Risk Factors Comparison 2025-04-15 to 2024-04-01 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

Investing in our common stock involves a high degree of risk. Before making an investment decision, you should carefully consider the risks described below, as well as the other information in this annual report. Our business, prospects, financial condition, or operating results could be harmed by any of these risks, as well as other risks not currently known to us or that we currently consider immaterial. If any such risks or uncertainties actually occur, our business, prospects, financial condition or operating results could differ materially from the plans, projections and other forward- looking statements included in the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " The trading price of our common stock could decline significantly due to any of these risks or other factors, and as a result, you may lose all or part of your investment. Risks related to our financial position and need for additional capital We could lose our listing on the Nasdaq Capital Market if we do not maintain our stockholders' equity or if the closing bid price of our common stock does not increase **or if we do not comply with other Nasdaq requirements** . The loss of our Nasdaq listing would in all likelihood make our common stock significantly less liquid and adversely affect its value, including a total loss of value. ~~On~~ **As disclosed in various Current Reports on Form 8- K filings with the SEC, we have not been in compliance with various Nasdaq rules at various times since** May ~~16,~~ 2023 ~~, we~~ **. We have** received ~~a letter~~ **letters** from the Listing Qualifications Department, or the Staff, of the Nasdaq Stock Market LLC, or Nasdaq, stating that we were not in compliance with **certain** ~~the stockholders' equity requirement~~ **requirements** for continued listing on the Nasdaq Capital Market. **In most of these instances, we have appealed the delisting determinations to** Nasdaq **Hearing Panels where we received extensions of time to regain compliance and maintain our Nasdaq** ~~Listing~~ **listing . However, there is no assurance** ~~Rule 5550 (b) (1) requires~~ that ~~companies~~ **in the event we do not meet Nasdaq listing requirements, we will receive any extensions of time to regain compliance and maintain our Nasdaq listing in which case our stock would be** ~~listed~~ **delisted from trading** on **Nasdaq. In the event of a delisting from** the Nasdaq Capital Market ~~maintain stockholders' equity of at least $ 2~~ , ~~500, 000, or~~ **our** ~~the Stockholders' Equity Requirement, or that they meet one of the alternative listing standards: market value of listed securities of at least $ 35 million or net income of $ 500, 000 from continuing operations in the most recently completed fiscal year, or in two of the three most recently completed fiscal years. On June 30, 2023, we submitted a plan to Nasdaq describing how we intended to seek to regain compliance with the Stockholders' Equity Requirement, or the Compliance Plan, but the Staff did not accept our Compliance Plan. Shortly thereafter, we submitted a request for a hearing to a Nasdaq Panel, or the Panel. The hearing was held on October 5, 2023. On October 26, 2023, we received a letter from the Panel granting an extension to continue our listing on Nasdaq until January 22, 2024, subject to two requirements, both of which we met. On January 31, 2024, we received notice from Nasdaq that it had determined that we had regained compliance with the minimum stockholders' equity requirement under Nasdaq Listing Rule 5550 (b) (1) (the Equity Rule) for continued listing on the Nasdaq Capital Market. Pursuant to Nasdaq Listing Rule 5815 (d) (4) (B), we are subject to a mandatory panel monitor through January 26, 2025. The Nasdaq notice also stated that if, within the one- year monitoring period, the Staff finds us again out of compliance with the Equity Rule that was the subject of the exception, notwithstanding Rule 5810 (c) (2), we will not be permitted to provide the Staff with a plan of compliance with respect to that deficiency and the Staff will not be permitted to grant additional time for us to regain compliance with respect to that deficiency, nor will we be afforded an applicable cure or compliance period pursuant to Rule 5810 (c) (3). Instead, the Staff will issue a Delist Determination Letter and we will have an opportunity to request a new hearing with the initial Hearing Panel or a newly convened Hearing Panel if the initial Panel is unavailable. We will have the opportunity to respond / present to the Hearing Panel as provided by Listing Rule 5815 (d) (4) (C). Our securities may at that time be delisted from Nasdaq. Additionally, on November 7, 2023, we received a letter from the Staff notifying us that for the 30 consecutive business day period between September 26, 2023, through November 6, 2023, our common~~ stock ~~had not maintained a minimum closing bid price of $ 1. 00 per share, or the Minimum Bid Price Requirement, required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550 (a) (2). Nasdaq provided us an initial period of 180 calendar days, or until May 6, 2024, or the Compliance Date, to regain compliance with the Minimum Bid Price Requirement. If, at any time during this 180- day period, the closing bid price for our common stock is $ 1. 00 per share or more for a minimum of 10 consecutive business days, or such longer period up to 20 consecutive business days as may be determined by the Staff in its discretion, the Staff will provide us written notification that we have complied with the Minimum Bid Price Requirement. On January 16, 2024, we effected a 1- for- 40 reverse stock split. However, the closing bid price of our common stock has not been above $ 1. 00 for a minimum of 10 consecutive business days since then. If we do not regain compliance with the Minimum Bid Price Requirement by the Compliance Date, we may be eligible for an additional 180 calendar day compliance period. To qualify, we~~ would **likely** be ~~required to meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and would need to provide written notice to Nasdaq of our intention to cure the deficiency during the additional compliance period. If it appears to the Staff that we will not be able to cure the Minimum Bid Price deficiency, the Staff will provide written notice to us that our common stock will be subject to delisting. At that time, we may appeal the Staff' s delisting determination to the Panel. There can be no assurance that if we do appeal any Staff delisting determination to the Panel, such appeal would be successful. In the event of a delisting from the Nasdaq Capital Market, we may seek to have our stock~~ traded in the over- the- counter inter- dealer quotation system, more commonly known as the OTC. OTC transactions involve risks in addition to those associated with transactions in securities traded on the securities exchanges, such as the Nasdaq

