Risk Factors Comparison 2025-03-10 to 2024-02-15 Form: 10-K

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Investing in our common stock involves a high degree of risk. Before making your decision to invest in shares of our common stock, you should carefully consider the risks and uncertainties described below, together with the other information contained in this Annual Report on Form 10- K, including our financial statements and the related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations ". The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could materially and adversely affect our business, financial condition, results of operations and prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment. Summary of Risk Factors Our business is subject to several risks and uncertainties, including those immediately following this summary. Some of these risks are: • We have incurred significant operating losses since our inception. We expect to incur continued losses for the foreseeable future and may never be profitable. • We have never generated any revenue and our inability to execute on our business plan may cause you the total or partial loss of your investment. • As we do not generate any revenue, we are dependent on working capital to fund our business plan, and we will require substantial additional funding to pursue our business objectives. If we are unable to raise capital when needed or on terms acceptable to us, we could be forced to delay, reduce or eliminate our research or drug development programs, any future commercialization efforts or other operations. • We are highly dependent on the success of our product candidates which are in early clinical development. We have not completed successful late- stage pivotal clinical trials or obtained regulatory approval for any product candidate. We may never obtain approval for any of our product candidates or achieve or sustain profitability. • We may incur additional costs or experience delays in completing, or ultimately be unable to complete , the development and / or commercialization of our product candidates. • If we experience delays or difficulties in enrolling patients in our ongoing or planned clinical trials, our receipt of necessary regulatory approval could be delayed or prevented. • Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials or abandon further development, limit the commercial profile of an approved product, or result in significant negative consequences following marketing approval, if any. • 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. • Health care policy changes, including U. S. health care reform legislation, may have a material adverse effect on our business. • We rely, and intend to continue to rely, on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or do not meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval, each of which may have an adverse effect on our business, financial condition, results of operations and prospects. • Manufacturing pharmaceutical products is complex and subject to product loss for a variety of reasons. We rely on third- party suppliers, including single source suppliers, to manufacture preclinical and clinical supplies of our product candidates and we intend to rely on third parties to produce commercial supplies of any approved product candidate. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. • We may enter into collaborations with third parties for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates. • The incidence and prevalence for target patient populations of our product candidates have not been established with precision. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue potential and ability to achieve profitability will be adversely affected. • We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. • Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop. • Our future success depends on our ability to retain key employees and to attract, retain and motivate qualified personnel and manage our human capital. • We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. • Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and / or adverse publicity and could negatively affect our operating results and business. • We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management. • If we are unable to obtain and maintain sufficient patent protection for our product candidates, or if the scope of the patent protection is not sufficiently broad, third parties, including our competitors, could develop and commercialize products similar or identical to ours, and our ability to commercialize our product candidates successfully may be adversely affected. • We may become involved in lawsuits or administrative disputes to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful. • We may not be able to effectively protect or enforce our intellectual property and proprietary rights throughout the world. • If we are sued for infringing, misappropriating or otherwise violating intellectual property or proprietary rights of third parties, such litigation or disputes could be costly and time consuming and could prevent

or delay us from developing or commercializing our product candidates. • Rights to improvements to our product candidates may be held by third parties. • An active and liquid trading market for our common stock may never be sustained. As a result, you may not be able to resell your shares of common stock at or above the purchase price. • The market price of our common stock has been and is likely to **continue to** be highly volatile, which could result in substantial losses for purchasers of our common stock. • Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval. • We are an " emerging growth company " and a " smaller reporting company " and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies or smaller reporting companies will make our common stock less attractive to investors. • We will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices. Risks Related to Our Financial Position and Need for Capital Investment in drug development is a highly speculative undertaking and involves a substantial degree of risk. For the year ended December 31, ~~2023~~ **2024** , we reported a net loss of $ **127. 2 million, compared to a net loss of $** 121. 8 million ~~. As of~~ **for the year ended** December 31, 2023 **. As of December 31, 2024** , we had an accumulated deficit of $ ~~456~~ **583** . ~~4~~ **6** million. We have not yet commercialized any product, and we do not expect to generate revenue from sales of any products for several years, if at all. We expect to continue to incur significant research and development and other expenses related to our ongoing operations. Since our inception, we have focused substantially all of our efforts and financial resources on the research, preclinical and clinical development of our product candidates, and our research efforts on other potential product candidates targeting PRMT5, MCL1, CDK9, and BRM, otherwise known as SMARCA2. As of December 31, ~~2023~~ **2024** , our cash, cash equivalents, and marketable securities were $ ~~232~~ **133** . ~~9~~ **6** million. We expect to incur ~~increasing levels of~~ operating losses for the foreseeable future, particularly as we advance our product candidates through clinical development. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect ~~our~~ **to incur** research and development expenses ~~to significantly increase~~ in connection with our additional planned clinical trials for our lead product candidates and the development and subsequent INDs of other future product candidates we may choose to pursue. In addition, if we obtain marketing approval for any of our product candidates, we will incur significant sales, marketing and outsourced manufacturing expenses in connection with the commercialization. As a result, we expect to continue to incur significant ~~and increasing~~ operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. We expect our financial condition and operating results to fluctuate significantly from quarter- to- quarter and year- to- year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance. **We have never generated any product revenue and our inability to execute on our business plan may cause you the total or partial loss of your investment.** Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any **product** revenue and we do not know when, or if, we will generate any **product** revenue. We do not expect to generate significant revenue unless and until we obtain marketing approval for, and begin to sell, one or more of our product candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to: • complete successful ~~Phase 1~~ clinical trials for our product candidates; • initiate and successfully complete all safety, pharmacokinetic and other studies required to obtain U. S. and foreign marketing approval for our product candidates; • initiate and complete successful later- stage clinical trials that meet their clinical endpoints; • obtain favorable results from our clinical trials and apply for and obtain marketing approval for our product candidates; • establish licenses, collaborations, or strategic partnerships that may increase the value of our programs; • successfully manufacture or contract with others to manufacture our product candidates; • commercialize our product candidates, if approved, by building a sales force or entering into collaborations with third parties; • submit INDs ~~for a kinase inhibitor~~ that ~~is~~ **are** made effective by the FDA; • obtain, maintain, protect and defend our intellectual property portfolio; and • achieve market acceptance of our successful product candidates with the medical community and with third- party payors. To become and remain profitable, we must succeed in designing, developing, and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials for our product candidates, designing additional product candidates, establishing arrangements with third parties for the manufacture of clinical supplies of our product candidates, obtaining marketing approval for our product candidates and manufacturing, marketing and selling any products for which we may obtain marketing approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. In cases where we are successful in obtaining regulatory approval to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, or if, we will be able to achieve profitability. If we decide to or are required by the FDA or regulatory authorities in other jurisdictions to perform studies or clinical trials in addition to those currently expected, or if there are any delays in establishing appropriate manufacturing arrangements for, in initiating or completing our current and planned clinical trials for, or in the development of, any of our product candidates, our expenses could increase materially and profitability could be further delayed. 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 offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment. We expect ~~our~~ **to continue to incur** expenses ~~to increase substantially~~ in connection with our ongoing activities, particularly as we advance our product candidates through clinical development ~~,~~ and seek to design additional product candidates from our discovery programs. We expect ~~increased~~ **to incur continued** expenses as we continue our research and development ~~, expand our operations and complete construction on our new facility~~ , initiate additional clinical trials, and seek marketing approval for our lead programs and our other product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on favorable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on favorable terms, we could be forced to delay, reduce or eliminate our research and development programs, our commercialization plans or other operations. We believe that our existing cash, cash equivalents, and marketable securities will enable us to fund our operating expenses, and capital expenditure requirements ~~into 2026~~ **for at least the next twelve months from the filing date of this Annual Report on Form 10- K** . We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Changes beyond our control may occur that would cause us to use our available capital before that time, including changes in and progress of our drug development activities and changes in regulation. Our future capital requirements will depend on many factors, including: • the progress, timing and results of preclinical studies and clinical trials for our current or any future product candidates; • the extent to which we develop, in- license or acquire other pipeline product candidates or technologies; • the number and development requirements of other product candidates that we may pursue, and other indications for our current product candidates that we may pursue; • the costs, timing and outcome of obtaining regulatory approvals of our current or future product candidates and any companion diagnostics we may pursue; • the scope and costs of making arrangements with third- party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our current or future product candidates; • the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or future product candidates; • the cost associated with commercializing any approved product candidates, including establishing sales, marketing and distribution capabilities; • the cost associated with completing any post- marketing studies or trials required by the FDA or other regulatory authorities; • the revenue, if any, received from commercial sales of our product candidates that receive marketing approval; • the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property- related claims that we may become subject to, including any litigation costs and the outcome of such litigation; • the costs associated with potential product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims; and • to the extent we pursue strategic collaborations, including collaborations to commercialize our product candidates, our ability to establish and maintain collaborations on favorable terms, if at all, as well as the timing and amount of any milestone or royalty payments we are required to make or are eligible to receive under such collaborations, if any. We will require additional capital to complete our planned clinical development programs for our current product candidates to obtain regulatory approval. Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or product candidates or we may be unable to take advantage of future business opportunities. Furthermore, any additional capital- raising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, as we can generate substantial product revenue, we expect to continue to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Unstable market, economic and political conditions may have serious adverse consequences on our business, financial condition, results of operations and prospects. Our business, financial condition, results of operations and prospects could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including our ability to

raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, service providers, manufacturers or other partners and there is a risk that one or more would not survive or be able to meet their commitments to us under such circumstances. ~~As widely reported, global~~ **Global** credit and financial markets have experienced volatility and disruptions in the past several years **partly** ~~and especially in 2020, 2021 and 2022~~ due to **widespread health concerns,** ~~the impacts of the COVID- 19 pandemic~~ **pandemics** ~~,~~ and ~~, more recently,~~ **other outbreaks of illness as well as** the ongoing conflicts in Ukraine and ~~Israel, including~~ **the Middle East. Such volatility includes** severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, inflation, increases in unemployment rates and uncertainty about economic stability. There can be no assurances that further deterioration in credit and financial markets and confidence in economic conditions will not occur. For example, U. S. debt ceiling and budget deficit concerns have increased the possibility of additional credit- rating downgrades and economic slowdowns, or a recession in the United States. Although U. S. lawmakers passed legislation to raise the federal debt ceiling on multiple occasions, including a suspension of the federal debt ceiling in June 2023, ratings agencies have lowered or threatened to lower the long- term sovereign credit rating of the United States. The impact of this or any further downgrades to the U. S. government' s sovereign credit rating or its perceived creditworthiness could adversely affect the U. S. and global financial markets and economic conditions. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Risks Related to Design and Development of our Product Candidates Our future success is highly dependent on our ability to obtain regulatory approval for, and then successfully commercialize, our product candidates. We are early in our development efforts and our lead product candidates are each currently in **early stage** ~~a Phase 1~~ clinical ~~trial~~ **development** . Our other product candidates are in earlier stages of development. We currently have no products that are approved for sale in any jurisdiction. There can be no assurance that our product candidates in development will achieve success in their clinical trials or obtain regulatory approval. Regulators may also request additional studies, data, and information, that we may need to develop and which were not originally planned. Any delays in obtaining regulatory approval, or if we never obtain regulatory approval, could have a material adverse effect on our business, financial condition and results of operations. The success of our product candidates will depend on several factors, including the following: • successful completion of preclinical studies and clinical trials; • acceptance of INDs by the FDA or other similar clinical trial applications from foreign regulatory authorities for our future clinical trials for our pipeline product candidates; • timely and successful enrollment of patients in, and completion of, clinical trials with favorable results; • demonstration of safety, efficacy and acceptable risk- benefit profiles of our product candidates to the satisfaction of the FDA and foreign regulatory agencies; • our ability, or that of our collaborators, to develop and obtain clearance or approval of companion diagnostics, on a timely basis, or at all; • receipt and related terms of marketing approvals from applicable regulatory authorities, including the completion of any required post- marketing studies or trials; • raising additional funds necessary to complete clinical development of and commercialize our product candidates; • obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates; • making arrangements with third- party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates; • developing and implementing marketing and reimbursement strategies; • establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others; • acceptance of our products, if and when approved, by patients, the medical community and third- party payors; • effectively competing with other therapies; • obtaining and maintaining third- party payor coverage and adequate reimbursement; • protecting and enforcing our rights in our intellectual property portfolio; and • maintaining a continued acceptable safety profile of the products following approval and compliance with any post- approval requirements and commitments, including REMS and post- approval studies required by FDA. Many of these factors are beyond our control, and it is possible that none of our product candidates will ever obtain regulatory approval even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. For example, our business could be harmed if results of our ongoing clinical trials vary adversely from our expectations. Drug development involves a lengthy and expensive process, and clinical testing is uncertain as to the outcome. We currently have ~~three~~ **several** product candidates in Phase 1 clinical development and additional product candidates in preclinical development, and the risk of failure for each is high. We are unable to predict when or if our product candidates will prove effective or safe in humans or will obtain marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials or of clinical trials of the same product candidates in other indications, and interim or preliminary results of a clinical trial do not necessarily predict final results. Later- stage clinical trials could differ in significant ways from early- stage clinical trials, including changes to inclusion and exclusion criteria, efficacy endpoints, dosing regimen and statistical design. In particular, the small number of patients in our current Phase 1 clinical trials may make the results of these trials less predictive of the outcome of later clinical trials **. We may incur additional costs or experience delays in completing, or ultimately be unable to complete the development and / or commercialization of our product candidates** . Before we can initiate clinical trials of a product candidate in any indication, we must submit the results of preclinical studies to the FDA or to comparable foreign authorities, respectively, along with other information, including information about the product candidate' s chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or comparable foreign regulatory filings. The FDA may require us to conduct additional preclinical studies for any product candidate before it allows us to initiate subsequent clinical trials under any IND, which may

