will no longer have any role~~ in ~~approving medicinal products destined~~ **the EU / European Economic Area, or EEA, member states** for ~~Northern Ireland~~ **approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA for product approvals granted in the United States. However, the concrete functioning of the IRP is currently unclear** . Any delay in obtaining, or an inability to obtain, any marketing **approvals** ~~authorizations, as a result of Brexit or otherwise,~~ may force us **or our collaborators** to restrict or delay efforts to seek regulatory approval in the ~~United Kingdom~~ **U. K.** for our product candidates, which could significantly and materially harm our business. In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission' s proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may however have a significant impact on the pharmaceutical industry and our business in the long ~~term92Any~~ **term. Any** delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business. We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States. We may not be able to obtain orphan drug designation or orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA from approving competing products. Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually in the United States. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the EMA will be precluded from approving

another marketing application for the same product for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States and ten years in the EU. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. We may seek orphan drug designations for our product candidates and may be unable to obtain such designations. Even if we do secure such designations and orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. Further, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, to be more effective or to make a major contribution to patient care. Finally, orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if ~~the~~ **88the** manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term " same disease or condition " means the designated " rare disease or condition " and could not be interpreted by the Agency to mean the " indication or use. " Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the " indication or use. " Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that court order, the FDA will continue to apply its existing regulations tying orphan- drug exclusivity to the uses or indications for which the orphan drug was approved. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. Any product candidate for which we obtain marketing approval is subject to ongoing regulation and could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements, when and if any of our product candidates are approved. Any product candidate for which we obtain marketing approval will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control and manufacturing, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. In addition, the approval may be subject to limitations on the ~~93indicated~~ -- **indicated** uses for which the product may be marketed or to the conditions of approval or contain requirements for costly post- marketing testing and surveillance to monitor the safety or efficacy of the medicine, including the requirement to implement a risk evaluation and mitigation strategy. Accordingly, if we receive marketing approval for one or more of our product candidates, we will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we fail to comply with these requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any products could be limited, which could adversely affect our ability to achieve or sustain profitability. Failure to comply with regulatory requirements, may yield various results, including: ● restrictions on such products, manufacturers or manufacturing processes; ● restrictions on the labeling or marketing of a product; ● restrictions on distribution or use of a product; ● requirements to conduct post- marketing studies or clinical trials; ● warning letters or untitled letters; ● withdrawal of the products from the market; ● refusal to approve pending applications or supplements to approved applications that we submit; ● recall of products; ● damage to relationships with collaborators; **89** ● unfavorable press coverage and damage to our reputation; ● fines, restitution or disgorgement of profits or revenues; ● suspension or withdrawal of marketing approvals; ● refusal to permit the import or export of our products; ● product seizure; ● injunctions or the imposition of civil or criminal penalties; and ● litigation involving patients using our products. Non- compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the EU' s requirements regarding the protection of personal information can also lead to significant penalties and sanctions. Further, the marketing and promotion of authorized drugs, including industry- sponsored continuing medical education and advertising directed toward the prescribers of drugs and / or the general public, are strictly regulated in the EU notably under Directive 2001 / 83EC, as amended, and are also subject to EU Member State laws. Direct- to- consumer advertising of prescription medicines is prohibited across the EU. Accordingly, assuming we, or our collaborators, receive marketing approval for one or more of our product candidates, we, and our collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all ~~94areas~~ -- **areas** of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we, and our collaborators, are not able to comply with post- approval regulatory requirements, our or our collaborators' ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post- approval regulations may have a negative effect on our operating results and financial condition. Any regulatory approval to market any of our products candidates for which we obtain approval will be limited by indication. If we fail to comply or are found to be in violation of FDA regulations restricting the promotion of any of our product candidates for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards. The regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA, EMA, MHRA and other government agencies. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a drug product. Physicians may nevertheless prescribe products off- label to their patients in a manner that is inconsistent with the approved label. Prior to the approval of any of our product candidates, we intend to implement compliance and training programs designed to ensure that any future sales and marketing practices comply with applicable regulations. Notwithstanding

these programs, the FDA or other government agencies may allege or find that our practices constitute prohibited promotion of our products for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses. Notwithstanding the regulatory restrictions on off- label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non- misleading, and non-promotional scientific communications concerning their products in certain circumstances. For example, in ~~October~~ **January** ~~2023~~ **2025** , the FDA published ~~draft~~ **final** guidance outlining **its** ~~the agency' s non- binding~~ policies governing the distribution of scientific information ~~on~~ **to healthcare providers about** unapproved uses ~~to healthcare providers~~ **of approved products** . ~~This draft~~ **The final** guidance calls for such communications to be truthful, non- misleading, ~~factual,~~ and ~~unbiased~~ **scientifically sound** and **to** include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use ~~. In addition, under some relatively recent guidance from the FDA and the Pre- Approval Information Exchange Act, or PIE Act, signed into law as part~~ of the **approved product. If a** ~~Consolidated Appropriations Act of 2023, companies~~ **company engages in such communications** ~~may also promote information that is~~ consistent with the ~~prescribing information and proactively speak to formulary committee members~~ **guidance' s recommendations, the FDA indicated that it will not treat such communications as evidence** of ~~payors regarding data~~ **90unlawful promotion of a new intended use** for **the** ~~an unapproved drug or unapproved uses of an~~ approved **product** ~~drug. We may engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices~~ . We will need to carefully navigate the FDA' s various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products. In recent years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U. S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission, or the FTC, and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the FDCA, the False Claims Act, the Prescription Drug Marketing Act and anti- kickback laws and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and / or Medicaid reimbursement. Many of these investigations originate as " qui tam " actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim or caused a false claim to be submitted to the government for payment. The person bringing a qui tam suit is entitled to a share of any recovery or settlement. Qui tam suits, also commonly referred to as " whistleblower suits, " are often brought by current or former employees. In a qui tam suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone. If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and ~~95corporate~~ -- **corporate** integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation. We may seek certain designations for our product candidates, including Breakthrough Therapy, Fast Track and Priority Review designations in the United States and PRIME Designation in the EU, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process. We may seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life- threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product' s application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. We may also seek a priority review designation for one or more of our product candidates. If the FDA determines that a product candidate **is intended to treat a serious condition and, if approved,** offers ~~major advances in treatment or provides~~ a ~~treatment where no adequate therapy exists~~ **significant improvement in safety or effectiveness** , the FDA may designate the product candidate for priority review **. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation** . A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. ~~These~~ **91These** designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and