Capital Market, or ~~, together,~~ Exchange- listed stocks. Many OTC stocks trade less frequently and in smaller volumes than Exchange- listed stocks. Accordingly, our stock would be less liquid than it would be otherwise. Also, the prices of OTC stocks are often more volatile than Exchange- listed stocks. Additionally, **many** institutional investors are ~~usually~~ prohibited from investing in OTC stocks, and it might be more challenging to raise capital **when** ~~. As further described below, in light of our financial position and our need~~ **needed** ~~to raise additional capital, in the event of a delisting from the Nasdaq Capital Market, delisting from the Nasdaq Capital Market would materially limit our ability to obtain additional equity capital~~ . We may need to seek an in- court or out- of- court restructuring of our liabilities. In the event of such restructuring activities, holders of our common stock and other securities will likely suffer a total loss of their investment. We have identified conditions and events that raise substantial doubt about our ability to continue operations in the near- term and our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern. We may need to seek an in- court or out- of- court restructuring of our liabilities, including potentially a bankruptcy proceeding, or to substantially reduce or totally cease our operations. We may be forced to amend, delay, limit, reduce or terminate the scope of our development programs and / or limit or cease our operations if we are unable to obtain additional funding. As of December 31, ~~2023~~ **2024** , we had cash of approximately $ ~~2~~ **5** . 8 million. We believe that ~~the~~ **these** ~~net proceeds from our January 2024 offering, together with our existing~~ funds ~~,~~ will **support** ~~enable us to fund~~ our operating expenses and capital requirements into ~~late third~~ **the middle of the second** quarter ~~or early fourth quarter of 2024~~ **2025** . Our recurring losses from operations and negative cash flow raise substantial doubt about our ability to continue as a going concern without sufficient capital resources. Our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the years ended December 31, **2024 and** 2023 ~~and 2022~~ , with respect to this uncertainty. Our ability to continue as a going concern is dependent on our available cash, how well we manage that cash, and our operating requirements. We will need to raise additional capital to continue as a going concern. The failure to obtain sufficient additional funds on commercially acceptable terms to fund our operations and satisfy our obligations to creditors may have a material adverse effect on our business, results of operations and financial condition and jeopardize our ability to continue operations in the near- term. We will likely need to consider additional cost reduction strategies, which may include, among ~~other~~ **others** ~~actions~~ , amending, delaying, limiting, reducing, or terminating our development programs, and we may need to seek an in- court or out- of- court restructuring of our liabilities, including potentially a bankruptcy proceeding, or to substantially reduce or totally cease our operations. In the event of such **future** restructuring activities, holders of our common stock and other securities will likely suffer a total loss of their investment. We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future. Investment in oncology product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential therapeutic candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable. We are still in the early stages of development of our therapeutic candidates. We **completed** ~~have initiated~~ a Phase 0 **clinical** trial in which we ~~have~~ dosed ~~1~~ **one** patient ~~having~~ **who had** advanced solid tumors **. We also initiated an open- label Phase I / II study and so far have successfully enrolled 10 patients in four treatment cohorts** . We have no products licensed for commercial sale and have not generated any revenue from product sales or otherwise to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We finance our current operations with funds obtained primarily from equity financings. ~~58We~~ **We** have incurred significant annual net losses in each period since inception. For the years ended December 31, **2024 and** 2023 ~~and 2022~~ , our net losses were approximately $ **16. 8 million and $** 18. 5 million ~~and $ 17. 6 million~~ , respectively. As of December 31, ~~2023~~ **2024** , our accumulated deficit was approximately $ ~~46~~ **63** . ~~4~~ **2** million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we: Øconduct preclinical studies and clinical trials for our current and future therapeutic candidates; Øcontinue our research and development efforts and submit INDs for future therapeutic candidates; Øseek marketing approvals for any therapeutic candidates that successfully complete clinical trials; Øbuild infrastructure to support sales and marketing for any approved therapeutic candidates; Øscale up external manufacturing and distribution capabilities for clinical trials and, if approved, commercial supply of our therapeutic candidates; Øexpand, maintain and attempt to protect our intellectual property portfolio; Øhire additional clinical, regulatory, scientific and other personnel; andØoperate as a public company. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in eventually commercializing one or more of our therapeutic candidates, we will continue to incur substantial research and development and other expenditures to develop, seek approval for, and market therapeutic candidates. We may never succeed in these activities and, even if we succeed in commercializing one or more of our current therapeutic candidates and any future therapeutic candidates, we may never generate revenues that are significant or large enough to achieve profitability. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on stockholders' equity (deficit). ~~We~~ **57We** have never generated any revenue from product sales and may never be profitable. Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from any product sales. We have no products approved for commercial sale, and do not anticipate generating any revenue from product sales until after we have received marketing approval for the commercial sale of a therapeutic candidate, if ever. Our ability to generate revenue and achieve profitability depends significantly on our success in achieving a number of goals, including: Øinitiating and completing research regarding preclinical and clinical development of, TTX- MC138 and any future therapeutic candidates; Ødeveloping a sustainable and scalable manufacturing process for TTX- MC138 or our other therapeutic candidates and any future therapeutic candidates,