lead to additional delays and increase the costs of our preclinical development programs. Any delays in the commencement or completion of our ongoing, planned or future clinical trials could significantly affect our product development costs. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to obtain marketing approval or commercialize our product candidates, including: • regulators, IRBs, or ethics committees, or ECs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; • the FDA may disagree as to the design or implementation of our clinical trials or with our proposed dose for any of our pipeline programs. For instance, in the oncology space, FDA has recently focused not only on maximum tolerated dose but also on dose optimization, with the issuance of a guidance on this topic. FDA has also expressed a preference for randomized controlled clinical trials to support accelerated approval, rather than single arm trials with response endpoint; • delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective contract research organizations, or CROs, and prospective trial sites; • clinical trials for our product candidates that may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, delay or halt clinical trials or abandon product development programs; • lack of adequate funding to continue the clinical trial; • the number of patients required for clinical trials for our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or may be lower than we anticipate due to challenges in recruiting and enrolling suitable patients that meet the study criteria, participants may drop out of these clinical trials at a higher rate than we anticipate or the duration of these clinical trials may be longer than we anticipate; • competition for clinical trial participants from investigational and approved therapies may make it more difficult to enroll patients in our clinical trials; • difficulties in maintaining contact with patients after treatment, resulting in incomplete data; • potential failures to obtain regulatory approval of companion diagnostic tests, if required, on a timely basis, or at all; • potential failures by our third- party contractors to meet their contractual obligations to us in a timely manner, or at all, or failure to comply with regulatory requirements; • the suspension or termination of clinical trials for our product candidates for various reasons, including a finding by us or by a Data Monitoring Committee for a trial that the participants are being exposed to unacceptable health risks; • undesirable or unexpected side effects or other unexpected characteristics from our product candidates, causing us or our investigators, regulators or IRBs / ECs to suspend or terminate the trials; • the cost of clinical trials for our product candidates may be greater than we anticipate; • changes to clinical trial protocol; • the supply or quality of our product candidates or other materials necessary to conduct clinical trials for our product candidates may be insufficient or inadequate and result in delays or suspension of our clinical trials; and • the impact **of any** ~~recent COVID- 19 pandemic, or another~~ widespread outbreak of **a** ~~any other~~ communicable disease, which may slow potential enrollment, reduce the number of eligible patients for clinical trials, or reduce the number of patients that remain in our trials. Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete a clinical trial or obtain timely marketing approvals. We do not know whether any of our planned preclinical studies or clinical trials will begin on a timely basis or at all, will need to be restructured or will be completed on schedule, or at all. For example, the FDA may place a partial or full clinical hold on any of our clinical trials for a variety of reasons, including safety concerns and noncompliance with regulatory requirements. If we are not able to complete successful clinical trials, we will not be able to obtain regulatory approval and will not be able to commercialize our product candidates. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. We may not be able to initiate or continue our ongoing or planned clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. In addition, some of our competitors currently have ongoing clinical trials for product candidates that would treat the same patients as our clinical product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment is also affected by other factors, including: • severity of the disease under investigation; • our ability to recruit clinical trial investigators of appropriate competencies and experience; • the incidence and prevalence of our target indications; • clinicians' and patients' awareness of, and perceptions as to the potential advantages and risks of our product candidates in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating; • competing studies or trials with similar eligibility criteria; • invasive procedures required to enroll patients and to obtain evidence of the product candidate' s performance during the clinical trial; • availability and efficacy of approved medications for the disease under investigation; • eligibility criteria defined in the protocol for the trial in question; • the size and nature of the patient population required for analysis of the trial' s primary endpoints; • efforts to facilitate timely enrollment in clinical trials; • disruptions caused by and the willingness of patients to enroll in a clinical trial during outbreaks of contagious disease; • whether we are subject to a partial or full clinical hold on any of our clinical trials; • reluctance of physicians to encourage patient participation in clinical trials; • the ability to monitor patients adequately during and after treatment; • our ability to obtain and maintain patient consents; and • proximity and availability of clinical trial sites for prospective patients. Our inability to enroll and maintain a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs, which would cause the value of our company to decline and limit our ability to obtain additional financing. Results of our ongoing and planned clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could result in the delay, suspension or termination of clinical trials by us or regulatory authorities for a number of reasons **or could result in a FDA determination not to approve the product** . Furthermore, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates or those of our competitors may only be uncovered with a significantly

larger number of patients exposed to the drug. Additionally, due to the high mortality rates of the cancers for which we are initially pursuing development and the pretreated nature of many patients in our ongoing clinical trials, a material percentage of patients in these clinical trials may die during a trial, which could impact the development of product candidates. If we elect or are required to delay, suspend or terminate any clinical trial, the commercial prospects of our product candidates will be harmed and our ability to generate product revenues from this product candidate will be delayed or eliminated. Adverse events observed in clinical trials could prevent approval of the product or, if approved, hinder or prevent market acceptance of our product candidates. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly. Moreover, if our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for our product candidates, if approved. We may also be required to modify our study plans based on findings in our clinical trials. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial. Many drugs that initially showed promise in early stage testing have later been found to cause side effects that prevented further development. In addition, regulatory authorities may draw different conclusions, require additional testing to confirm these determinations, require more restrictive labeling, or deny regulatory approval of the product candidate. It is possible that, as we test our product candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of our product candidates becomes more widespread following any regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly. In addition, if any of our product candidates receive marketing approval, and we or others later identify undesirable side effects caused by treatment with such drug, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw approval of the drug; • we may be required to recall a product or change the way the drug is administered to patients; • regulatory authorities may require additional warnings in the labeling, such as a contraindication or a boxed warning, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product; • we may be required to implement a REMS, or create a medication guide outlining the risks of such side effects for distribution to patients; • additional restrictions may be imposed on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof; • we could be sued and held liable for harm caused to patients; • we may be subject to regulatory investigations and government enforcement actions; • the drug could become less competitive; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates, if approved, and could significantly harm our business, financial condition, results of operations and prospects. Preliminary, interim and topline 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 publicly disclose preliminary, interim or topline data from our clinical trials. These updates are based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. Additionally, 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. Therefore, positive interim results in any ongoing clinical trial may not be predictive of such results in the completed study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Adverse changes between preliminary or interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock. See the description of risks under the heading “ Risks Related to our Common Stock ” for more disclosure related to the risk of volatility in our stock price. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the material, or otherwise appropriate, information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize any product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects. Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our 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 commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. We may not be successful in our efforts to design additional potential product candidates. A key element of our strategy is to identify molecular targets and intervention points leading to treatment failure and then apply our expertise of cancer biology and medicinal chemistry, as well as our in- depth understanding of the current landscape of oncology treatments, to design solutions that can be precisely tailored in a target class agnostic fashion. The therapeutic design and development activities that we are conducting may not be successful in developing product candidates that are safe and effective in treating cancer or other diseases. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including: • the target selection methodology used may not be successful in identifying potential product candidates; • potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will obtain marketing approval or achieve market acceptance; or • potential product candidates may not be effective in treating their targeted diseases. Research programs to identify and design new product candidates require substantial technical, financial and human resources. We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. If we are unable to identify and design suitable product candidates for preclinical and clinical development, we will not be able to obtain revenues from the sale of products in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price. Risks Related to Government Regulation The development and commercialization of pharmaceutical products are subject to extensive regulation, and we may not obtain regulatory approvals for any product candidates, on a timely basis or at all. The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post- marketing information and reports, and other possible activities relating to our product candidates are subject to extensive regulation. Marketing approval of drugs in the United States requires the submission of an NDA to the FDA, and we are not permitted to market any product candidate in the United States until we obtain approval from the FDA of the NDA for that product. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls. Our product candidates must be approved by comparable regulatory authorities in other jurisdictions prior to commercialization. FDA approval of an NDA is not guaranteed, and the review and approval process is an expensive and uncertain process that may take several years. Of the large number of drugs in development in the United States, only a small percentage will successfully complete the FDA regulatory approval process and will be commercialized. Accordingly, there can be no assurance that any of our product candidates will receive regulatory approval in the United States, or other jurisdictions. 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 NDA 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 results of preclinical and early clinical trials of any product candidate may not be predictive of the results of our later- stage clinical trials. Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits, and failure in clinical trials can occur at any stage. Companies in the pharmaceutical industry frequently suffer setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval. The FDA could delay, limit or deny approval of a product candidate for many reasons, including because the FDA: • may not deem our product candidate to be safe and effective; • determines that the product candidate does not have an acceptable benefit- risk profile; • determines, in the case of an NDA seeking accelerated approval, that the NDA does not provide evidence that the product candidate represents a meaningful advantage over available therapies; • determines that the objective response rate, or ORR, and duration of response are not clinically meaningful; • may require that we do additional work to determine the optimal dose; • may not agree that the data collected from preclinical studies and clinical trials are acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval and may impose requirements for additional preclinical studies or clinical trials; • may determine that adverse events experienced by participants in our clinical trials represent an unacceptable level of risk; • may determine that population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval; • may not **agree with the design of our clinical or preclinical trials, or may not agree with the method of data analysis; • may not** accept clinical data from trials, which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of **the United States or the population is different than in** the United States; • may disagree regarding the formulation, labeling and / or the specifications; • may not approve the manufacturing processes associated with our product candidate or may determine that a manufacturing facility does not have an acceptable compliance status; • may change approval policies or adopt new regulations; or • may not file a submission due to, among other reasons, the content or formatting of the submission. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials, and the review process. For example, the Oncology Center of Excellence, or OCE, within the FDA ~~has recently~~ advanced Project Optimus, which is an initiative to reform the dose optimization and dose selection paradigm in