does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In the EU, we may seek PRIME designation for some of our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA' s role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the EU or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the EU and the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims. The benefits of a PRIME designation include the appointment of a CHMP rapporteur to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to ~~96conventional --~~ **conventional** EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA' s grant of a marketing authorization. Accelerated approval by the FDA, even if granted for any of our current or future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval. We may seek approval of any of our current and future product candidates using the FDA' s accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life- threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA or other applicable regulatory agency makes the determination regarding whether a surrogate endpoint is reasonably likely to predict long- term clinical benefit. Prior to seeking such accelerated approval, we will seek feedback from the FDA and otherwise evaluate our ability to seek and receive such accelerated approval. As a condition of approval, the FDA requires that a sponsor of a product receiving accelerated approval perform an adequate and well- controlled post- marketing confirmatory clinical trial or trials. These confirmatory trials must be completed with due diligence and we may be required to evaluate different or additional endpoints in these post- marketing confirmatory trials. These confirmatory trials may require enrollment of more patients than we currently anticipate and will result in additional costs, which may be greater than the estimated costs we currently anticipate. In addition, the FDA currently requires as a condition for accelerated approval preapproval of promotional materials, which could adversely impact the timing of the commercial launch of the product. There can be no assurance that the FDA will agree with any proposed surrogate endpoints or that we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval for any of our current or future product candidates. Similarly, there can be no assurance that, after feedback from FDA, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted or that any expedited review or approval will be granted on a timely basis, or at all. ~~The~~ **92The** FDA may withdraw approval of a product candidate approved under the accelerated approval pathway if, for example, the trial required to verify the predicted clinical benefit of our product candidate fails to verify such benefit or does not demonstrate sufficient clinical benefit to justify the risks associated with the drug. The FDA may also withdraw approval if other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use, we fail to conduct any required post approval trial of our product candidate with due diligence or we disseminate false or misleading promotional materials relating to our product candidate. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates, or withdrawal of a product candidate, would result in a longer time period for commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace. **Further, there can be no assurance that we will satisfy all FDA requirements, including new provisions that govern accelerated approval. For example,** ~~With~~ **with the** passage of ~~the~~ FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to ~~:~~ require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded **and** ~~, require a sponsor of a product granted accelerated approval~~ to submit progress reports on its post- approval studies to the FDA every six months until the study is completed ~~; and use~~ **. Moreover, FDORA established** expedited procedures **authorizing FDA** to withdraw **an** accelerated approval ~~of~~ **if certain conditions are met, including where** a **required** ~~new drug application or BLA after the~~ confirmatory trial fails to verify **and describe** the product' s **predicted** clinical benefit **or where evidence demonstrates the product is not shown to be safe or effective under the conditions of use** . **The** ~~Further, FDORA --~~ **FDA may also use such procedures to withdraw an accelerated approval if a sponsor fails to conduct any** ~~requires~~ **required** ~~the agency to publish on its website " the rationale for why a~~ post- approval study ~~is not appropriate or necessary~~ **of the product with due diligence, including with respect to " conditions specified by the Secretary.** ~~"~~ ~~whenever it decides not to require such~~ **The new procedures include the provision of due notice and an explanation for** a ~~study upon granting~~ **proposed withdrawal, and opportunities for a meeting with the FDA commissioner or the FDA commissioner' s designee and a written appeal, among other things. We will need to fully comply with these and other requirements in connection with the development and approval of any product candidate that qualifies for**

accelerated approval. More recently, in March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The FDA indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life- threatening nature of cancer. Although single- arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. To that end, the FDA outlined considerations ~~97for~~ -- **for** designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics **. Subsequently, in December 2024 and January 2025, the FDA issued additional draft guidance relating to accelerated approval. This guidance describe the FDA' s views on what it means to conduct a confirmatory trial with due diligence and how the agency plans to interpret whether such a study needs to be underway at the time of approval** . While this guidance is currently only in draft form and will **ultimately** not be legally binding even when finalized, **sponsors typically observe** ~~we will need to consider~~ the FDA' s guidance closely ~~if we seek~~ **to ensure that their investigational products qualify for** accelerated ~~approval for any of our products. Accordingly, even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA~~ approval. In the EU, a " conditional " marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a " standard " marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed. Current and future legislation may increase the difficulty and cost for us to obtain reimbursement for any of our candidate products that do receive marketing approval. In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as 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 may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed. ~~In~~ **93In** March 2010, President Obama signed into law the ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation' s automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year, which went into effect in April 2013 and will remain in effect through 2031 under the CARES Act. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Under current legislation, the actual reductions in Medicare payments may vary up to 4 %. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Consolidated Appropriations Act delays the 4 % Statutory Pay- As- You- Go Act of 2010, or PAYGO, sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4 % cut to the Medicare program would have taken effect in January 2023. The Consolidated Appropriation Act' s health care offset title includes Section 4163, which extends the 2 % Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031. Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Act, which was signed by President Trump on December 22, 2017, Congress repealed the " individual mandate. " The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, on June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. ~~98The~~ **During the first** Trump **presidential** ~~Administration~~ **administration** ~~also took~~ **, Congress and administration sought to overturn the ACA and related measures. Shortly after taking office in January 2025, President Trump revoked numerous** executive **orders issued by** ~~actions to undermine or delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however,~~ President Biden ~~issued an~~ **, including at least two** executive ~~order~~ **orders , EO 14009, Strengthening Medicaid and** ~~that initiated a special enrollment period for purposes of obtaining health insurance coverage through~~ the Affordable Care Act ~~marketplace~~ **, and EO 14070, Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage** , which **were designed** ~~began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies~~ to **further implement** ~~review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or~~ the ACA. ~~It is possible that~~ **We anticipate similar efforts to undermine** the ACA ~~will~~