including establishing and maintaining commercially viable supply and manufacturing relationships with third- parties; Ølaunching and commercializing TTX- MC138, our other therapeutic candidates and any future therapeutic candidates for which we obtain marketing approvals, either directly or with a collaborator or distributor; Øobtaining market acceptance of TTX- MC138, our other therapeutic candidates and any future therapeutic candidates as viable treatment options; ~~59Øaddressing~~ -- **Øaddressing** any competing technological and market developments; Øidentifying, assessing, acquiring and developing new therapeutic candidates; Ønegotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter; Øobtaining, maintaining, attempting protection of, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know- how; andØattracting, hiring, and retaining qualified personnel. Even if our current therapeutic candidates or any future therapeutic candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any such therapeutic candidate. Our expenses could increase beyond expectations if we are required by the FDA or comparable foreign regulatory authorities to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate. If in the future we obtain regulatory approvals to market TTX- MC138 or other therapeutic candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the price for the product we obtain, the ability to obtain reimbursement at any price and whether we own the commercial rights for that territory. If the number of addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, the labels for our current therapeutic candidates and any future therapeutic candidates contain significant safety warnings, regulatory authorities impose burdensome or restrictive distribution requirements, or the reasonably accepted patient population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate sufficient revenue from the sale of any approved products, we could be prevented from or significantly delayed in achieving profitability. Even if we 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 development efforts, obtain product approvals, diversify our product offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment. ~~We~~ **58We** will need to raise substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, scale back or discontinue some of our therapeutic candidate development programs or commercialization efforts. The development of pharmaceutical drugs is capital intensive. As of December 31, ~~2023~~ **2024** , we had cash totaling approximately $ ~~2~~ **5** . 8 million. We believe that these funds ~~,~~ together with the net proceeds **of approximately $ 8. 8 million** from ~~this offering~~ **our equity financing completed March 25, 2025** , will be sufficient to ~~fund~~ **support** our operating expenses and capital expenditure requirements into the ~~third~~ **fouth** quarter ~~of 2024~~ **2025** . As a result, we will need to raise additional capital to continue as a going concern. Unless we receive additional funding, we may not be able to complete our ~~planned~~ Phase 1 trial. Further, we may only be able to complete the trial in a small subset of patients and in only one tumor type. Even if completed, we will require additional funds to advance further. If we are capital constrained, we may not be able to meet our obligations. If we are unable to meet our obligations, or we experience a disruption in our cash flows, it could limit or halt our ability to continue to develop our therapeutic candidates or even to continue operations, either of which occurrence would have a material adverse effect on us. We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we continue the research and development of, advance the preclinical and clinical activities of, and seek marketing approval for, our current or future therapeutic candidates. In addition, if we obtain marketing approval for any of our current or future therapeutic candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution to the extent that such sales, marketing, product manufacturing and distribution are not the responsibility of our collaborators. We may also need to raise additional funds sooner if we choose to pursue additional indications and / or geographies for our current or future therapeutic candidates or otherwise expand more rapidly than we presently anticipate. Furthermore, we expect to continue to incur significant costs associated with operating as a public company. If we are unable to raise capital when needed, we would be forced to delay, scale back or discontinue the development and commercialization of one or more of our therapeutic candidates, delay our pursuit of potential licenses or acquisitions, or significantly reduce our operations. ~~60Our~~ -- **Our** future capital requirements will depend on and could increase significantly as a result of many factors, including: Øthe scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our current or future therapeutic candidates ~~; Øthe potential additional expenses attributable to adjusting our development plans (including any supply- related matters) to the COVID- 19 pandemic~~ ; Øthe scope, prioritization and number of our research and development programs; Øthe costs, timing and outcome of regulatory review of our current or future therapeutic candidates; Øour ability to establish and maintain collaborations on favorable terms, if at all; Øthe achievement of milestones or occurrence of other developments that trigger payments under any additional collaboration agreements we obtain; Øthe extent to which we are obligated to reimburse, or are entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any; Øthe costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property- related claims; Øthe extent to which we acquire or license other current or future therapeutic candidates and technologies; Øthe costs of securing manufacturing arrangements for commercial production; andØthe costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our current or future therapeutic candidates. Identifying potential current or future therapeutic candidates, manufacturing, and conducting preclinical testing and clinical trials is a time- consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve drug sales. In addition, our current or future therapeutic candidates, if ~~approved~~ **59approved** , may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be