oncology drug development to emphasize selection of an optimal dose, which is a dose or doses that maximizes not only the efficacy of a drug but the safety and tolerability as well. This shift from the prior approach, which generally determined the maximum tolerated dose, may require sponsors to spend additional time and resources to further explore a product candidate' s dose- response relationship to facilitate optimum dose selection in a target population. Other ~~recent~~ OCE initiatives have included Project FrontRunner, a new initiative with a goal of developing a framework for ~~identifying candidate~~ **encouraging sponsors to consider developing cancer** drugs ~~for initial clinical development~~ in the earlier advanced setting rather than for treatment of patients who have received numerous prior lines of therapies or have exhausted available treatment options. We are considering these **and any other** policy changes **, including initiatives with respect to accelerated approval and to coordinate review of oncology products among international regulators,** as they relate to our programs. 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 our clinical product candidates. If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, our commercial prospects will be harmed and our ability to generate revenues will be materially impaired which would adversely affect our business, prospects, financial condition and results of operations. The accelerated approval pathway for our product candidates may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval. Under the FDA' s accelerated approval program, the FDA may approve a drug for a serious or life- threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. We may seek accelerated approval for one or more of our product candidates on the basis of ORR with an acceptable duration of response, a surrogate endpoint that we believe is reasonably likely to predict clinical benefit. For drugs granted accelerated approval, post- marketing confirmatory trials are required to describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. These confirmatory trials must be completed with due diligence. By the date of approval of an accelerated approval product, **the** FDA must specify the conditions for the required post approval studies, including enrollment targets, the study protocol, milestones, and target completion dates. **The** FDA may also **, and frequently does,** require that the confirmatory Phase 4 studies be commenced prior to **the** FDA granting a product accelerated approval. Reports on the progress of the required Phase 4 confirmatory studies must be submitted to **the** FDA every 180 days after approval. If the trials fail to verify the clinical benefit of the drug or biologics product, the FDA may withdraw approval of the application through a statutorily defined streamlined process **or we may voluntarily decide to withdraw the product from the market** . Failure to conduct the required Phase 4 confirmatory studies or to conduct such studies with due diligence, as well as failure to submit the required update reports can subject a sponsor to penalties **. The FDA may also require that we conduct additional confirmatory studies, which would require a significant dedication of time and resources** . If any of our competitors were to receive full approval on the basis of a confirmatory trial for an indication for which we are seeking accelerated approval before we receive accelerated approval, the indication we are seeking may no longer qualify as a condition for which there is an unmet medical need and accelerated approval of our product candidate would be more difficult, or impossible, to obtain. Also, the existing treatment landscape may change, which may necessitate that we conduct additional studies or collect additional data to obtain accelerated approval. Moreover, the FDA may withdraw approval of our product candidate approved under the accelerated approval pathway if, for example: • the trial or trials required to verify the predicted clinical benefit of our product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug; • 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 the relevant product candidate. Recently, the accelerated approval pathway has come under scrutiny within the FDA **, the Department of Health and Human Services,** and by Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. For example, FDA convened its Oncologic Drugs Advisory Committee to review what the FDA has called dangling or delinquent accelerated approvals where confirmatory studies have not been completed or where results did not confirm benefit. In addition, the OCE **implemented** ~~has announced~~ Project Confirm, which is an initiative to promote the transparency of outcomes related to accelerated approvals for oncology indications and provide a framework to foster discussion, research and innovation in approval and post- marketing processes, with the goal to enhance the balance of access and verification of benefit for therapies available to patients with cancer and hematologic malignancies. We may see further legislative or regulatory changes to this program in the future **. There may be future changes in legal and regulatory requirements that may materially impact our results of operation. Future changes in legal and regulatory requirements may introduce new risks into our operations and future prospects, which we are not able to currently anticipate. By example, changes taking place in the United States associated with a new federal administration, as well as changes in legal standards, including the reduced level of judicial deference due to administrative agencies following a 2024 Supreme Court decision, may introduce uncertainties with respect to our current and future operations and our future likelihood of success. It is possible that new federal or state laws or regulations may be passed, or laws and regulations may be enforced differently than they were before, which may expose us to additional legal and regulatory risk or uncertainty and require the expenditure of additional resources to ensure that we are able to comply. Such actions could also adversely restrict our business and operations. There could also be changes in FDA' s approval standards that could impact our ability to obtain product approval and market our product candidates within the currently anticipated timeframes or otherwise impact the competitive market for our product candidates. Such changes may necessitate the conduct of additional development work, including**

preclinical and clinical trials, and manufacturing development. By example, for products intended for rare and serious diseases with unmet medical needs, FDA is authorized to exercise regulatory flexibility when making a medical risk-benefit judgment. It is possible that whether and how FDA exercises any regulatory flexibility, including with respect to specialized pathways, such as accelerated approval, may change, which could impact our ability to obtain product approval. Further, legal and regulatory changes may impact how we may market and sell our products in the future, if they are approved, as well as how they are reimbursed. Moreover, there could be changes in the federal workforce and agency policies that may result in regulatory delays, including with respect to FDA' s review of marketing applications and other submissions, and that may impact the ability to communicate with and obtain guidance from the agencies. At this time, it is too early to predict the exact nature of any changes that may take place or whether and how they may impact our business and results of operation . Our failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed in those jurisdictions, and any approval we are granted for our product candidates in the United States would not assure approval of product candidates in foreign jurisdictions. In order to market and sell our products in any jurisdiction outside the United States, 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 regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. 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 not be able to submit for marketing approvals and may not receive necessary approvals to commercialize our products in any market. We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates. Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as " orphan drugs. " Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals in the United States, or if the disease or condition affects more than 200, 000 individuals in the United States and there is no reasonable expectation that the cost of developing the drug for the type of disease or condition will be recovered from sales of the product in the United States. Orphan drug designation ~~entitles a party to~~ **can provide opportunities for** financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages and user- fee waivers. Additionally, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in certain circumstances, such as a showing of clinical superiority (i. e., another product is safer, more effective or makes a major contribution to patient care) over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. Competitors, however, may receive approval of different products for the same indication for which the orphan product has exclusivity, or obtain approval for the same product but for a different indication than that for which the orphan product has exclusivity. We may apply for an orphan drug designation in the United States or other geographies for our product candidates, where such designation is available, in the future. However, obtaining an orphan drug designation can be difficult, and we may not be successful in doing so. Even if we obtain orphan drug designation for our product candidates in specific indications, we may not be the first to obtain regulatory approval of these product candidates for the orphan- designated indication, due to the uncertainties associated with developing pharmaceutical products, in which case we may be blocked by other' s periods of regulatory exclusivity or may need to demonstrate clinical superiority, which we may not be able to do **. We also may never obtain orphan drug exclusivity, even if we obtain a designation** . In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan- designated indication or may be lost if the FDA later determines that the request for orphan designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan drug designation does not ensure that we will receive marketing exclusivity in a particular market, and we cannot assure you that any future application for orphan drug designation in any other geography or with respect to any other product candidate will be granted. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process **. Moreover, the scope of and protection offered by orphan drug exclusivity, and any advantages of the designation, may change** . A Breakthrough Therapy Designation by the FDA for any of our current or future product candidates may not lead to a faster development or regulatory review or approval process, and it would not increase the likelihood that the product candidate will receive marketing approval. We may seek a Breakthrough Therapy Designation for one or more of our current or future product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs 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. Drugs designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the NDA. Designation as a breakthrough therapy is at the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a drug may not result in a faster development

process, review, or approval compared to drugs considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. **Further, even if any of our product candidates do receive Breakthrough Therapy Designation, or any other special designation intended to facilitate development, we will need to be prepared for a more rapid pace of development, including with respect to manufacturing and any necessary companion diagnostics, which we may not be able to do.** In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. If we are unable to successfully develop, validate, obtain regulatory approval of and commercialize companion diagnostic tests for any product candidates that require such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these product candidates. A companion diagnostic is a medical device, often an in vitro device, which provides information that is essential for the safe and effective use of a corresponding therapeutic drug product. A companion diagnostic can be used to identify patients who are most likely to benefit from the therapeutic product. In the future, we may evaluate opportunities to develop, either by ourselves or with collaborators, companion diagnostic tests for our product candidates for certain indications. A companion diagnostic is generally developed in conjunction with the clinical program for an associated therapeutic product. To date, the FDA has required premarket approval of the vast majority of companion diagnostics for cancer therapies **, except in limited cases where FDA allows the use of an LDT as a companion diagnostic (as discussed above, LDTs are generally subject to FDA enforcement discretion and do not require FDA premarket approval, but remain subject to CLIA regulatory requirements)** . Generally, when a companion diagnostic is essential to the safe and effective use of a drug product, the FDA requires that the companion diagnostic be approved before or concurrent with approval of the therapeutic product and before a product can be commercialized. The approval of a companion diagnostic as part of the therapeutic product' s labeling limits the use of the therapeutic product to only those patients who express the specific genetic alteration that the companion diagnostic was developed to detect. Development of a companion diagnostic could include additional meetings with regulatory authorities, such as a pre- submission meeting and the requirement to submit an investigational device exemption application. In the case of a companion diagnostic that is designated as a " significant risk device, " approval of an investigational device exemption by the FDA and IRB is required before such diagnostic is used in conjunction with the clinical trials for a corresponding product candidate. To be successful in developing, validating, obtaining approval of and commercializing a companion diagnostic, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. We have no prior experience with medical device or diagnostic test development. If we choose to develop and seek FDA approval for companion diagnostic tests on our own, we will require additional personnel. ~~We~~ **If we seek to develop an LDT as a companion diagnostic, we will need to establish a CLIA- certified clinical laboratory and ensure both the laboratory and LDT comply with the applicable CLIA regulations. For companion diagnostics that are not LDTs, we** may rely on third parties for the design, development, testing, validation and manufacture of companion diagnostic tests for our therapeutic product candidates that require such tests, the application for and receipt of any required regulatory approvals, and the commercial supply of these companion diagnostics. If these parties are unable to successfully develop companion diagnostics for these therapeutic product candidates, or experience delays in doing so, we may be unable to enroll enough patients for our current and planned clinical trials, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. For any product candidate for which a companion diagnostic is necessary to select patients who may benefit from use of the product candidate, any failure to successfully develop a companion diagnostic may cause or contribute to delayed enrollment of our clinical trials ~~,~~ and may prevent us from initiating a pivotal trial. In addition, the commercial success and approval of any of our product candidates that require a companion diagnostic will be tied to and dependent upon the receipt of required regulatory approvals and the continued ability of such third parties to make the companion diagnostic commercially available to us on reasonable terms in the relevant geographies. Any failure to do so could materially harm our business, results of operations and financial condition. If we decide to pursue a Fast Track Designation by the FDA, it may not lead to a faster development or regulatory review or approval process. We may seek Fast Track Designation for one or more of our product candidates. If a drug is intended for the treatment of a serious or life- threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA Fast Track Designation. The FDA has broad discretion whether to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Even if we obtain marketing approval for our product candidates, the terms of approvals, ongoing regulation of our products or other post- approval restrictions may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue. Any product candidates for which we receive accelerated approval from the FDA are required to undergo one or more confirmatory clinical trials. If such a product candidate fails to meet its safety and efficacy endpoints in such confirmatory clinical trials, the regulatory authority may withdraw its ~~conditional~~ approval. There is no assurance that any such product **candidate** will successfully advance through its confirmatory clinical trial (s). Therefore, even if a product candidate receives accelerated approval from the FDA, such approval may be withdrawn at a later date. Even if marketing approval of a product candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, which may include the requirement to implement a REMS or to conduct costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval.

Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product' s approved labeling, among other requirements. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to ensure that quality control and manufacturing procedures conform to cGMPs **,** which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our CMOs could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs. Accordingly, assuming we obtain marketing approval for one or more of our product candidates, we and our CMOs will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post- approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. As a result, the cost of compliance with post- approval regulations may have a negative effect on our operating results and financial condition. Any product candidate for which we obtain marketing approval will be subject to ongoing enforcement of post- marketing requirements by regulatory agencies, and we could be subject to substantial penalties, including withdrawal of our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved. Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post- approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post- marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding drug distribution and the distribution of samples to physicians and recordkeeping. The FDA and other federal and state agencies, including the Department of Justice, closely regulate compliance with all requirements governing prescription drug products, **both before and after approval,** including requirements pertaining to **clinical trials,** marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. For example, the FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses, and a company that is found to have improperly promoted off- label uses may be subject to significant liability. Violations of such requirements may lead to investigations alleging violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, and other statutes, including the False Claims Act and other federal and state healthcare fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements either before or after approval, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various **adverse** results, including: • litigation involving patients taking our products; • restrictions on such products, manufacturers or manufacturing processes; • restrictions on the labeling or marketing of a product; • restrictions on product distribution or use; • requirements to conduct post- marketing studies or clinical trials; • warning or untitled letters; • withdrawal of the products from the market; • refusal to approve pending applications or supplements to approved applications that we submit; • recall of products; • fines, restitution or disgorgement of profits or revenues; • suspension or withdrawal of marketing approvals **or clinical trials** ; • damage to relationships with any potential collaborators; • unfavorable press coverage and damage to our reputation; • refusal to permit the import or export of our products; • debarment or exclusion; • product seizure; or • injunctions or the imposition of civil or criminal penalties. Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties. Our current and future relationships with customers and third- party payors may be subject to applicable anti-kickback, fraud and abuse, transparency, health privacy, and other healthcare laws and regulations, which could expose us to significant sanctions, including criminal, civil, and administrative penalties, contractual damages, reputational harm and diminished profits and future earnings. Healthcare providers, including physicians, and third- party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third- party payors and customers may 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 **any product candidates** , as well as ~~,~~ market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations that may be applicable to our business include the following: • the federal Anti- Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, 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 a federal healthcare program such as Medicare and Medicaid; • the federal civil and criminal false claims laws, including the federal civil False Claims Act, which can be enforced by individual whistleblowers in " qui tam " actions brought on behalf of the government, and criminal false claims laws and the civil monetary penalties law, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented **,** false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government; • ~~the federal Health Insurance Portability and Accountability Act of 1996, or~~ HIPAA, **which** prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, regardless of the payor (e. g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services

relating to healthcare matters; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure ~~of~~ **of** individually identifiable health information, relating to the privacy, security, and transmission of such individually identifiable health information; • **The** ~~the federal transparency reporting requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to as the~~ ACA ~~, which~~ requires certain manufacturers of drugs, devices, biologics and medical supplies to annually report to ~~the Centers for Medicare & Medicaid Services, or~~ CMS ~~,~~ information related to certain payments and other transfers of value provided to teaching hospitals and to U. S.- licensed physicians, (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse- midwives. Applicable manufacturers also ~~most~~ **must** report ownership and investment interests held by physicians and their immediate family members; and • analogous state laws and regulations **,** such as state anti- kickback and false claims laws **,** and analogous non- U. S. fraud and abuse laws and regulations ~~,~~ may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines or the Compliance Program ~~Guidelines~~ **Guidance** for Pharmaceutical Manufacturers published by the U. S. Department of Health & Human Services, Office of Inspector General ~~,~~ **;** **to** implement gift bans, and ~~may require drug manufacturers~~ to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing, including price increases. Some state and local laws require the registration of pharmaceutical sales representatives. **Various** ~~State~~ **state** and non- U. S. laws ~~that~~ 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. Efforts to ensure that our business arrangements with third parties 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 **or the operations of vendors or third parties working on our behalf** 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 sanctions, including civil and administrative penalties and damages, criminal fines and confinement, disgorgement, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid and other federal healthcare programs, suspension and debarment from government procurement and non- procurement programs, refusal of orders under existing government contracts, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business ~~is~~ **are** found to be not in compliance with applicable laws, they may be subject to significant criminal, civil and administrative sanctions, including exclusion from participation in government funded healthcare programs, which could have a material adverse effect on our business, results of operations, financial condition and prospects. In response to perceived increases in health care costs in recent years, there have been and continue to be proposals by the federal government, state governments, regulators, and third- party payors to control these costs and, more generally, to reform the U. S. health care system. Certain of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could limit the acceptance and availability of our products. Further, while the United States has begun experimenting with pay- for- performance rather than fee- for- service models and has been embracing many shared- risk arrangements, CMS and OIG specifically excluded manufacturers and others from utilizing **certain beneficial** ~~the new, more flexible Stark Law~~ exceptions and ~~Anti- Kickback Statute~~ safe harbors ~~for value- based care under the Final Rules, part of the U. S. Department of Health and Human Services' Regulatory Sprint to Coordinated Care, which were published on December 2, 2020 in the Federal Register and were largely effective January 19, 2021~~ . The exclusion of manufacturers from utilizing these exceptions and safe harbors will not allow us to avail ourselves of immunity from liability under the laws, potentially inviting greater scrutiny over our shared risk arrangements. **The** ~~Comprehensive healthcare legislation, signed into law in the United States in March 2010, titled the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively, the~~ ACA ~~,~~ imposes certain stringent compliance, recordkeeping, and reporting requirements on companies in various sectors of the life sciences industry, and enhanced penalties for non- compliance. Despite the ACA going into effect over a decade ago, there have been numerous legal and Congressional challenges to the law' s provisions and the effect of certain provisions have made compliance costly. We cannot predict what additional new legislation, agency priorities, and rulemakings may be on the horizon as the United States continues to reassess how it pays for healthcare. As a result, we cannot quantify or predict what impact any changes might have on our business and results of operations. However, any changes that restrict coverage or lower reimbursement for our products could materially and adversely affect our business, financial condition and results of operations. Other legal, regulatory and commercial policy influences are subjecting our industry to significant changes, and we cannot predict whether new regulations or policies will emerge from U. S. federal or state governments, foreign governments, or third- party payors. Government and commercial payors may, in the future, consider healthcare policies and proposals intended to curb rising healthcare costs, including those that could significantly affect reimbursement for healthcare products such as our systems. These policies have included ~~,~~ and may in the future include: basing reimbursement policies and rates on clinical outcomes, the comparative effectiveness, and costs, of different treatment technologies and modalities; imposing price controls and taxes on medical device providers; and other measures. These policies ~~recently~~ culminated in the enactment of the Inflation Reduction Act, or IRA, in August 2022, which

~~will~~ , among other things, ~~allow~~ **allows** the U. S. Department of Health and Human Services, or HHS, to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D. The **IRA requires manufacturers of selected drugs to negotiate discounted prices with the Secretary of HHS. Failure of a manufacturer to reach an agreement can subject manufacturers to an excise tax or withdraw of all drug products from coverage under Medicare and Medicaid. The** negotiated prices, which will first become effective in 2026 **and were** ~~, will be~~ capped at a statutory ceiling price beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions ~~will take~~ **began taking** effect ~~progressively starting~~ in 2023 **and have since been** ~~, although they may be~~ subject to **multiple** legal challenges. Future significant changes in the healthcare systems in the United States or elsewhere could also have a negative impact on the demand for our current and future products. These include changes that may reduce reimbursement rates for our products and changes that may be proposed or implemented by the current or future laws or regulations **. It is unclear exactly how the 2024 presidential election will impact healthcare reform measures of the existing administration or whether a new administration could impose other reform efforts, including what, if any, impact such changes will have on our business. For example, drug price negotiations and other IRA program implementation measures could potentially be affected by the Executive Order, Initial Rescissions of Harmful Executive Orders and Actions, issued by President Trump on January 20, 2025 and / or the anticipated changes in leadership at HHS and CMS under the new administration** . Governments outside of the United States tend to impose strict price controls, which may adversely affect our revenues, if any. In some countries, particularly the countries of the European Union, or the EU, the pricing of prescription pharmaceuticals is subject to governmental control. 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 may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidates 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 harmed. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states ~~,~~ and parallel trade, such as arbitrage between low- priced and high- priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products. Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates and products outside of the United States and require us to develop and implement costly compliance programs. We currently are subject to a number of government laws and regulations and, in the future, could become subject to new government laws and regulations. The costs of compliance with such laws and regulations, or the negative results of non- compliance, could adversely affect our business, cash flow, results of operations, financial condition and prospects. For example, if we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate, including anti- corruption laws. The U. S. Foreign Corrupt Practices Act, or FCPA, prohibits any U. S. individual or business, and third- party agents acting on their behalf, from paying, offering, or authorizing the payment or offering of anything of value, directly or indirectly, to any foreign official, foreign political party or official thereof, or candidate for foreign political office, for the purpose of influencing any act or decision of such official in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions and disposition of the company' s assets, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Compliance with the FCPA' s provisions can be costly and challenging, particularly in countries in which corruption is deemed to be a significant risk and in the life sciences industries, where, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials per se. Certain payments to hospitals in connection with clinical trials and other work have been considered improper payments to government officials and led to FCPA enforcement actions with significant fines and penalties. Various international trade, export control and sanctions laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non- U. S. persons in the United States, of personal identifying information and products, technology or sensitive personal data controlled for export, as well as restricting our ability to deal with certain persons subject to sanctions. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain product candidates and products outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties for both the company and individuals, as well as possible suspension or debarment from government contracting. The Securities and Exchange Commission, or the SEC, also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA' s accounting provisions. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business. We and our third- party contractors are subject to numerous foreign, federal, state and local environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of

these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources, including any available insurance. In addition, our leasing and operation of real property may subject us to liability pursuant to certain of these laws or regulations. Under existing U. S. environmental laws and regulations, current or previous owners or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases. We could incur significant costs and liabilities which may adversely affect our financial condition and operating results for failure to comply with such laws and regulations, including, among other things, civil or criminal fines and penalties, property damage and personal injury claims, costs associated with upgrades to our facilities or changes to our operating procedures, or injunctions limiting or altering our operations. Although we maintain liability insurance to cover us for costs and expenses we may incur due to injuries to our employees, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations, which are becoming increasingly more stringent, may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions **. The Company may be exposed to liabilities under the FCPA and Chinese anti- corruption law. The Company is subject to the FCPA, and other laws that prohibit improper payments or offers of payments to foreign governments, foreign government officials and political parties by U. S. persons as defined by the statute for purposes of obtaining or retaining businesses. The Company may have agreements with third parties who may make sales in mainland China and the U. S., during the process of which the Company may be exposed to corruption. Activities in Taiwan create the risk of unauthorized payments or offers of payments by an employee, consultant or agent of the Company because these parties are not always subject to the Company' s control. Although the Company believes to date it has complied in all material aspects with the provisions of the FCPA and Chinese anti- corruption law, the existing safeguards and any future improvements may prove to be less than effective and any of the Company' s employees, consultants or agents may engage in corruptive conduct for which the Company might be held responsible. Violations of the FCPA or Chinese anti- corruption law may result in severe criminal or civil sanctions against the Company and individuals and therefore could negatively affect the Company' s business, operating results and financial condition. In addition, the Taiwanese government may seek to hold the Company liable as a successor for FCPA violations committed by companies in which the Company invests or acquires** . Risks Related to Our Reliance on Third Parties We do not have the ability to independently conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are dependent on third parties to conduct our ongoing and planned clinical trials of our product candidates and any preclinical studies and clinical trials of any other product candidates. The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Specifically, we expect CROs, clinical investigators, laboratories and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these CROs and other third parties are not our employees, and we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each clinical trial is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. By example, we are required to monitor the activities of third parties undertaking clinical trials on our behalf, but our monitoring may not be able to detect any existing or emerging issues. We and our CROs **, as well as other third parties, including investigators,** are required to comply with good clinical practices, or GCP, requirements, which are regulations and guidelines enforced by the FDA for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements or to conduct a trial in accordance with its investigational plan, the data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that our clinical trials comply with GCPs. In addition, our clinical trials must be conducted with product produced under cGMP regulations applicable to the stage of product development and our preclinical trials must be conducted in accordance with good laboratory practices. Our failure or the failure of third parties on whom we rely on to comply with these regulations may require us to stop and / or repeat clinical trials or other studies, which would delay the marketing approval process. There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise perform in a substandard manner, or terminate their engagements with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated **. We may also have to conduct additional clinical or preclinical trials** . If our clinical trial site terminates for any reason, we may experience the loss of follow- up information on subjects enrolled in such clinical trial unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors for whom they may also be conducting clinical trials or other pharmaceutical product development activities that could harm our competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may