be subject to judicial , **and the accompanying uncertainty,** or **for** Congressional challenges in the **foreseeable** future . It is unclear how such other challenges to repeal or replace the ACA or the health reform measures of the Biden administration will impact the ACA or our business . In the EU, on December 13, 2021, Regulation No 2021 / 2282 on Health Technology Assessment, or HTA, amending Directive 2011 / 24 / EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation- related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products as well as certain high- risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non- clinical (e. g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement. We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and / or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are **94are** prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates. Current and future legislative efforts may limit the prices for our products, if and when they are licensed for marketing, and that could materially impact our ability to generate revenues. The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U. S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid . In 2020, President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician- administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, the Centers for Medicare & Medicaid Services, or CMS, issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence- based care . In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. That 99regulation -- **regulation** was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Nine **Seven** states (Colorado, Florida, Maine, New Hampshire, New Mexico, North Dakota, Texas , **and** Vermont and Wisconsin) have passed laws allowing for the importation of drugs from Canada. Certain of **North Dakota and Virginia have passed legislation establishing working groups to examine** these -- **the impact of a state importation program. As of May 2024, five** states have **(Colorado, Florida, Maine, New Hampshire and New Mexico) had** submitted Section 804 Importation Program proposals **to the FDA,** and **on** are awaiting approval. On January 5, 2023, the FDA approved Florida' s plan for Canadian drug importation **. Florida now has authority to import certain drugs from Canada for a period of two years once certain conditions are met, but it will first need to submit a pre- import request for each drug selected for importation, which must be approved by the FDA. Florida will also need to relabel the drugs and perform quality testing of the products to meet FDA standards** . Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration until January 1, 2026 by the Infrastructure Investment and Jobs Act. The final rule would eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point- of- sale discounts and pharmacy benefit manager service fees. It originally was set to go into effect on January 1, 2022, but with the passage of the Inflation Reduction Act of 2022, or the IRA, has been delayed by Congress to January 1, 2032 . On July 9, 2021, President Biden signed Executive Order 14063, which focuses on, among other things, the price of pharmaceuticals. The Order directs HHS to create a plan within 45 days to combat " excessive pricing of prescription pharmaceuticals and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the federal government for such pharmaceuticals, and to address the recurrent problem of price gouging. " On September 9, 2021, HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (a) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (b) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (c) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments . On August 16, 2022, the 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 Department of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single- source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high- cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our drug products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years. Further, the legislation subjects drug manufacturers to civil monetary ~~penalties~~ **95penalties** and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated " maximum fair price " under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out- of- pocket drug costs at an estimated $ 4, 000 a year in 2024 and, thereafter beginning in 2025, at $ 2, 000 a year **. The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023. On August 15, 2024, the HHS published the results of the first Medicare drug price negotiations for ten selected drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis. The prices of these ten drugs will become effective January 1, 2026. On January 17, 2025, CMS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations. Thereafter, following the change in U. S. presidential administrations, CMS issued a public statement on January 29, 2025, declaring that lowering the cost of prescription drugs is a top priority of the Trump administration and CMS is committed to considering opportunities to bring greater transparency in the negotiation program. The second cycle of negotiations with participating drug companies will occur during 2025, and any negotiated prices for this second set of drugs will be effective starting January 1, 2027** . In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or " catastrophic period " of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period must pay 100 % of the cost of their prescriptions until they reach ~~100the~~ **the** catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co- insurance and co- payment costs, expanding eligibility for lower income subsidy plans, and price caps on annual out- of- pocket expenses, each of which could have potential pricing and reporting implications. We expect that current or future litigation involving provisions of the IRA will have unpredictable and uncertain results on the implementation and impact of the IRA on biotechnology industry generally, as well as our business and current or future products. For example, on June 6, 2023, Merck & Co., or Merck, filed a lawsuit against the HHS and CMS asserting that, among other things, the IRA' s Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including the U. S. Chamber of Commerce, Bristol Myers Squibb Company, the PhRMA, Astellas, Novo Nordisk, Janssen Pharmaceuticals, Novartis, AstraZeneca and Boehringer Ingelheim, also filed lawsuits in various courts with similar constitutional claims against the HHS and CMS. **There have been various decisions by the courts considering these cases since they were filed. The HHS has generally won the substantive disputes in these cases, and various federal district court judges have expressed skepticism regarding the merits of the legal arguments being pursued by the pharmaceutical industry. Certain of these cases are now on appeal, and oral arguments took place on October 30, 2024.** We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results. Accordingly, while it is currently unclear how the IRA will 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. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures **. This may be increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and 96implementing**

significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA' s standards for accelerated approval . Finally, outside the United States, in some nations, including those of the EU, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost- effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed. We may be subject to certain healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, fines, disgorgement, exclusion from participation in government healthcare programs, curtailment or restricting of our operations, and diminished future profits and earnings, if any. Healthcare providers, third- party payors and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with healthcare providers and third- party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research as well as market, sell and distribute any products for which we obtain marketing approval. Potentially applicable U. S. federal and state healthcare laws and regulations include the following: ● Anti- Kickback Statute. The federal Anti- Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. ● False Claims Laws. The federal false claims laws and civil monetary penalties laws, including the civil False Claims Act and the Civil Monetary Penalty Law, impose criminal and civil penalties, including those from civil ~~101whistleblower~~ --- **whistleblower** or qui tam actions against individuals or entities for knowingly presenting, or causing to be presented to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. ● HIPAA. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program. ● HIPAA and HITECH. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, also imposes obligations on certain types of individuals and entities, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. ● False Statements Statute. The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. ● Transparency Requirements. The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children' s Health Insurance Program, with specific exceptions, to report annually to the Department of Health and Human Services information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare providers, and ownership and investment interests by physicians and their immediate family members. As of January 1, 2022, applicable manufacturers are also required to report such information regarding its payments and other transfers of value to ~~physician~~ **97physician** assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year. ● Analogous State and Foreign Laws. Analogous state laws and regulations, such as state anti- kickback and false claims laws, and transparency laws, may apply to sales or marketing arrangements, and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. Many state laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Foreign laws also govern the privacy and security of health information in many circumstances. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician' s employer, his or her competent professional organization and / or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, and reputational harm, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do ~~102business~~ --- **business** is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. We 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 to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations. We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally identifiable 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 United Kingdom. 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. Failure to comply with any of these laws and regulations could result in 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. There are numerous U. S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can ~~be~~ **98be** complex and may be subject to changing interpretation. These obligations may be applicable to some or all of our business activities now or in the future. 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, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems. There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission, or FTC, and state attorneys general all are aggressive in reviewing privacy and data security protections for consumers. In addition, new laws have been enacted or are considered at both the federal and state levels. As a result, we will need to seek to ensure our business practices comply with evolving rules and guidance at the federal and state level related to privacy and data security in order to mitigate our risk for any potential enforcement action, which may be costly. In addition, if we are subject to an enforcement action and settlement order, we may be required to adhere to very specific privacy and data security practices or pay fines and adhere to specified compliance requirements, all of which could be costly and adversely impact our business. For example, the FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be " unfair " under Section 5 of the FTC Act, as well as the types of activities it views to trigger the Health Breach Notification Rule, which the FTC also has the authority to enforce, and is in the process of developing rules related to commercial surveillance and data security. Similarly, in 2018, California passed into law the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California ~~103residents~~ --- **residents** . Many of the CCPA' s requirements are similar to those found in the General Data Protection Regulation, or the GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt- out of " sales " of their personal information. The CCPA contains significant penalties for companies that violate its requirements. In addition, the California Privacy Rights Act, or the CPRA, went into effect on January 1, 2023 and significantly expanded the CCPA to incorporate additional GDPR- like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created the California Privacy Protection Agency, a new enforcement agency whose sole responsibility is to enforce the CPRA. In addition to California, at least ~~11~~ **18** other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect **now** or will go into effect **in** ~~sometime before~~ the **future** ~~end of 2026~~ . Like the CCPA and CPRA, 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). Some of the provisions of these laws may apply to our business activities ~~. There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2023 legislative sessions that will go into effect in 2024 and beyond, including New Hampshire and New Jersey. Other states will be considering these laws in the future, and Congress has also been debating passing a federal privacy law~~ . There are also states that are specifically regulating health information that may affect our business. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. **Other states, including New York, will be considering similar laws.** 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 **. 99Plaintiffs' lawyers are also increasingly using privacy- related statutes at both the state and federal level to bring lawsuits against companies for their data- related practices. In particular, there have been a significant number of cases filed against companies for their use of pixels and other web trackers. These cases often allege violations of the California Invasion of Privacy Act and other state laws regulating wiretapping, as well as the federal Video Privacy Protection Act. The rise in these types of lawsuits creates potential risk for our business** . 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 the 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 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. The GDPR places restrictions on the cross- border transfer of personal data from the EU to countries that have not been found by the **European Commission, or** EC **,** to offer adequate data protection legislation, such as the United States. There are ongoing concerns about the ability of companies to transfer personal data from the EU to other countries. In July 2020, the Court of Justice of the European Union, or the CJEU, invalidated the EU- U. S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision also drew into question the long- term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States. While we were not self- certified under the Privacy Shield, this CJEU decision may lead to increased scrutiny on data transfers from the EEA to the United States generally and increase our costs of compliance with data privacy legislation, as well as our costs of negotiating appropriate privacy and security agreements with our vendors and business partners. Additionally, in October 2022, President Biden signed an executive order to implement the EU- U. S. Data Privacy Framework, which would serve as a replacement to the EU- U. S. Privacy Shield. The EU initiated the process to adopt an adequacy decision for the EU- U. S. Data Privacy Framework in December 2022 and the European Commission adopted the adequacy decision on July 10, 2023. The adequacy decision will permit U. S. companies who self- certify to the EU- U. S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the EU to the United ~~104States~~ --- **States** . However, some privacy advocacy groups have already suggested that they will be challenging the EU- U. S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU- U. S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business at the international level. Furthermore, while the Data Protection Act of 2018 in the United Kingdom that " implements " and complements the GDPR has achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is still unclear whether transfer of data from the EEA to the United Kingdom will remain lawful under GDPR. The Trade and Cooperation Agreement provides for a transitional period during which the United Kingdom will be treated like a EU member state in relation to processing and transfers of personal data for four months from January 1, 2021. This may be extended by two further months. After such period, the United Kingdom will be a " third country " under the GDPR unless the European Commission adopts an adequacy decision in respect of transfers of personal data to the United Kingdom. The United Kingdom has already determined that it considers all of the EU 27 and EEA member states to be adequate for the purposes of data protection, ensuring that data flows from the United Kingdom to the EU / EEA remain unaffected. Beyond GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow GDPR as a model, other laws contain different or conflicting provisions. These laws will impact our ability to conduct our business activities, including both our clinical trials and the sale and distribution of commercial products, through increased compliance costs, costs associated with contracting and potential enforcement actions. ~~While~~ **100While** 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. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it 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 to comply with data protection and privacy laws could result in government- imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and 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. We are subject to U. S. and certain foreign export control, import, sanctions, anti- corruption, and anti- money laundering laws and regulations with respect to our operations and non- compliance with such laws can subject us to criminal and / or civil liability and harm our business. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Control, the U. S. Foreign Corrupt Practices Act of