commercially available for many years, if ever. Accordingly, we will need to continue to rely on additional funding to achieve our business objectives. Any additional fundraising efforts may divert our management from ~~their~~ **other** day- to- day activities, which may adversely affect our ability to develop and commercialize our current or future therapeutic candidates. Disruptions in the financial markets in general have made equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms favorable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness could result in fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or current or future therapeutic candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. ~~61If~~ **If** we are unable to obtain funding on a timely basis, we may be required to significantly delay, scale back or discontinue one or more of our research or development programs or the commercialization of any therapeutic candidates or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations. The amount of our future losses is uncertain, and 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. Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following: Øthe timing and success or failure of clinical trials for our therapeutic candidates or competing therapeutic candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners; Øour ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts; Øour ability to obtain marketing approval for our therapeutic candidates, and the timing and scope of any such approvals we may receive; Øthe timing and cost of, and level of investment in, research and development activities relating to our therapeutic candidates, which may change from time to time; Øthe cost of manufacturing our therapeutic candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers; Øthe quality and stability of our manufactured therapeutic candidates; Øour ability to attract, hire and retain qualified personnel; Øexpenditures that we will or may incur to develop additional therapeutic candidates; Øthe level of demand for our therapeutic candidates should they receive approval, which may vary significantly; ~~Øthe~~ **60Øthe** risk / benefit profile, cost and reimbursement policies with respect to our therapeutic candidates, if approved, and existing and potential future therapeutics that compete with our therapeutic candidates; Øgeneral market conditions or extraordinary external events, such as a recession **, civil uprisings** or **military conflicts** ~~the COVID- 19 pandemic~~; Øthe changing and volatile U. S. and global economic environments; andØfuture accounting pronouncements or changes in our accounting policies. The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even if we meet any guidance we may have provided publicly previously. ~~62Risks~~ -- **Risks** related to research and development and the biopharmaceutical industryOur limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability. We are an early, clinical- stage oncology company with a limited operating history. We commenced operations in 2016, and until our IPO, our operations were limited to organizing and staffing our company, business planning, raising capital, conducting limited discovery and research activities, filing patent applications, identifying potential therapeutic candidates, undertaking preclinical studies and preparing for clinical trials, process development and manufacturing of initial quantities of our therapeutic candidates and component materials. Our lead therapeutic candidate, TTX- MC138, is currently in the early stages of clinical development. We have not yet demonstrated our ability to successfully complete any clinical trials, obtain marketing approvals, manufacture a commercial- scale product or arrange for a third- party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. Investment in oncology product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential therapeutic candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We are unable to predict the full range of risks that may emerge, and we cannot guarantee that we will meet or achieve the clinical or commercial results we expect. The future of our business depends on us successfully developing, obtaining marketing approval for, and marketing profitably our therapeutic candidates. This requires many complex scientific activities, successful pursuit of regulatory approvals, appropriate market assessments, the strategic management of intellectual property and financial resources and effective management of many other aspects of our business. Products for which we receive regulatory approval must demonstrate safety and efficacy. Competitively, the products must improve patient outcomes, deliver benefits to intended customers, maintain an affordable price, and be superior to competitive products. To be successful, we must also be effective in driving awareness of our therapeutics to achieve market adoption for our approved products and to be profitable. The risks of missteps, setbacks, errors and failings with respect to any aspect of

managing our business are an inherent part of attempted innovation in the life sciences industry. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may materially and adversely affect our business. In addition, as an early- stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. ~~We~~ **61We** expect our financial condition and operating results to continue 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. Because our therapeutic candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products or generating therapeutic revenues. Our therapeutic candidates are development- stage technologies which require more, complex future development as well as regulatory approval prior to commercialization. It is impossible to fully mitigate the risks associated with bringing forward new technology and developing therapeutic candidates. These therapeutic candidates may fail at any point in development, manufacturing or in clinical trials. Therefore, there is no assurance that any of our therapeutic candidates will be successfully developed, be approved or cleared for sale by regulators, be accepted in the market or be profitable. Any delay or setback in the development of a product- candidate could materially adversely affect us. We may not be successful in our efforts to identify or discover additional therapeutic candidates or we may expend our limited resources to pursue a particular therapeutic candidate or indication and fail to capitalize on therapeutic candidates or indications that may be more profitable or for which there is a greater likelihood of success. ~~63In~~ **In** addition to development risks, we also face the risk that existing or evolving drug regulations may create barriers to licensure that we are unable to overcome, making it impossible for us to license any product we develop. Our therapeutic candidates may fail in clinical trials. We may never achieve the product claims necessary to successfully launch any products commercially. We may not succeed in changing the practice of medicine such that our products are adopted as we anticipate. The data we