be delayed in our efforts to, successfully commercialize our products. We do not have any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, product development purposes, to support regulatory application submissions, as well as for commercial manufacture if any of our product candidates obtain marketing approval. In addition, we expect to contract with analytical laboratories for release and stability testing of our product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. We may be unable to establish any agreements with third- party manufacturers or do so on favorable terms. Even if we are able to establish agreements with third- party manufacturers, reliance on third- party manufacturers entails additional risks, including: • reliance on the third party for regulatory, compliance and quality assurance; • reliance on the third party for product development, analytical testing, and data generation to support regulatory applications; • operations of our third- party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, the issuance of an FDA Form 483 notice or warning letter, or other enforcement action by FDA or other regulatory authority; • the possible breach of the manufacturing agreement by the third party; • the possible misappropriation of our proprietary information, including our trade secrets and know- how; • the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; • carrier disruptions or increased costs that are beyond our control; and • failure to deliver our drugs under specified storage conditions and in a timely manner. We have only limited supply arrangements in place with respect to our product candidates, and these arrangements do not extend to commercial supply. We acquire many key materials on a purchase order basis. As a result, we do not have long- term committed arrangements with respect to our product candidates and other materials. We will need to establish one or more agreements with third parties to develop and scale up the drug manufacturing process, conduct drug testing, and generate data to support a regulatory submission. If we obtain marketing approval for any of our product candidates, we will need to establish an agreement for commercial manufacture with a third party. In addition, we are dependent on a sole supplier for certain components of our manufacturing process. Even if we are able to replace any raw materials or other materials with an alternative, such alternatives may cost more, result in lower yields or not be as suitable for our purposes. In addition, some of the materials that we use to manufacture our product candidates are complex materials, which may be more difficult to substitute. Therefore, any disruptions arising from our sole suppliers could result in delays and additional regulatory submissions. Third- party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. While we would not be manufacturing the products ourselves, we will still be responsible for the ultimate quality of any product or product candidate that we put into distribution. If the FDA determines that our CMOs are not in compliance with FDA laws and regulations, including those governing cGMPs, **or if FDA determines that our manufacturing processes are not sufficient,** the FDA may deny a new drug application, or NDA, approval until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is in compliance. Moreover, our failure, or the failure of our third- party manufacturers and suppliers, to comply with applicable regulations could result in the need to repeat clinical or preclinical trials, sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, approved products and the facilities at which they are manufactured are required to maintain ongoing compliance with extensive FDA requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. As such, our CMOs are subject to continual review and periodic inspections to assess compliance with cGMPs. Furthermore, although we do not have day- to- day control over the operations of our CMOs, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs. In addition, our third- party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of regulatory actions that may be brought against these third parties in the future, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business. Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. As we prepare for later- stage clinical trials and potential commercialization, we will need to take steps to increase the scale of production of our product candidates. We have not yet scaled up the manufacturing process for any of our product candidates. Third party manufacturers may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost- effective manner, or at all. In addition, quality issues may arise during scale- up or commercial activities. For example, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current CMOs for preclinical and clinical testing cannot perform as agreed, we may be required to replace such CMOs **. Additionally, if legal and regulatory requirements change, we may need to seek CMOs outside of certain territories or domestically** . Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement manufacturer or be able to reach agreement with any alternative manufacturer. Further, our third- party manufacturers may experience manufacturing or shipping difficulties due to resource constraints or as a result of natural disasters, labor disputes, unstable political environments,

including the ongoing ~~conflict~~ **conflicts** in Ukraine **and the Middle East** , or public health epidemics such as the COVID- 19 pandemic. If our current third- party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that obtain marketing approval on a timely and competitive basis. We may enter into collaborations with third parties for the further development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates. We may seek third- party collaborators for the further development and commercialization of some of our product candidates on a select basis. Our likely collaborators for any future collaboration arrangements include large and mid- size pharmaceutical companies and biotechnology companies. We face significant competition in seeking appropriate collaborators and may not be able to secure an appropriate collaborator. Our ability to reach a definitive agreement for a future collaboration will depend, among other things, upon our assessment of the future collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. If we do enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our future collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our future collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations with future collaborators involving our product candidates would pose numerous risks to us, including the following: • collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected; • collaborators may de- emphasize or 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 the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing **; • collaborators may not comply with the applicable legal and regulatory requirements** ; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or 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; • a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products; • collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings; • disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources; • collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; • collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and • if a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated. If we establish one or more collaborations, all of the risks relating to product development, regulatory approval and commercialization described herein would also apply to the activities of any such future collaborators. **Changes in United States and China relations, as well as relations with other countries, and / or regulations may adversely impact our business, our operating results, our ability to raise capital and the market price of our shares. The U. S. government, including the SEC, has made statements and taken certain actions that led to changes to United States and international relations and will impact companies with connections to the United States or China, including imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China and issuing statements indicating enhanced review of companies with significant China- based operations. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the U. S. or to China, our industry or on us. Any unfavorable government policies on cross- border relations and / or international trade, including increased scrutiny on companies with significant China- based operations and escalation of tensions between China and Taiwan, such as the ongoing step up of military exercises around Taiwan by China, capital controls or tariffs, may affect our ability to raise capital and the market price of our shares. There have been Congressional legislative proposals, such as the recent bill titled the Biosecure Act, to discourage contracting with Chinese companies on the development or manufacturing of pharmaceutical products. If any new legislation, executive orders, tariffs, laws and / or regulations are implemented, if existing trade agreements are renegotiated or if the U. S. or Chinese governments take retaliatory actions due to the recent U. S.- China tension, such changes could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our shares. We are no longer developing our PRMT5 inhibitor, PRT811, and are dependent on our license agreement with Pathos AI, Inc. to develop and commercialize the asset. Pursuant to the terms of the license agreement with Pathos (the " Pathos License Agreement "), we granted an exclusive, world- wide license for our selective, brain- penetrant PRMT5 inhibitor, PRT811. Consequently, the commercial success of PRT811 will depend in significant part on the efforts of Pathos. Pathos will pay us milestone payments upon the achievement of specified**

development and sales milestone events, as well as royalties on sales of the licensed products. If Pathos is unable to commercialize PRT811 or determines not to pursue development or commercialization of PRT811, we will not receive any sales milestones or royalty payments under the Pathos License Agreement. Risks Related to Commercialization of our Product Candidates The total addressable market opportunity for any product candidates we may develop will ultimately depend upon, among other things, the diagnosis criteria included in the final labeling for each such product candidate if our product candidates are approved for sale for these indications, acceptance by the medical community, patient access, drug and any related companion diagnostic pricing and their reimbursement. We may initially seek regulatory approval of some of our product candidates as therapies for relapsed or refractory patients. The number of patients in our targeted commercial markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. For example, current cancer treatments, such as existing targeted therapies, chemotherapy, and radiation therapy, are well established in the medical community, and doctors may continue to rely on these treatments. If our product candidates 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 our product candidates, if approved for commercial sale, will depend on a number of factors, including: • the efficacy and potential advantages compared to alternative treatments; • the acceptance of our product candidates as front- line treatment for various indications; • the prevalence and severity of any side effects, in particular compared to alternative treatments; • limitations or warnings contained in the labeling approved for our product candidates by the FDA; • the size of the target patient population; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • our ability to offer our products for sale at competitive prices; • the convenience and ease of administration compared to alternative treatments; • the strength of marketing and distribution support; • publicity for our product candidates and competing products and treatments; • the existence of distribution and / or use restrictions, such as through a REMS; • the availability of third- party payor coverage and adequate reimbursement; • the timing of any marketing approval in relation to other product approvals; • support from patient advocacy groups; and • any restrictions on the use of our products together with other medications. We currently have no marketing and sales organization and have no experience as a company in commercializing products and we may have to invest significant resources to develop these capabilities. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate revenue. We currently have no sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish sales, marketing and distribution capabilities, either ourselves or through collaboration or other arrangements with third parties. There are risks involved with establishing our own sales and marketing capabilities. For example, recruiting and training a sales force is expensive and time- consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts are expected to be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our products on our own include: • our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; • our inability to raise financing necessary to build our commercialization infrastructure; • the inability of sales personnel to obtain access to physicians or educate an adequate number of physicians as to the benefits of our products; • **any sales or marketing personnel' s failure to comply with applicable legal or regulatory requirements; •** unfavorable third- party payor coverage and reimbursement in any geography; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and • unforeseen costs and expenses associated with creating an independent sales and marketing organization. If we enter into arrangements with third parties to perform sales and marketing services, our product revenues and our profitability, if any, are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to market and sell our product candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell and market our products effectively **or may not do so in a compliant manner, for which we could be held responsible** . If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any of our product candidates for which we receive marketing approval. The development and commercialization of pharmaceutical 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 companies, specialty pharmaceutical companies and existing or emerging biotechnology companies, academic research institutions and governmental agencies and public and private research institutions worldwide. There are a number of pharmaceutical and biotechnology companies that currently are pursuing the development of precision oncology therapies optimized to effectively target the key driver mechanisms in cancers with high unmet need, including **Amgen Inc.,** Arvinas Inc., **AstraZeneca plc,** Aurigene ~~, Black Diamond Therapeutics, Inc.~~, Boehringer Ingelheim, C4 Therapeutics ~~, Constellation Pharmaceuticals, Inc.~~, Eli Lilly and Company, F. Hoffman- La Roche, Foghorn Therapeutics Inc., ~~Fochon Pharmaceuticals~~ **Gan & Lee** , ~~G1 Therapeutics~~ **Genentech, Gilead Sciences,** Inc., ~~Genentech~~ **GlaxoSmithKline plc, Johnson & Johnson** , Kronos Bio ~~, Inc., Kura Oncology~~ , Inc., Kymera Therapeutics Inc., ~~Mirati~~ **Nanjing Zaiming**