1977, as amended, or the FCPA, the U. S. domestic bribery statute contained in 18 U. S. C. § 202, the U. S. Travel Act, the USA PATRIOT Act, and other state and national anti- bribery and anti- money laundering laws in countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, third- party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities and other organizations. In addition, we may engage third- party intermediaries to promote our clinical research activities abroad and / 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, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities. ~~105Noncompliance~~ --- **Noncompliance** with the laws and regulations described above 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, investigations or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition 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 and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens. 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 recently made statements and taken certain actions that may lead to potential changes to U. S. and international trade policies, including imposing several rounds of tariffs and export control restrictions affecting certain products manufactured in China, and ~~,~~ most recently, proposing legislation that, if **enacted** ~~passed,~~ would restrict trade with certain Chinese companies that provide biopharmaceutical research, development **,** and manufacturing services. Recently ~~,~~ both China and the United States have each imposed tariffs indicating the potential for further trade barriers. **In addition, in the past the U. S. Commerce Department has implemented export controls adding numerous Chinese entities to its " unverified list, " which requires U. S. exporters to go through more procedures before exporting goods to such entities.** It is unknown ~~whether~~ **101whether** and to what extent new tariffs, export controls, trade restrictions, or other new laws or regulations will be adopted, or the effect that any such actions would have on us or our industry. Sustained uncertainty about, or the further escalation of, trade and political tensions between the United States and China could result in a disadvantageous research and manufacturing environment in China, particularly for U. S. ~~-~~ based companies, including retaliatory restrictions that hinder or potentially inhibit our ability to rely on ~~our CDMO~~ **CDMOs** and other service providers that operate in China. For example, proposed legislation has been introduced in Congress that could prohibit, among other things, the use of U. S. government executive agency contract, grant, or loan funding to ~~provide~~ **procure** or ~~to~~ **obtain, or** enter into, extend or renew contracts involving the use of certain equipment or services produced or provided by certain Chinese companies, **including our current CDMO, WuXi Biologics,** which could cause us to reevaluate our relationship with our current CDMO **. In addition to our CDMO, WuXi Biologics, some of our other suppliers, vendors and service providers are located in China. Trade tensions and conflicts between the United States and China have been escalating in recent years and, as such, we are exposed to the possibility of supply disruptions and increased costs and expenses in the event of changes to the laws, rules, regulations and policies of the governments of the United States or China, or due to geopolitical unrest and unstable economic conditions. Certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements or proposed legislation by the U. S. government** , which ~~is located~~ **could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting their supply of material to us. For example,** in **February 2024, U. S. lawmakers called for investigations into and the imposition of possible trade sanctions against certain Chinese biotechnology companies including WuXi AppTec and WuXi Biologics, or collectively WuXi, over alleged ties to the Chinese military. Escalating tensions between the United States and** China **may prevent or hinder the export of materials or technical information between us and our CDMO and third parties, such as pharmaceutical partners . Additionally, third parties may voluntarily require compliance or supply chain requirements that go above and beyond potential legislation to address perceived risk of " pass through, " which would make it difficult for us to operate our business. In addition, in September 2024 during the 118th Congress, the U. S. House of Representatives passed the BIOSECURE Act (H. R. 8333). This bill names the following as biotechnology companies of concern: BGI, MGI, Complete Genomics, WuXi AppTec, and WuXi Biologics. The Senate advanced a substantially similar bill (S. 3558) but it did not pass. The Senate bill named the following as biotechnology companies of concern: " BGI, MGI, Complete Genomics, WuXi, AppTec and any subsidiary, parent affiliate, or successor of such entities. " If this legislation had been enacted into law** ~~While~~ **while** ~~we~~ **both bills had certain grandfather provisions, the legislation would have potentially restricted the ability of U. S. biotechnology companies like ours to purchase services or products from, or otherwise collaborate with, specifically named Chinese biotechnology companies, including WuXi, and it would have authorized the U. S. government to impose such restrictions on entities' transactions with additional Chinese biotechnology companies as a condition of U. S. government contract, grant and loan funding. We anticipate these bills will be reintroduced during the 119th Congress, but as of February 20, 2025, they** have not ~~started commercialization~~ **been introduced in either chamber. If these bills become law, or similar laws are passed, they would have the potential to severely restrict the ability** of ~~drug~~ **companies like ours to contract with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise received funding from, the U. S. government. Such disruptions could have adverse effects on**

the development of our product candidates ~~, any~~ **and our business operations. Any** unfavorable government policies on international trade, such as export controls, capital controls ~~,~~ **or** tariffs **, may increase the cost of manufacturing** ~~or our other trade restrictions~~ **product candidates and platform materials** , ~~may~~ affect the demand for our drug products **(if and once approved)** , the competitive position of our product candidates, and import or export of raw materials and finished product candidate used in our **and our collaborators'** preclinical studies and clinical trials, particularly with respect to **any** ~~our manufactured~~ product candidates **and materials** that we import from China, including pursuant to our manufacturing **service** arrangements ~~and license agreement~~ with WuXi ~~Biologics~~ . If any new tariffs, export controls, legislation and / or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if **either** the U. S. **or Chinese** government takes retaliatory trade actions due to the recent ~~U. S. China~~ trade tension, such changes could have an adverse effect on our business, financial condition and results of operations. ~~If~~ **102If** we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, however this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. ~~106In~~ **In** addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions. Our employees, independent contractors, CROs, consultants, commercial partners, vendors and principal investigators may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, CROs, consultants, commercial partners, vendors and ~~, if we commence clinical trials,~~ our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the EU and other jurisdictions, provide accurate information to the FDA, the EC and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. Even with appropriate policies and procedures, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent such 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 laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions. Risks Related to Our Business Operations, Employee Matters and Managing GrowthOur future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel. We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers, as well as the other members of our scientific and clinical teams. Although we have employment **agreements that** ~~offer letters which~~ outline the terms of employment with each of our executive officers, each of them may terminate their employment with us at any time. As such, these employment **agreements** ~~offer letters~~ do not guarantee our retention of ~~our~~ **103our** executive officers for any period of time. In addition, **the cost of** ~~insurance coverage is increasingly expensive, including with respect to~~ directors' and officers' liability insurance, or D & O insurance **, is subject to change, which could result in D & O insurance becoming significantly more expensive for us to maintain or require us to accept coverage terms or policy limits that are less favorable** . ~~We may~~ **Accordingly, there is** ~~not~~ **no guarantee that we will** be able to maintain D & O insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. An inability to secure and maintain D & O insurance may make it difficult for us to retain and attract talented and skilled directors and officers to serve our company, which could adversely affect our business. We do not maintain " key person " insurance for any of our employees. Recruiting and retaining qualified scientific and clinical personnel and, if we are successful in obtaining marketing approval for our product candidates, sales and marketing personnel, is and will be critical to our success. The loss of the services of our executive officers or other key employees could impede, delay or prevent the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and other 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 for and commercialize products in the life sciences industry, and specifically our product candidates. We are based in Massachusetts, a state that is home to many other biopharmaceutical companies as well as many