generate in our clinical programs may not be viewed by physicians as strong enough for them to use and by third- party payers as effective enough for them to reimburse the cost of our products. Further, changes in the practice of medicine may render our approved products obsolete. We also face the risk of: Øcompetitors introducing technologies which render our development efforts or approved products obsolete; Ødata from our clinical trials not being strong enough to support therapeutic approval or the marketing claims needed for market success and to achieve our financial projections; andØbeing unable to manufacture or supply, or have manufactured or supplied on our behalf, approved products cost- effectively. Our business is highly dependent on the success of TTX- MC138, our lead candidate which is at the early stages of development. All of our therapeutic candidates may require significant additional manufacturing, preclinical and clinical development before we may be able to seek regulatory approval for and launch a product commercially. We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We are very early in our development efforts, and only one of our therapeutic candidates, TTX- MC138, is in clinical development with an open Phase **I / II** ~~0 clinical trial and a planned Phase 1~~ clinical trial. If we are unable to successfully develop, obtain regulatory approval for, and commercialize TTX- MC138, or we experience significant delays in doing so, our business will be materially harmed. Advancing TTX- MC138 will require substantial investment before we can seek regulatory approval and potentially launch commercial sales. Further development of TTX- MC138 will require production scaleup, clinical studies, regulatory review and approval in the U. S. and other jurisdictions, development of sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate any revenue from product sales, if approved. In developing TTX- MC138, among other risks, we may not be successful in synthesizing or producing the components of our proprietary formulation, or there may be toxicology issues from key components of our formulation that we have not anticipated. We have not manufactured TTX- MC138 using the current synthesis protocol, production processes, equipment and materials in the larger quantities that would be necessary to meet clinical trial treatment demands for all anticipated patients. ~~We~~ **62We** may experience setbacks that could delay or prevent regulatory approval of, or our ability to commercialize, our therapeutic candidates, including: Ønegative or inconclusive results from our preclinical studies or clinical trials or positive results from the clinical trials of others for competing therapeutic candidates similar to ours, leading to their approval and a possible decision by us to conduct additional preclinical testing or clinical trials or abandon a program; Øside effects related to our therapeutic candidates experienced by patients or subjects in our clinical trials or by individuals using drugs or therapeutics that we, the FDA, other regulators or others view as relevant to the development of our therapeutic candidates; Ødelays in submitting IND applications or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced; Øconditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials, including our clinical endpoints; Ødelays in enrolling subjects in clinical trials ~~, including due to the COVID- 19 pandemic~~ ; ~~64Øhigh~~ -- **Øhigh** drop- out rates of subjects from clinical trials; Øinadequate supply or quality of therapeutic candidates or other materials necessary for the conduct of our clinical trials; Øgreater than anticipated clinical trial costs; Øinability to compete with other therapies; Øpoor efficacy of our therapeutic candidates during clinical trials; Øtrial results taking longer than anticipated; Øtrials being subjected to fraud or data capture failure or other technical mishaps leading to the invalidation of our trials in whole or in part; Øunfavorable FDA or other regulatory agency inspection and review of a clinical trial site; Øfailure of our third- party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all; Ødelays ~~related to the impact of the spread of the COVID- 19 pandemic, including the impact of COVID- 19 on the FDA' s ability to continue its normal operations; Ødelays~~ and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical development generally or with respect to our technology in particular; orØvarying interpretations of data by the FDA and similar foreign regulatory agencies. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats

to our intellectual property rights and our manufacturing, marketing, distribution and sales efforts or that of any future collaborator. Our therapeutic candidates may cause undesirable side effects or death or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences. Undesirable side effects or death caused by any of our therapeutic candidates could cause IRBs, our contract research organizations, or CROs, the FDA or other regulatory authorities to interrupt, delay or discontinue clinical trials and could result in the ~~denial~~ **63denial** of regulatory approval for our therapeutic candidates. This, in turn, could prevent us from commercializing our therapeutic candidates and generating revenues from their sale. Also, any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from becoming profitable. ~~65Clinical~~ -- **Clinical** development involves a lengthy, complex and expensive process, with an uncertain outcome, and the results of preclinical studies and early- stage clinical trials of our therapeutic candidates may not be predictive of the results of later- stage clinical trials. To obtain the requisite regulatory approvals to commercialize any therapeutic candidates, we must demonstrate through extensive preclinical studies and clinical trials that our therapeutic candidates are safe and effective in humans. Clinical trials are expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, the general approach for FDA approval of a new drug is dispositive data from two well- controlled, Phase 3 clinical trials of the relevant drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. A therapeutic candidate can fail at any stage of testing, even after observing promising signals of activity in earlier preclinical studies or clinical trials. The results of preclinical studies and early clinical trials of our therapeutic candidates may not be predictive of the results of later- stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of therapeutic candidates proceeding through clinical trials. Therapeutic candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biotechnology and biopharmaceutical industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most therapeutic candidates that commence clinical trials