Pharmaceutical Co. Ltd., Nurix Therapeutics ~~Inc.~~, **Oncopia** ~~Nuvation Bio Inc. Repare~~ Therapeutics ~~Inc., Revolution Medicines, Inc., Relay Therapeutics, Inc., Springworks Therapeutics, Inc., Syndax Pharmaceuticals, Inc., and Zentalis Pharmaceuticals, Inc. In addition, we may face competition from companies developing product candidates that are based on targeting pathways of adaptive resistance, including Amgen Inc., AbbVie Inc., AstraZeneca plc, GlaxoSmithKline plc, Ideaya Biosciences, Johnson & Johnson Services, Inc.~~, Pfizer Inc., ~~Tango Therapeutics~~ **Plexium, Sellas Life Science Group**, Inc. **, Suzhou Zanrong Pharmaceutical Technology Co. Ltd**, Vincerx Pharma, Inc., Novartis AG, and ~~Gilead Sciences, Inc~~ **Shanghai Haiyan Pharmaceutical Technology Co Ltd**. For our ~~MCL1 program, PRT1419, other companies are developing MCL1 inhibitors with monotherapy and / or combination trials ongoing, including Amgen (AMG176), AstraZeneca (AZD5991), Novartis (MIK665), and Gilead (GS- 9716). For our CDK9 program, PRT2527, both AstraZeneca (AZD4573), Vincerx (VIP512), and Kronos (KB- 0742) have CDK9 programs in Phase 1 clinical trials. For our CDK4 / 6 program, PRT3645, Novartis (ribociclib), Lilly (abemaciclib), Pfizer (53albociclib), G1 Therapeutics (G1T38), and Fochon Pharmaceuticals (FCN- 437) have clinical trials ongoing. For our SMARCA2~~ - **SMARCA 2** (BRM) degrader program, other companies, including Amgen, Aurigene, C4 Therapeutics ~~, F. Hoffmann- La Roche~~, Foghorn Therapeutics, Inc., Kymera Therapeutics, Arvinas, Genentech, Boehringer Ingelheim, and Lilly have publicly disclosed their pre- clinical research efforts. Many of the companies against which we are competing or against which we may compete in the future, either alone or through collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and sales and marketing personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Furthermore, we also face competition more broadly across the oncology market for cost- effective and reimbursable cancer treatments. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our product candidates, if any are approved, may compete with these existing drugs and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates may not be competitive with them. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third- party payors may also encourage the use of generic products or specific branded products. As a result, obtaining market acceptance of, and gaining significant share of the market for, any of our product candidates that we successfully introduce to the market may pose challenges. In addition, many companies are developing new oncology therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, are less expensive or with a more favorable labeling than our current or future product candidates. Our competitors also may obtain FDA, foreign regulatory authority, or other marketing or regulatory approval for their products more rapidly than any approval we may obtain for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third- party payors. Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third- party reimbursement practices or healthcare reform initiatives, which would harm our business. The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval. Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third- party payors, including government healthcare programs **(e. g., Medicare and Medicaid)**, private health insurers and other organizations. Third- party payors decide which medications they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS, which decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors often, but not always, follow CMS' s decisions regarding coverage and reimbursement. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory to cover the costs of research, development, manufacture, sale and distribution. Reimbursement may affect the

demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining coverage and adequate reimbursement for our products may be difficult **and can change over time** . We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. Additionally, we may develop, either by ourselves or with collaborators, companion diagnostic tests for our product candidates for certain indications. We, or our collaborators, if any, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. While we have not yet developed any companion diagnostic test for our product candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates. There may also be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs 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 drugs from countries where they may be sold at lower prices than in the United States. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare determinations. Our inability to promptly obtain coverage and adequate reimbursement rates from third- party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercialize any products that we may develop. If we cannot successfully defend ourselves against any claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any product candidates or products that we may develop; • injury to our reputation and significant negative media attention; • initiation of investigations by regulators; • withdrawal of clinical trial participants; • significant time and costs to defend the related litigation; • diversion of management and scientific resources from our business operations; • substantial monetary awards to trial participants or patients; • loss of revenue; • reduced resources of our management to pursue our business strategy; and • the inability to commercialize any products that we may develop. Our current product liability insurance coverage for the United States and certain other jurisdictions may not be adequate to cover all liabilities that we may incur. We likely will need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. A successful product liability claim or series of claims brought against us could decrease our cash and adversely affect our business and financial condition. Risks Related to Employee Matters and Our Operations Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on the development and management expertise of Kris Vaddi, Ph. D., our founder and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical team. We currently do not maintain key person insurance on these individuals. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. Our industry has experienced a high rate of turnover in recent years. Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract, retain and motivate highly skilled and experienced personnel with scientific, clinical, regulatory, manufacturing and management skills and experience. We conduct our operations in the greater Delaware area, a region that is home to other pharmaceutical companies as well as many academic and research institutions. ~~Additionally, companies are more willing to hire remote workers following the COVID- 19 pandemic resulting in fierce competition for qualified personnel.~~ We may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among pharmaceutical companies **, including from companies in other geographic areas hiring remote workers** . Many of the other pharmaceutical companies against which we compete have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation, more diverse opportunities and / or better opportunities for career advancement. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize our product candidates and to grow our business and operations as currently contemplated. **In the future, we may expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.** As of December 31, ~~2023~~ **2024** , we had ~~128~~ **131** full- time employees. We expect significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, clinical operations, manufacturing, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a

company with such anticipated growth and with developing sales, marketing and distribution infrastructure, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Further, we currently rely, and for the foreseeable future will continue to rely, in substantial part on certain third- party contract organizations, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our clinical trials and the manufacturing of any of our product candidates. We cannot assure you that the services of such third- party contract organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by our vendors or consultants is compromised for any reason, our clinical trials may be extended, delayed **, repeated,** or terminated, and we may not be able to obtain marketing approval of any of our product candidates or otherwise advance our business. We cannot assure you that we will be able to properly manage our existing vendors or consultants or find other competent outside vendors and consultants on economically reasonable terms, or at all. If we are not able to effectively manage growth and expand our organization, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals. Our employees, clinical trial investigators, CROs, CMOs, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements and insider trading. We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, CMOs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad, (iv) sexual harassment and other workplace misconduct laws, or (v) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, consultants, vendors and other potential commercial partners, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from an alleged 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, including the imposition of significant civil and administrative penalties and damages, criminal fines and confinement, disgorgement, exclusion from participation in government funded healthcare programs, such as Medicare, Medicaid and other federal healthcare programs, suspension and debarment from government procurement and non-procurement programs, refusal of orders under existing government contracts, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Our internal information technology systems, or those of our third- party CROs, CMOs, or other vendors, contractors or consultants, may fail or suffer security breaches, cyber- attacks, loss or leakage of data and other disruptions, which could result in a material disruption of our development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business. We are increasingly dependent upon information technology systems ~~, infrastructure~~ and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third- party CROs, CMOs, vendors, and other contractors and consultants who have access to our confidential information. ~~Our internal information technology systems and infrastructure are also vulnerable to damage from natural disasters, terrorism, war, telecommunication and electrical failures. System failures or outages could compromise our ability to perform these functions in a timely manner, which could harm our ability to conduct business or delay our financial reporting. Such failures could materially adversely affect our operating results and financial condition.~~ Despite the implementation of **reasonable technical, administrative, and physical** security measures ~~, given their size and complexity and the increasing amounts of confidential information that they maintain~~ , our internal information technology systems and those of our third- party CROs, CMOs, vendors and other contractors and consultants (collectively, " Third Parties ") are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, accidents by our employees or third party service providers, natural disasters, terrorism, war and telecommunication and electrical failures. Our systems, and those of Third Parties, may also experience security breaches from inadvertent or intentional actions by our employees, or from cyber- attacks by malicious third parties including the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. The risk of a security breach or disruption, particularly through cyber- attacks or cyber intrusion, including by computer hackers, 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. We may not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized

until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. If a disruption or security breach were to result in a loss of, or damage to, our data or applications, or those of our Third Parties, or inappropriate disclosure of confidential ~~or proprietary~~ information, we could incur liability and reputational damage and the further development and commercialization of our product candidates could be delayed. Any breach, loss or compromise of clinical trial participant personal data may also subject us to civil damages and penalties, under HIPAA and other relevant state and federal privacy laws. The costs related to significant security breaches or disruptions could be material and exceed the limits of the cybersecurity insurance we maintain against such risks. If the information technology systems of our Third Parties become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Any such incident that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could **require public notification and / or notification to governmental entities and individuals,** harm our reputation directly ~~, compel us to comply with federal and / or state breach notification laws and foreign law equivalents~~ , subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. **Failure to comply with health and data protection, privacy, cybersecurity, artificial intelligence (AI), and operational resilience laws and regulations (including enacted by governmental authorities in the European Economic Area (" EEA "), Switzerland, and the UK, collectively, " Europe ") could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and / or adverse publicity and could negatively affect our operating results and business.** We and any potential collaborators may be subject to federal, state and foreign data protection laws and regulations (i. e., laws and regulations that address **data protection,** privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, state consumer privacy laws, and federal and state consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health- related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy, data protection and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. International data protection laws, including **EU** Regulation 2016 / 679, known as the **EU** General Data Protection Regulation, or **along with related data protection, privacy, and cybersecurity laws in Europe, including the UK General Data Protection Regulation, collectively, the "** GDPR **")** , may also apply to health- related and other personal information obtained outside of the United States. The ~~regulation~~ **GDPR** imposes numerous new requirements for the collection, use and disclosure of personal information **and the protection and resiliency of certain network and information systems** , including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information (e. g., the right to access, correct and delete their data). In addition, the GDPR includes restrictions on cross- border data transfer, which may require ongoing changes to our business operations, implementation of revised legal mechanisms, and other challenges. **We are also required to undertake appropriate measures to ensure the confidentiality, availability, and integrity of personal information, which may be challenging considering ever- growing and impactful cyber threats.** The **EU** GDPR ~~features potential fines~~ **allows European Economic Area supervisory authorities to impose penalties** for ~~noncompliant companies~~ **non- compliance** of up to the greater of ~~€~~ **EUR** 20 **. 0** million ~~or~~ **and** 4 % of annual ~~global~~ **worldwide gross** revenue **of the corporate group in question. (There are similar caps in GBP under the UK GDPR). Supervisory authorities in the EEA and UK may potentially levy such fines directly upon on the non- compliant entity and / or on the parent company of the non- compliant entity. Separate from regulatory enforcement actions, individuals may bring private actions (including potentially group or representative actions) against us. There is no statutory cap in the GDPR on the amount of compensation or the damages which individuals may recover** . The GDPR and other international data protection laws will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance **. Any failure to do so could have an adverse impact on our business, reputation, financial condition, and results of operations. We may also be subject to additional industry- specific privacy, cybersecurity, data protection, operational and information systems resilience, and AI- related laws in Europe which may subject us to additional similar risks and impacts as under the GDPR** . In addition, data protection requirements and risk are increasing in the United States. The state of California enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the CCPA), including the rights to access, correction, and deletion and places increased privacy and security obligations on entities handling certain personal data of consumers or households. The CCPA requires covered companies to provide detailed disclosures to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt- out of certain sales or transfers of personal information, and provide consumers with additional causes of action. Following California' s lead, other states have adopted similar comprehensive consumer privacy laws, all of which may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. The CCPA and other state privacy laws provide for significant civil penalties for violations, and California now provides for a