academic and research institutions, resulting in fierce competition for qualified personnel. Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their ~~107former~~ **former** employers own their research output. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Additionally, the **biotechnology industry generally** ~~United States is experiencing a workforce shortage, which in turn~~ has ~~created~~ **continued to experience** a competitive wage environment, which is likely to further exacerbate the foregoing risks and may impact our ability to retain our executive officers or other key employees. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited and could adversely affect our business, prospects, financial condition and results of operations ~~. Our cost savings plan and the associated workforce reduction implemented in March 2024 may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business. In connection with our strategic portfolio reprioritization in March 2024, we implemented a workforce reduction, representing approximately 21 % of our workforce prior to the reduction in headcount. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. We expect to incur one- time costs of approximately $ 1. 0 million primarily related to cash expenditures for severance and benefits continuation, and we estimate the workforce reduction will be substantially completed in the first half of 2024. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition could be adversely affected. We also cannot guarantee that we will not have to undertake additional workforce reductions or restructuring activities in the future. Furthermore, our workforce reduction may be disruptive to our operations, or could yield unanticipated consequences, such as attrition beyond planned staff reductions, or disruptions in our day- to- day operations. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, clinical, and manufacturing personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our product candidates in the future, if approved~~ .

We depend on our information technology systems and those of our third- party service providers, and any failure of these systems could harm our business. Security breaches, loss of data, inability to access systems, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability or competitive or reputational harm, which could adversely affect our business, results of operations and financial condition. We collect and maintain information in digital and other forms that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the privacy, security, confidentiality, availability and integrity of such confidential information. Our internal information technology systems and infrastructure, and those of our contractors, consultants, vendors, service providers and other third parties on which we rely, are vulnerable to damage or unauthorized access or use resulting from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber- attacks or cyber- intrusions over the Internet, denial or degradation of service attacks, ransomware, hacking, phishing and other social engineering attacks, attachments to emails, intentional or accidental actions or inactions by persons inside our organization or by persons with access to systems inside our organization. The risk of a security breach or disruption or data loss, particularly through cyber- attacks or cyber intrusion, including by computer hackers, supply chain attacks, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Additionally, attackers may use artificial intelligence and machine learning to launch more automated, targeted and coordinated attacks against targets. In addition, the prevalent use of mobile devices that access confidential information increases the risk of lost or stolen devices, security incidents and data security breaches, which could lead to the loss of confidential information or other intellectual property. We also may face increased risks of a security breach or disruption due to our reliance on ~~internet~~ **104internet** technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. The costs to us to mitigate network security problems, bugs, ~~108viruses~~ **viruses** , worms, malicious software programs 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, delays, cessation of service, negative publicity and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. Any security compromise affecting us, our partners, our service providers or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures and lead to regulatory scrutiny. If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information (violating certain privacy laws, as applicable, such as HIPAA, CCPA, HITECH and GDPR), it could result in a material disruption of our discovery and development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Notifications and follow- up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from

completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We would also be exposed to a risk of loss, governmental investigations or enforcement, or litigation and potential liability, any of which could materially adversely affect our business, results of operations and financial condition. While we do maintain cyber liability insurance, our insurance coverages may not be sufficient in type or amount to cover us against any such losses, claims, or liabilities related to security breaches, cyber- attacks, cyber intrusion, or other related breaches or disruptions. A variety of risks associated with marketing our product candidates internationally, if approved, could materially adversely affect our business. We also plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating, including conducting marketing and sales activities, in international jurisdictions if we obtain the necessary approvals, including: ● regulatory requirements in foreign countries that differ from those in the United States; ● unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements; ● economic weakness, including inflation, or political instability in particular foreign economies and markets; ● compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; ● foreign taxes, including withholding of payroll taxes; ● foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; ● complexities associated with managing multiple payor reimbursement regimes, government payors or patient self- pay systems; ● difficulties staffing and managing foreign operations; ● workforce uncertainty in countries where labor unrest is more common than in the United States; **105** ● potential liability under the FCPA or other comparable foreign regulations; ~~109~~ ● challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; ● production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and ● business interruptions resulting from geopolitical actions, including war, armed conflicts and terrorism or natural disasters, including pandemics or other outbreaks of infectious disease, earthquakes, typhoons, floods and fires. Any of these factors, along with other risks associated with international operations, could materially adversely affect our future international expansion and operations and, consequently, our results of operations. We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management. From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out- licensing or in- licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin- offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long- term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in- process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain sufficient additional capital, which may not be available on favorable terms or at all. These transactions may not be successful and may require significant time and attention of management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize any or all potential benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects. Our operations or those of the third parties upon whom we depend might be affected by the occurrence of a catastrophic event, such as a terrorist attack, war or other armed conflict, geopolitical tensions or trade wars, pandemic or natural disaster. We depend on our employees, consultants, CDMOs, CROs, as well as regulatory agencies and other parties, for the continued operation of our business. While we maintain disaster recovery plans, they might not adequately protect us. Despite any precautions that we or any third parties on whom we depend take for catastrophic events, including terrorist attacks, wars or other armed conflicts, geopolitical tensions or trade wars, pandemics or natural disasters, these events could result in significant disruptions to our research and development, manufacturing, preclinical studies, clinical trials, and, ultimately, if approved, the commercialization of our products. Long- term disruptions in the infrastructure caused by these types of events, such as natural disasters, which are increasing in frequency due to the impacts of climate change, the outbreak of wars or other armed conflicts, the escalation of hostilities, geopolitical tensions or trade wars, acts of terrorism or " acts of God, " particularly involving geographies in which we or third parties on whom we depend have offices, manufacturing or clinical trial sites, could adversely affect our businesses. Although we carry business interruption insurance policies and typically have provisions in our contracts that protect us in certain events, our coverage might not include or be adequate to compensate us for all losses that may occur. Any catastrophic event affecting us, our CDMOs, our CROs, regulatory agencies or other parties with which we are engaged could have a material adverse effect on our operations and financial performance. ~~110Risks~~ **106Risks** Related to Ownership of Our Common Stock and Our Status as a Public **CompanyOur** ~~CompanyAn active trading market for our~~ common stock may ~~never develop or~~ be **subject to a low** ~~sustained. Although our common stock is listed on the Nasdaq Global Select Market, an active~~ trading **volume and volatile** ~~market for our shares may never develop or be sustained. As a result, it may be difficult for our stockholders to sell their shares without depressing the~~ market price ~~for the shares, or at all. The price of our common stock has been, and could continue to be, subject to volatility~~ related or unrelated to our operations and purchasers of our common stock could **have difficulty selling their shares or could** suffer a decline in value. The **trading volume and** market price of our common stock has been, and may continue to be, subject to significant fluctuations in response to numerous factors, many of which are beyond our control. The stock market in general and the market for biotechnology and pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The **trading volume and** market price for our common stock may be influenced by many