are never approved as therapeutic products, and there can be no assurance that any of our future clinical trials will ultimately be successful or support further clinical development of TTX- MC138 or any of our other therapeutic candidates. Therapeutic candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including: Øpreclinical studies or clinical trials may show the therapeutic candidates to be less effective than expected (e. g., a clinical trial could fail to meet its primary endpoint (s)) or to have unacceptable side effects or toxicities; Øfailure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful; Øfailure to receive the necessary regulatory approvals; Ømanufacturing costs, development, scaling and formulation issues, pricing or reimbursement issues, or other factors that make a therapeutic candidate uneconomical; andØthe proprietary rights of others and their competing products and technologies that may prevent one of our therapeutic candidates from being commercialized. In addition, differences in trial design between early- stage clinical trials and later- stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Our FIH clinical trial with radiolabeled TTC-MC138 ~~is~~ **was** designed as a single microdose trial, the purpose of which ~~is~~ **was** to demonstrate safety and proof of delivery of TTX- MC138 to metastatic lesions. This design ~~is~~ **was** not meant or expected to produce efficacy signals or to show that TTX-MC138 reaches into metastatic tumor cells ~~although these may occur~~ . Our ~~planned~~ **open** Phase ~~1~~ **I / II** clinical trial with TTX-MC138 is a Bayesian Optimal Interval Design, or BOIN design, with dose escalation and expansion **. Key assessments in the clinical trial characterize the safety, pharmacokinetic, pharmacodynamic and anti- tumor activity thus identifying a maximum tolerated dose (MTD) and ensuring the mechanism of action is on target. The study also is exploring the effect of TTX- MC138 on biomarker expression, which may include miR- 10b expression, and miR- 10b downstream targets (ribonucleic acid [RNA] sequencing). Clinical assessments to further evaluate TTX = MC138 include clinical laboratory exams, CT scan assessments, and response assessments per RECIST** . Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their therapeutic candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. ~~Additionally~~ **64Additionally** , we expect that some of our trials will be open- label studies, where both the patient and investigator know whether the patient is receiving the investigational therapeutic candidate as a monotherapy or in combination with an existing approved drug. Most typically, open- label clinical trials test only the investigational therapeutic candidate and sometimes do so at different dose levels. Open- label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open- label clinical trials are aware when they are receiving treatment. In addition, open- label clinical trials may be subject to an " investigator bias " where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Therefore, it is possible that positive results observed in open- label trials will not be replicated in later placebo-controlled trials. ~~66In~~ **In** addition, the standards that the FDA and comparable foreign regulatory authorities use when regulating our therapeutic candidates require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Although we are initially focusing our efforts on development of small- molecule drug products, we may in the future pursue development of biological products, which could make us subject to additional regulatory requirements. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations. Examples of such regulations include future legislation or administrative action, or changes in FDA policy during the period of product development and FDA regulatory review. We cannot predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact

of such changes, if any, may be. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any therapeutic candidates that we develop. We may seek to conduct clinical trials in foreign countries, as well as in the United States. If we continue to seek to conduct clinical trials in foreign countries or pursue marketing approvals in foreign jurisdictions, we must comply with numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third- party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval from foreign regulatory agencies may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa. Successful completion of clinical trials is a prerequisite to submitting a marketing application to the FDA and similar marketing applications to comparable foreign regulatory authorities, for each therapeutic candidate and, consequently, the ultimate approval and commercial marketing of any therapeutic candidates. We may experience negative or inconclusive results, which may result in our deciding, or our being required by regulators, to conduct additional clinical studies or trials or abandon some or all of our product development programs, which could have a material adverse effect on our business. Caution should be taken when interpreting the preliminary results of our preclinical studies or clinical trials, including our **completed** Phase 0 **and currently- open Phase I / II clinical** ~~trial~~ **trials** . These data may differ from future results of this study, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. From time to time, we may publicly disclose interim, preliminary or topline data from our preclinical studies and clinical trials, including our Phase 0 trial with radiolabeled TTX- MC138 **and Phase I / II clinical trials** , which are based on preliminary analyses of then- available data. These results and related findings and conclusions are subject to change following more comprehensive reviews of the data related to the particular 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 interim, preliminary or 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. Interim data from studies or **clinical** trials ~~that we may complete, such as our Phase 0 trial for TTX- MC138,~~ are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available or as patients from our clinical trials continue other treatments for their disease. The final results of the trial may not be as positive as the interim data and these differences could be meaningful. Topline data from completed studies remain subject to audit and verification procedures that may result in the final data ~~being~~ **65being** materially different from the topline data we previously published. As a result, preliminary and topline data should be viewed with caution until the final data are available. 