private right of action for data breaches that is expected to increase data breach litigation. These regulatory changes may increase our compliance costs and potential liability, particularly in the event of a data breach. Compliance with U. S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U. S. and international data protection laws and regulations could result in government enforcement actions (which could include civil, criminal, and administrative penalties), private litigation and / or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business. We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Our company is located in Delaware. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemic, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third- party CMOs, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. For example, our operations are concentrated primarily on the east coast of the United States, and any adverse weather event or natural disaster, such as a hurricane or heavy snowstorm, could have a material adverse effect on a substantial portion of our operations. Extreme weather conditions or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. In addition, the long- term effects of climate change on general economic conditions and the pharmaceutical industry in particular are unclear and may heighten or intensify existing risk of natural disasters. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third- party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third- party CMOs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption could have a material and adverse effect on our business, financial condition, results of operations and prospects. Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or government shutdowns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely is subject to the impacts of political events, which are inherently fluid and unpredictable. Disruptions at the FDA and other agencies may slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which could adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA and the SEC to timely review and process our submissions, which could have a material adverse effect on our business. Changes in tax laws or regulations that are applied adversely to us may have a material adverse effect on our business, cash flow, financial condition or results of operations. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Cuts and Jobs Act, enacted many significant changes to the U. S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Cuts and Jobs Act may affect us, and certain aspects of the Tax Cuts and Jobs Act could be repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the Tax Cuts and Jobs Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, the CARES Act, or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Cuts and Jobs Act, the CARES Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one- time charges, and could increase our future U. S. tax expense. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused losses incurred in taxable years beginning on or prior to December 31, 2017, will carry forward to offset future taxable income, if any, until such unused losses expire. Under the Tax Cuts and Jobs Act, as modified by the CARES Act, unused U. S. federal net operating losses generated in tax years

beginning after December 31, 2017 will not expire and may be carried forward indefinitely but the deductibility of such federal net operating losses (particularly those generated in taxable years beginning after December 31, 2020) in taxable years beginning after December 31, 2020 is limited to 80 % of current year taxable income. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act or the CARES Act. In addition, both our current and our future unused losses and other tax attributes may be subject to limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code) if we undergo, or have undergone, an " ownership change, " generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a three- year period. We have not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation due to the complexity and cost associated with such a study and the fact that there may be additional ownership changes in the future. As a result, our net operating loss carryforwards generated in taxable years beginning on or before December 31, 2017, may expire prior to being used, and the deductibility of our net operating loss carryforwards generated in taxable years beginning after December 31, 2017 in taxable years beginning after December 31, 2020 may be limited, and, if we undergo an ownership change (or if we previously underwent such an ownership change), our ability to use all of our pre- change net operating loss carryforwards and other pre- change tax attributes (such as research tax credits) to offset our post- change income or taxes may be limited. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows. From time to time, we may consider strategic transactions, such as acquisitions of companies, businesses or assets and out- licensing or in- licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin- offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non- recurring or other charges, may increase our near term or long- term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including: • exposure to unknown liabilities; • disruption of our business and diversion of our management' s time and attention in order to develop acquired products, product candidates or technologies; • incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions; • higher than expected acquisition and integration costs; • write- downs of assets or goodwill or impairment charges; • increased amortization expenses; • difficulty and cost in combining the operations, systems and personnel of any acquired businesses with our operations, systems and personnel; • impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and • inability to retain key employees of any acquired businesses. Our portfolio of investments or bank deposits may be subject to market, interest and credit risk that may reduce in value. The value of our investments may decline due to increases in interest rates, downgrades of the bonds and other securities included in our commercial money market account portfolio and instability in the global financial markets that reduces the liquidity of securities included in our portfolio. Furthermore, a possible recession, rising inflation, and the ~~ongoing~~ **lingering effects of the** COVID- 19 pandemic has and may continue to adversely affect the financial markets in some or all countries worldwide. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio or sell investments for less than our acquisition cost. Although we attempt to mitigate these risks through diversification of our investments and continuous monitoring of our portfolio' s overall risk profile, the value of our investments may nevertheless decline. Risks Related to Intellectual Property Our success depends in large part on our ability to protect our proprietary technologies that we believe are important to our business, including pursuing, obtaining and maintaining patent protection in the United States and other countries intended to cover the compositions of matter of our product candidates, their methods of use, related technologies and other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. If we do not adequately pursue, obtain, maintain, protect or enforce our intellectual property, third parties, including our 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 have currently filed patent applications in the United States related to our product candidates that we consider important to our business, including patent applications relating to compositions of matter covering our compounds, the processes for manufacturing such compounds and use of such compounds in therapies. We have also filed patent applications in foreign jurisdictions relating to our product candidates. The patent application and approval process is expensive, time- consuming and complex. We may not be able to file, prosecute and maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions. We also cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, depending on the terms of any future license agreements to which we may become a party, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain the patents, covering technology licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Furthermore, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. The standards applied by the United States Patent and Trademark Office, or the USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably. In addition, the determination of patent rights with respect to biological and pharmaceutical products commonly involves complex legal and factual questions, which have in recent years been the subject of much litigation. As a

result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Thus, we cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents, whether any issued patents will be found invalid and unenforceable or will be threatened by third parties or whether any issued patents will effectively prevent others from commercializing competing technologies and product candidates. We do not yet have issued patents on all of our product candidates. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until at least one patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file or invent (prior to March 16, 2013) any patent application related to our product candidates. In addition, we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, CMOs, hospitals, independent treatment centers, consultants, independent contractors, suppliers, advisors and other third parties; however, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Furthermore, if third parties have filed patent applications related to our product candidates or technology, we may not be able to obtain our own patent rights to those product candidates or technology. Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third- party pre-issuance submission of prior art to the USPTO or become involved in post- grant review procedures, oppositions, derivations, revocation, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse 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, or result in our inability to manufacture or commercialize products without infringing third- party rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post- grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of exclusivity or in our patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and products. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, our patents protecting such product candidates might expire before or shortly after such product 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, some of our patents and patent applications may in the future be co- owned with third parties. 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, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co- owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued and its scope can be reinterpreted after issuance. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors and other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non- infringing manner. Our competitors and other third parties may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors or other third parties may seek to market generic versions or " follow- on " versions of any approved products by submitting abbreviated new drug applications, or ANDAs, or new drug applications under Section 505 (b) (2) of the FDCA, respectively, to the FDA during which they may claim that patents owned by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non- infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. Furthermore, future patents may be subject to a reservation of

rights by one or more third parties. For example, to the extent the research resulting in future patent rights or technologies is funded in the future in part by the U. S. government, the government could have certain rights in any resulting patents and technology, including a non- exclusive license authorizing the government to use the invention or to have others use the invention on its behalf for non- commercial purposes. If the U. S. government then decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. These rights may also permit the government to disclose our confidential information to third parties and to exercise march- in rights to use or allow third parties to use our licensed technology. The government may also exercise its march- in rights if it determines that action is necessary because we failed to achieve practical application of the government- funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U. S. industry. In addition, our rights in such government- funded inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of aforementioned proprietary rights could harm our competitive position, business, financial condition, results of operations, and prospects. Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. **The** ~~Recent patent reform legislation in the United States and other countries, including the~~ Leahy- Smith America Invents Act, or the Leahy- Smith Act, **was** signed into law in September 2011 ~~, could increase those uncertainties and costs~~ . The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost- effective avenues for competitors to challenge the validity of patents. For example, the Leahy- Smith Act allows third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post- grant proceedings, including post- grant review, inter partes review, and derivation proceedings. In addition, the Leahy- Smith Act has transformed the U. S. patent system from a " first- to- invent " system to a " first- to- file " system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The first- to- file provisions, however, only became effective on March 16, 2013. It is not yet clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our or our future collaboration partners' patent applications and the enforcement or defense of our or our future collaboration partners' issued patents, all of which could harm our business, results of operations, financial condition and prospects. In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. The U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Depending on future actions by the U. S. Congress, the U. S. courts, the USPTO and the relevant law- making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Competitors and other third parties may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights, trade secrets or other intellectual property. To counter infringement, misappropriation or other violations, we may be required to file infringement, misappropriation or other violation claims, which can be expensive and time consuming and divert the time and attention of our management and business and scientific personnel. In addition, many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their patents or their other intellectual property, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. Similarly, third parties may initiate legal proceedings against us seeking a declaration that certain of our intellectual property is non- infringed, invalid or unenforceable. The outcome of any such proceeding is generally unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent' s claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one of our product candidates, we could lose at least a part, and perhaps all, of the patent protection covering such a product candidate. Competing drugs may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor' s patents, we could be prevented from marketing our drugs in one or more foreign countries. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if

we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Furthermore, third parties may also raise invalidity or unenforceability claims before administrative bodies in the United States or foreign authorities, even outside the context of litigation. Such mechanisms include re- examination, inter partes review, post- grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non- enablement or written description. Grounds for an unenforceability assertion could be an allegation that someone connected with the prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution of the patent. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our licensors, our patent counsel and the patent examiner were unaware during prosecution. Moreover, it is possible that prior art may exist that we are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of our product candidates. Any such loss of patent protection could have a material adverse impact on our business, financial condition, results of operations and prospects. Filing, prosecuting and defending patents with respect to our product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. The requirements for patentability may differ in certain countries, particularly in developing countries. In addition, any future intellectual property license agreements may not always include worldwide rights. Consequently, competitors and other third parties may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States and where our ability to enforce our patents to stop infringing activities may be inadequate. These products may compete with our products in such territories and in jurisdictions where we do not have any patent rights or where any future patent claims or other intellectual property or proprietary rights may not be effective or sufficient to prevent them from competing with us, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, our ability to protect and enforce our intellectual property and proprietary rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, the laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property and proprietary rights in certain foreign jurisdictions. The legal systems of some countries, including, for example, India, China and other developing countries, do not view favorably the enforcement of patents and other intellectual property or proprietary rights, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property or proprietary rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business, could put our patents, trademarks or other intellectual property and proprietary rights at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property and proprietary rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property and proprietary rights in such countries may be inadequate. Further, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, **the** ~~a new~~ unitary patent system was introduced in early 2023, which could significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court, or the UPC. As the UPC is a new court system, there is no

precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC could be potentially vulnerable to a single UPC- based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long- term effects of any potential changes. Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. If any third- party patents, patent applications or other proprietary rights are found to cover our product candidates or any related companion diagnostics or their compositions, methods of use or manufacturing, we may be required to pay damages, which could be substantial, and we would not be free to manufacture or market our product candidates or to do so without obtaining a license, which may not be available on commercially reasonable terms, or at all. We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property or proprietary rights with respect to our product candidates and technologies we use in our business. Our competitors or other third parties may assert infringement claims against us, alleging that our product candidates are covered by their patents. We cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. If a patent holder believes our product candidate infringes its patent rights, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property or proprietary rights with respect to our product candidates, including interference proceedings before the USPTO. Third parties may assert infringement, misappropriation or other claims against us based on existing or future intellectual property or proprietary rights. The outcome of intellectual property litigation and other disputes is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of using or manufacturing products. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods of use, manufacturing or other applicable activities either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be successful in doing so. However, proving invalidity or unenforceability is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, or enforceability. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and business and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If we are found to infringe, misappropriate or otherwise violate a third party' s intellectual property or proprietary rights and we are unsuccessful in demonstrating that such intellectual property or proprietary rights are invalid or unenforceable, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non- exclusive terms, thereby giving our competitors and other third parties access to the same technologies licensed to us. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed such third- party patent rights. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects. We may be subject to claims by third parties asserting that our employees or consultants or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property. Some of our employees and consultants are currently or have been previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. These employees and consultants may have executed proprietary rights, non- disclosure and non- competition agreements, or similar agreements, in connection with such other current or previous employment. Although we try to ensure that our employees and consultants do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of third parties. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property or personnel or sustain damages. Such intellectual property could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, while it is our policy to