factors, including: ● the results from our preclinical studies and clinical trials; ● the commencement, enrollment or results of any current or future clinical trials we may conduct, or changes in the development status of our product candidates; ● adverse results from, delays in initiating or completing, or termination of clinical trials; ● unanticipated serious safety concerns related to the use of our product candidates; ● clinical trial results from, or regulatory developments regarding, a competitor' s product candidate; ● adverse regulatory decisions, including failure to receive regulatory approval of our product candidates; ● regulatory or legal developments in the United States and foreign countries; ● any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such filings, including without limitation the FDA' s issuance of a " refusal to file " letter or a request for additional information; ● the public' s response to press releases or other public announcements by us or third parties, including our filings with the SEC, and announcements relating to acquisitions, strategic transactions, licenses, joint ventures, collaborations, capital commitments, intellectual property, litigation or other disputes impacting us or our business; ● lower than expected market acceptance of our product candidates, if approved; ● adverse developments concerning our manufacturers; ● our inability to obtain adequate product supply for any **product candidate, or** approved product or inability to do so at acceptable prices; ● variations in the level of expenses related to our preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites; ● variations in the level of expenses related to our commercialization activities, if any product candidates are approved; ~~111~~ ● the clinical results of our competitors or potential competitors; **107** ● introduction of new products or services by our competitors; ● changes in financial estimates by us or by any securities analysts who might cover our common stock; ● conditions or trends in our industry; ● our cash position; ● sales of our common stock by us or our stockholders in the future; ● adoption of new, or changes to current accounting standards; ● ineffectiveness of our internal controls; ● changes in the market valuations of similar companies; ● stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biotechnology and pharmaceutical industry; ● publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts; ● announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures; ● announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us; ● changes in the structure of healthcare payment systems; ● investors' general perception of our company and our business; ● overall performance of the equity markets; ● ~~trading volume of our common stock; ●~~ potential inclusion or exclusion of our common stock in exchange, industry, or other tracking indices; ● disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies and product candidates; ● significant lawsuits, including patent or stockholder litigation; ● proposed changes to healthcare laws, intellectual property laws or pharmaceutical pricing in the United States or foreign jurisdictions, or speculation regarding such changes; ● future sales of our common stock by our officers, directors and significant stockholders; ● recruitment or departure of key personnel; ● public health epidemics or pandemics, such as the COVID- 19 pandemic, and any recession, depression, or other sustained adverse market event or economic impact resulting from such epidemics or pandemics; ~~112~~ ● general political, economic, industry and market conditions; and ● other events or factors described in this " Risk Factors " section, many of which are beyond our control. ~~In~~ **108In** addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. This risk is especially relevant for us, because biopharmaceutical companies have experienced significant stock price volatility in recent years. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management' s attention and resources from our business. If securities or industry analysts do not publish research or reports about our company, or if they issue unfavorable or inaccurate research regarding our business, or if they publish negative evaluations of our stock, the price and trading volume of our stock could decline. The trading market for our common stock relies, in part, on the research and reports that securities or industry analysts publish about us or our business. A limited number of securities and industry analysts currently publish research on our company. There can be no assurance that existing analysts will continue to cover us or that new analysts will begin to cover us. There is also no assurance that any covering analyst will provide favorable coverage. Although we have obtained analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock or publish inaccurate or unfavorable research about our business, or provides more favorable relative recommendations about our competitors, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price and trading volume to decline. Unstable global economic and political conditions, including economic uncertainty tied to interest rates and heightened inflation, credit and financial market instability, and uncertainty related to ongoing geopolitical conflicts, could adversely affect our business, financial condition, stock price and ability to raise capital. Unstable global economic and political conditions, including economic uncertainty tied to interest rates and heightened inflation, credit and financial market instability, and uncertainty related to ongoing geopolitical conflicts, could adversely affect our business, financial condition, stock price and ability to raise capital. The global economy, in particular the financial markets, have recently experienced significant disruption and volatility, including without limitation, as a result of heightened inflation, capital market volatility, interest rate and currency rate fluctuations, volatility in commodity prices, decline in consumer confidence and economic growth, supply chain disruptions, banking disruptions, and uncertainty resulting from geopolitical events, including trade wars, civil and political unrest, wars and other armed conflicts. In addition, market volatility, high levels of inflation and high interest rates may increase our cost of financing or restrict our access to potential sources of future capital. Furthermore, our stock price may further decline due in part to the volatility of the stock market and any general economic downturn. If the disruption and volatility persist or deepen, we may be unable to raise sufficient additional capital on acceptable terms, or at all. If we are unable to raise sufficient additional capital, our business, financial condition, stock price and results of operations could be adversely affected, and we will need to implement cost reduction strategies, which could include delaying, reducing or altogether terminating both internal