require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. In addition, such agreements may not be self-executing such that the intellectual property subject to such agreements may not be assigned to us without additional assignments being executed, and we may fail to obtain such assignments. In addition, such agreements may be breached. In addition, we have multiple sponsored research agreements relating to our lead product candidates with various academic institutions. Some of these academic institutions may not have intellectual property assignments or similar agreements with their employees and consultants, which may result in claims by or against us related to ownership of any intellectual property. Accordingly, we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel, which would have a material adverse effect on our business, financial condition, results of operations and prospects. In the course of testing our product candidates, we have entered into agreements with third parties to conduct clinical testing, which provide that improvements to our product candidates may be owned solely by a party or jointly between the parties. If we determine that rights to such improvements owned solely by a third party are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing the product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non- exclusive terms, thereby giving our competitors and other third parties access to the same technologies licensed to us. Failure to obtain a license on commercially reasonable terms or at all, or to obtain an exclusive license, could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. If we determine that rights to improvements jointly owned between us and a third party are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain an exclusive license from such third party. If we are unable to obtain an exclusive license to any such third- party co- owners' interest in such improvements, such co- owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co- owners of our intellectual property in order to enforce such intellectual property against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. The term of our patents may be inadequate to protect our competitive position on our products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Depending upon the timing, duration and other factors relating to any FDA marketing approval we receive for any of our 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 Action of 1984, or the Hatch- Waxman Amendments. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Hatch- Waxman Amendments permit a patent term extension of up to five years beyond the normal expiration of the patent, limited to the approved indication (or any additional indications approved during the period of extension), as compensation for patent term lost to the regulatory review process during which the sponsor was unable to commercially market its new product. A patent term extension cannot extend the ~~remaining~~ **total** term of a patent beyond ~~a total of~~ 14 years from the date of product approval, only one patent applicable to an approved drug is eligible for the extension ~~and~~ **,** only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended, and the application for the extension must be submitted prior to the expiration of the patent. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available for our patents, may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may ~~not~~ be ~~granted~~ **denied** 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. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors and other third parties may be able to obtain approval of competing products following our patent expiration and take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects. Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent offices, and our patent protection could be reduced or eliminated for noncompliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patent are due to be paid to the USPTO and patent offices in foreign countries in several stages over the lifetime of the patent. The USPTO and patent offices in foreign countries require compliance with a number of procedural, documentary, fee payment and other requirements during the patent application process. In the future, we may rely on licensing partners to pay these fees due to U. S. and non- U. S. patent agencies and to comply with these other requirements with respect to any future licensed patents and patent applications. While an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of a patent or patent rights in the

relevant jurisdiction. Non- compliance 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 and other third parties might be able to enter the market with similar or identical products of technology, which would have a material adverse effect on our business, financial condition, results of operations and prospects. If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed. We rely on proprietary know- how and trade secret protection and confidentiality agreements to protect proprietary know- how or trade secrets that are not patentable or that we elect not to patent. We seek to protect our trade secrets and proprietary know- how in part by entering into non- disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, consultants, independent contractors, advisors, CMOs, CROs, hospitals, independent treatment centers, suppliers, collaborators and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary know- how. Additionally, our confidentiality agreements and other contractual protections may not be adequate to protect our intellectual property from unauthorized disclosure, third- party infringement or misappropriation. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our business, financial condition, results of operations and prospects our business and competitive position could be materially harmed. Intellectual property rights do not necessarily address all potential threats. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make products similar to any product candidates we may develop or utilize similarly related technologies that are not covered by the claims of the patents that we may license or may own in the future; • we, or any future license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future; • we, or any future license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating any of our owned or licensed intellectual property rights; • it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents; • issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties; • our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; • the patents of others may harm our business; and • we may choose not to file a patent in order to maintain certain trade secrets or know how, and a third party may subsequently file a patent covering such intellectual property. Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects. Risks Related to Our Common Stock As of December 31, ~~2023~~ **2024** , our executive officers, directors, beneficial owners of 5 % or more of our capital stock and their respective affiliates beneficially owned approximately ~~45~~ **50** % of our common stock and securities convertible into shares of our common stock. The voting power of this group may increase to the extent they convert shares of non- voting common stock or pre- funded warrants that they hold into shares of our common stock. This concentration of control creates a number of risks. This group of stockholders has the ability to control us through this ownership position and are able to determine all matters requiring stockholder approval. For example, these stockholders are able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction, and other stockholders may find it difficult to replace members of management should they disagree with the manner in which the Company is operated. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders **,** and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock. An active **and liquid** trading market for our common stock may ~~never~~ **not be sustained. As a result, you may not be able to resell your shares of common stock at or above the original price paid to acquire such shares. An active trading market for our common stock may not** be sustained. The market value of our common stock may decrease from the purchase price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the purchase price. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration. Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating

results will be affected by numerous factors, including: • variations in the level of expense related to the planned and ongoing development of our product candidates or future development programs, including scale- up CMC expenses; • results of clinical trials, or the addition or termination of future preclinical or clinical trials or funding support by us, or future collaborators or licensing partners; • our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements; • any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved; • additions and departures of key personnel; • strategic decisions by us or our competitors, such as acquisitions, divestitures, spin- offs, joint ventures, strategic investments or changes in business strategy; • if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates; • regulatory developments affecting our product candidates or those of our competitors; and • changes in political, economic and general macroeconomic conditions, including but not limited to the ongoing ~~conflict~~ **conflicts** in Ukraine **and the Middle East**, supply chain disruptions, rising interest rates, rising inflation rates, a potential recession or the ~~ongoing~~ **lingering effects of the** COVID- 19 pandemic. If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance. The market price of our common stock has been, and is likely to be, highly volatile, which could result in substantial losses for purchasers of our common stock. From January 1, ~~2023~~ **2024** to December 31, ~~2023~~ **2024**, the closing price of common stock on the Nasdaq Global Select Market ranged from $ ~~1~~ **0**. ~~69~~ **80** to $ ~~8~~ **6**. ~~12~~ **37** per share. The market price of our common stock is likely to continue to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid. The market price for our common stock may be influenced by many factors, including the other risks described in this section of this Annual Report on Form 10- K and the following: • enrollment or results of clinical trials of our product candidates, or those of our competitors or our future collaborators, or changes in the development status of our product candidates; • the failure of any product candidates; • regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our product candidates; • the success of competitive products or technologies; • introductions and announcements of new products by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements; • actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms; • actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us; • the success of our efforts to acquire or in- license additional technologies, products or product candidates; • developments concerning any future collaborations, including but not limited to those with development and commercialization partners; • market conditions in the pharmaceutical and biotechnology sectors; • developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates and products; • our ability or inability to raise additional capital and the terms on which we raise it; • the recruitment or departure of key personnel; • changes in the structure of healthcare payment systems; • announcement and expectation of additional financing efforts; • sales or purchases of our common stock by us, insiders or our stockholders; • general economic, industry and market conditions, or other events or factors, many of which are beyond our control, including but not limited to a potential recession, rising interest rates, rising inflation, and the ~~recent~~ **lingering effects of the** COVID- 19 pandemic. In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this " Risk Factors " section, could have a dramatic and adverse impact on the market price of our common stock. The dual class structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions. The dual class structure of our common stock may limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non- voting common stock are not entitled to any votes. Nonetheless, each share of our non- voting common stock, as well as our pre- funded warrants, may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our restated certificate of incorporation. Consequently, if holders of our non- voting common stock and pre- funded warrants exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our non- voting common stock, and correspondingly decreasing the voting power of the holders of our common stock, which may limit your ability to influence corporate matters. For example, on ~~February 9~~ **March 6**, ~~2024~~ **2025**, the common stock will have 100 % of the voting power, but if the holders of non- voting common stock or pre- funded warrants were to convert all of their shares or pre- funded warrants into common stock, the prior common stock would have **56** ~~55. 5~~ % of the voting power, and the former non- voting common stock and holders of pre- funded warrants would represent 44 **%** ~~. 5~~ of the voting power. Additionally, stockholders who hold, in the aggregate, more than 10 % of our common stock, non- voting common stock and pre- funded warrants, but 10 % or less of our common stock, and are not otherwise an insider of the company, may not be required to report changes in their ownership due to transactions in our non- voting common stock pursuant to Section 16 (a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and may not be subject to the short- swing profit provisions of Section 16 (b) of the Exchange Act. We are an " emerging growth company " as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor

attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002, as amended, or the Sarbanes- Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in this Annual Report on Form 10- K as well as our periodic reports and proxy statements and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements in this Annual Report on Form 10- K .~~-~~Under the JOBS Act,emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies.We have elected to take advantage of the benefits of this extended transition period.Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards.Until the date that we are no longer an " emerging growth company " or affirmatively and irrevocably opt out of the exemption provided by Section 7 (a) (2) (B) of the Securities Act,upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies,we will disclose the date on which adoption is required for non- emerging growth companies and the date on which we will adopt the recently issued accounting standard **.** . We could be an emerging growth company until December 31, 2025, although circumstances could cause us to lose that status earlier, including if we are deemed to be a " large accelerated filer, " which occurs when the market value of our common stock that is held by non- affiliates equals or exceeds $ 700 million as of the prior June 30, or if we have total annual gross revenue of $ 1. 235 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $ 1. 0 billion in non- convertible debt during any three- year period before that time, in which case we would no longer be an emerging growth company immediately. **When we cease to be an emerging growth company, we could be required to incur additional professional fees and internal costs related to any heightened disclosure. However,** ~~Even~~ **even** after we no longer qualify as an emerging growth company, we may still qualify as a " smaller reporting company, " which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, if our revenues remain less than $ 100. 0 million, and reduced disclosure obligations regarding executive compensation in this Annual Report on Form 10- K as well as our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile. Under the JOBS Act, emerging growth..... adopt the recently issued accounting standard. We are also a " smaller reporting company, " meaning that the market value of our stock held by non- affiliates is less than $ 700. 0 million as of the prior June 30 and our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non- affiliates is less than $ 250. 0 million or (ii) our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year and the market value of our stock held by non- affiliates is less than $ 700. 0 million as of the prior June 30. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10- K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. Anti- takeover provisions in our charter documents and under Delaware law could prevent or delay an acquisition of us, which may be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management. Our restated certificate of incorporation and our restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions: • establish a classified board of directors so that not all members of our board are elected at one time; • permit only the board of directors to establish the number of directors and fill vacancies on the board; • provide that directors may only be removed " for cause " and only with the approval of two- thirds of our stockholders; • require super- majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws; • authorize the issuance of " blank check " preferred stock that our board could use to implement a stockholder rights plan; • eliminate the ability of our stockholders to call special meetings of stockholders; • prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders; • prohibit cumulative voting; and • establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings. In addition, Section 203 of the Delaware General Corporation Law, or DGCL, may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15 % or more of our common stock. The exclusive forum provision in our organizational documents may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Our restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision. This choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate

of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our restated bylaws provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or a Federal Forum Provision. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder. Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit a stockholders' ability to bring a claim in a judicial forum of their choosing for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. As a public company, and particularly after we are no longer an emerging growth company, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business or increase the prices of our products once commercialized. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. General Risk Factors If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline. The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If no or few securities or industry analysts commence coverage of us, the trading price for our common stock could be impacted negatively. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume. If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and the listing requirements of the Nasdaq Global Select Market. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Annual Report on Form 10- K filing for that year, as required by Section 404 (a) of the Sarbanes- Oxley Act. This requires that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system' s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that

were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC, or other regulatory authorities. We may be subject to securities litigation, which is expensive and could divert management attention. The market price of our common stock may be volatile. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management' s attention from other business concerns, which could seriously harm our business. **Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data. Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may adopt and integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third- party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business 77**