and external costs related to our operations and research and development programs. In addition, political developments impacting government spending and international trade, including changes in trade agreements, trade disputes, tariffs and investment restrictions, such as the ongoing trade dispute between the United States and China, may negatively impact markets and cause weaker macroeconomic conditions. These global economic and political factors could also strain certain of our suppliers and manufacturers, including our primary CDMO, possibly resulting in supply disruptions or increased raw material or manufacturing costs, or adversely impacting their ability to manufacture clinical trial materials for our product candidates. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic and geopolitical climate and financial market conditions could adversely impact our business. Our principal stockholders and management own a significant percentage of our common stock and exert significant control over matters subject to stockholder approval. As of ~~March 25~~ **December 31**, 2024, our executive officers, directors, holders of 5 % or more of our common stock and their respective affiliates beneficially owned shares in the aggregate representing a majority of our outstanding common stock. As a result ~~113of~~ **of** their share ownership, these stockholders, if they act together, would have the ability to influence our management and policies and would be able to significantly affect the outcome of matters requiring stockholder approval, such as elections of directors, amendments of our organizational documents or approvals of any merger, sale of assets or ~~other~~ **109other** major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest. Some of these persons or entities may have interests different than our unaffiliated stockholders, or they may want us to pursue strategies that deviate from the interests of other stockholders. In addition, this concentration of ownership might adversely affect the market price of our common stock by: ● delaying, deferring or preventing a change of control of us; ● entrench our management and board of directors; ● impeding a merger, consolidation, takeover or other business combination involving us; or ● discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us. We have broad discretion regarding use of our cash and cash equivalents, and we may not use them effectively. Our management has broad discretion in the application of our cash and cash equivalents and could use such funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest these funds in a manner that does not produce income or that loses value. We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any determination to pay dividends in the future will be at the sole discretion of our board of directors. In addition, the terms of any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited in the foreseeable future to the appreciation of their stock. We are an " emerging growth company " and a " smaller reporting company " and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors. We are an " emerging growth company, " or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We may remain an EGC until December 31, 2026, although if the market value of our common stock that is held by non- affiliates exceeds $ 700. 0 million as of any June 30 before that time or if we have annual gross revenues of $ 1. 235 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than $ 1. 0 billion of non- convertible debt over a three- year period. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. These exemptions include: ● being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced " Management' s Discussion and Analysis of financial Condition and Results of Operations " disclosure; ● not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting; ~~114~~ ● not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the financial statements; **110** ● reduced disclosure obligations regarding executive compensation; and ● exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Even after we no longer qualify as an emerging growth company, we may continue to qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation. In addition, if we are a smaller reporting company with less than $ 100 million in annual revenue, we would not be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002, or Section 404. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. In addition, the JOBS Act permits an EGC to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to " opt out " of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we can adopt the new or revised standard at the time private companies adopt the new or revised standard and may do so until such time that we either (1) irrevocably elect to " opt out " of such extended transition period or (2) no longer qualify as an EGC or a smaller reporting company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies. We have incurred and will continue to incur substantial costs as a result of operating as a public company, and our management has devoted and will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices. As a public company, we

have incurred and will continue to incur substantial legal, accounting and other expenses. The Sarbanes- Oxley Act of 2002, or the Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, Nasdaq listing requirements, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time- consuming and costly. We evaluate developments in these rules and regulations as they are promulgated and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to continue to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management' s time and attention from revenue- generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be materially adversely effected. Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an EGC or a smaller reporting company with less than $ 100 million in annual revenue, we will not be required to include an attestation report on internal control over financial reporting issued by our ~~115independent~~ **independent** registered public accounting firm. To comply with Section 404, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as ~~appropriate~~ **111appropriate** , validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock. Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also subject us to regulatory scrutiny and sanctions, impair our ability to raise revenue and cause investors to lose confidence in our reported financial information, which could harm our business and have a negative effect on the trading price of our common stock and adversely affect our results of operations and financial condition. We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an EGC or a smaller reporting company with less than $ 100 million in annual revenue, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. ~~We could be an EGC for up to five years.~~ An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management' s assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation, which could have a negative effect on the trading price of our common stock and adversely affect our results of operations and financial condition. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. As a public company, we are subject to certain reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal control over financial reporting, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected. ~~116Changes~~ **Changes** in tax laws or in their implementation or interpretation may adversely affect our business and financial condition. Changes in tax law may adversely affect our business or financial condition. The Tax Act, enacted on December 22, 2017, as amended by the CARES Act, enacted on March 27, 2020, significantly revises the Code. The Tax Act contains, among other things, significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35 % to a flat rate of 21 % and the limitation of the deduction for net operating losses to 80 % of current- year taxable income for losses arising in taxable years beginning after December 31, 2017 (though any such net

operating losses may be carried forward indefinitely). In addition, beginning in 2022, the Tax Act eliminates the option to deduct research and ~~development~~ **112development** expenditures currently and requires corporations to capitalize and amortize them over five years or fifteen years (for expenditures attributable to foreign research). In addition to the CARES Act, as part of Congress' s response to the COVID- 19 pandemic, economic relief legislation was enacted in 2020 and 2021 containing tax provisions. The IRA was also signed into law in August 2022. The IRA introduced new tax provisions, including a 1 % excise tax imposed on certain stock repurchases by publicly traded corporations. The 1 % excise tax generally applies to any acquisition by the publicly traded corporation (or certain of its affiliates) of stock of the publicly traded corporation in exchange for money or other property (other than stock of the corporation itself), subject to a de minimis exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases. Regulatory guidance under the Tax Act, the CARES Act, the IRA, and such additional legislation is and continues to be forthcoming. Such guidance could ultimately increase or lessen the impact of these laws on our business and financial condition. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, the IRA, and additional tax legislation. Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current directors and members of management. Provisions in our restated certificate of incorporation and our second amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also 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. Among other things, these provisions: ● establish a classified board of directors such that only one of three classes of directors is elected each year; ● allow the authorized number of our directors to be changed only by resolution of our board of directors; ● limit the manner in which stockholders can remove directors from our board of directors; ● establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors; ● require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent; ● limit who may call stockholder meetings; ● authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a " poison pill " that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; ~~and117~~ **and** ● require the approval of the holders of at least two- thirds of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws. In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the **113** ~~person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Our restated certificate of incorporation designates the Court of Chancery of the State of Delaware and the federal district courts of the United States of America as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers and employees and increase the costs to our stockholders of bringing such claims. Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and 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 asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to our company or our stockholders; ● any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or ● any action asserting a claim arising pursuant to any provision of our certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. These choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. 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 restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any claims arising under the Securities Act. 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 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 the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, and increase the costs to such stockholders of bringing such a claim, either of which may discourage such lawsuits against us and our directors, officers and employees. If a court were~~

~~to find the either exclusive forum provision contained in our 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 materially adversely affect our business, financial condition and operating results. 118~~