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 based on extensive data, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. ~~67If~~ **If** the interim, preliminary or topline data that we report differs from subsequent results, or if others, including regulatory authorities, disagree with the conclusions we reach, our ability to seek and obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. In addition, disclosure of interim, preliminary or topline data by us or by our competitors could result in volatility in the price of our common stock. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. We may experience difficulties in patient enrollment in our clinical trials for many reasons. The number of qualified clinical trial investigators and sites is limited. We expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use. This could reduce the number of patients available for our clinical trials at such clinical trial site. Clinical trials of other companies may be in similar therapeutic areas as ours. This competition will reduce the number and types of patients and qualified clinical investigators available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by a competitor or clinical trial sites may not allow us to conduct our clinical trial at such site if competing trials are already being conducted there. We may also encounter difficulties finding a clinical trial site at which to conduct our trials. Because our therapeutics represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as checkpoint inhibitors, chemotherapy, radiation and monoclonal antibodies, rather than enroll patients in any of our clinical trials. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our therapeutic or any other future versions of it. Our preclinical studies of, and clinical trials, if any, with, any of our therapeutic candidates may fail to demonstrate adequately the safety, potency, purity and efficacy necessary for continued and timely development, regulatory approval and commercialization. Since the number of subjects that we plan to dose in our **ongoing** ~~planned Phase 0 and~~ Phase 1 clinical ~~trials~~ - **trial** of TTX- MC138 is relatively small, the results from ~~such~~ **this** clinical ~~trials~~ - **trial** , ~~once~~ **if** completed, may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for our therapeutic candidates. Due to our limited resources and access to capital, we must make decisions on the allocation of resources to certain programs and therapeutic candidates; these decisions may prove to be wrong and may adversely affect our business. We have limited financial and human resources and intend to initially focus on research programs and therapeutic candidates for a limited set of indications. As a result, we may forgo or delay pursuit of opportunities with other therapeutic candidates or for

other indications that later prove to have greater commercial potential or a greater likelihood of success. In addition, we may seek to accelerate our development timelines, including by initiating certain clinical trials of our therapeutic candidates before earlier- stage studies have been completed. This approach may cause us to commit significant resources to prepare for and conduct later- stage trials for one or more therapeutic candidates that subsequently fail earlier- stage clinical testing. Therefore, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities or expend resources on therapeutic candidates that are not viable. ~~There~~ **66There** can be no assurance that we will ever be able to identify additional therapeutic opportunities for our therapeutic candidates or to develop suitable potential therapeutic candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential therapeutic candidates or other potential programs that ultimately prove to be unsuccessful. ~~68We~~ **We** may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of TTX- MC138 or any of our other therapeutic candidates in development. Clinical trials are required to apply for regulatory approval to market TTX- MC138 or any of our other therapeutic candidates. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. We do not know whether any clinical trials we begin will continue as planned, will need to be restructured or will be completed on schedule or at all. Significant clinical trial delays also could allow competitors to bring products to market before we do and could impair our ability to successfully commercialize our therapeutic candidates, any of which could materially harm our business. There is no assurance that we will not experience additional or other delays. We also may experience numerous unforeseen events during, or as a result of, any future clinical trials that could delay or prevent our ability to receive marketing approval for, or to commercialize, TTX- MC138 or any of our other therapeutic candidates in development, including: Øregulators, IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; Øthe FDA or other comparable regulatory authorities may disagree with our clinical trial design, including with respect to dosing levels administered in our planned clinical trials, which may delay or prevent us from initiating our clinical trials with our originally intended trial design; Øwe may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; Øthe number of subjects required for clinical trials of any therapeutic candidates may be larger than we anticipate, or subjects may drop out of these clinical trials or fail to return for post- treatment follow- up at a higher rate than we anticipate; Øour third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators ~~; Ødue to the impact of the COVID- 19 pandemic, we have experienced delays in our preclinical development, including access to our lab and access to our animal facility, and may continue to experience delays and interruptions to our preclinical studies and clinical trials, we may experience delays or interruptions to our manufacturing supply chain, or we could suffer delays in reaching, or we may fail to reach, agreement on acceptable terms with third- party service providers on whom we rely~~ ; Ødelays and interruptions to our clinical trials could extend the duration of the trials and increase the overall costs to finish the trials as our fixed costs are not substantially reduced during delays; Øwe may elect to, or regulators, IRBs, Data Safety Monitoring Boards, or DSMBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; Øwe may not have the financial resources available to begin and complete the planned trials, or the cost of clinical trials of any therapeutic candidates may be greater than we anticipate; Øthe supply or quality of our therapeutic candidates or other materials necessary to conduct clinical trials of our therapeutic candidates may be insufficient or inadequate to initiate or complete a given clinical trial; andØthe FDA or other comparable foreign regulatory authorities may require us to submit additional data such as long- term toxicology studies or may impose other requirements before permitting us to initiate a clinical trial. ~~69Our~~ **67Our** product development costs will increase if we experience delays in clinical trials or in obtaining marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. If we do not achieve our product development goals in the time frames we announce and expect, the approval and commercialization of our therapeutic candidates may be delayed or prevented entirely. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our therapeutic candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our therapeutic candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly. Changes in methods of therapeutic candidate manufacturing or formulation may result in additional costs or delay. As therapeutic candidates progress through preclinical to late- stage clinical trials to marketing approval and commercialization, various aspects of the development program, such as manufacturing methods and the product' s formulation, may be altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. These changes carry the risk that they will not achieve their intended objectives. Any of these changes could cause our therapeutic candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our therapeutic candidates and jeopardize our ability to commercialize our therapeutic candidates and generate revenue. In addition, there are risks associated with process development and large- scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale- up, process reproducibility, stability issues, compliance with current good manufacturing practice, or cGMP, requirements, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our therapeutic candidates, there is no assurance that our third- party manufacturers will be able to manufacture the approved

product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If our contract manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. Quality problems could delay or prevent delivery of our products to clinical trials or the market. Quality is important due to (i) the serious and costly consequences of process or product failure and (ii) it being one required element of the regulatory approval process. Receiving quality certifications is critical to the development and marketing success of our technologies. If we fail to meet existing or future quality standards, development or commercialization of our technologies could be materially and adversely affected. We are required to comply with FDA' s good clinical practice, or GCP, regulations for our clinical programs. As it relates to the manufacturing of both our drug substance and drug product, we are required to adhere to FDA' s current good manufacturing practice, or cGMP, regulations. Additionally, we must follow guidelines promulgated by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, or ICH Guidelines. The ICH Guidelines to which we are subject are ICH E6 (R2) and ICH E8 (R1), " Designing quality into clinical studies, " for all tasks related to clinical programs, and ICH Q7 for the manufacture of our drug substance and drug product. We need to implement a quality system designed to meet applicable requirements to conduct clinical trials and sell any therapeutic and diagnostic candidates for which we obtain approval in the U. S., Europe and in other countries. We cannot guarantee that our development standards, processes and procedures will meet applicable requirements for regulatory approval in any jurisdiction or that they will mitigate all of the risks associated with the development and commercialization of our therapeutic candidates. Even if we receive quality certifications, we could subsequently lose them or be required to take corrective actions if we do not continue to meet the requirements under applicable standards. If we fail to meet applicable quality requirements, it could have a material adverse effect on us. ~~70We~~ **68We** may not be successful in our efforts to identify or discover additional therapeutic candidates in the future. Our research programs may initially show promise in identifying potential therapeutic candidates, yet fail to yield therapeutic candidates for clinical development for a number of reasons, including: Øour inability to design such therapeutic candidates with the pharmacological properties that we desire or attractive pharmacokinetics; Øour inability to design and develop a suitable manufacturing process; orØpotential therapeutic candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance. Research programs to identify new therapeutic candidates require substantial technical, financial and human resources. If we are unable to identify suitable compounds for preclinical and clinical development, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price. If product liability lawsuits are brought against us, we may incur substantial financial or other liabilities and may be required to limit commercialization of our therapeutic candidates. We face an inherent risk of product liability once we begin testing TTX- MC138 and any of our other therapeutic candidates in clinical trials and will face an even greater risk if we commercialize any products. For example, we may be sued if our therapeutic candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our therapeutic candidates. Even a successful defense of these claims would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: Øinability to bring a therapeutic candidate to the market; Ødecreased demand for our products; Øinjury to our reputation; Øwithdrawal of clinical trial subjects and inability to continue clinical trials; Øinitiation of investigations by regulators; Øregulatory or IRB action resulting in a clinical trial being placed on clinical hold; Øfines, injunctions or criminal penalties; Øcosts to defend the related litigation; Ødiversion of management' s time and our resources; Øsubstantial monetary awards to trial participants; Øproduct recalls, withdrawals or labeling, marketing or promotional restrictions; ~~71Øloss~~ **69Øloss** of revenue; Øexhaustion of any available insurance and our capital resources; Øthe inability to commercialize any therapeutic candidate, if approved; andØdecline in our share price. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We will need to obtain insurance for clinical trials as TTX- MC138, and any of our other therapeutic candidates begin clinical development. However, we may be unable to obtain, or may obtain on unfavorable terms, clinical trial insurance in amounts adequate to cover any liabilities from any of our clinical trials. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. Risks related to regulatory approval, healthcare regulations and ongoing regulatory complianceWe are very early in our development efforts. Only one of our therapeutic candidates has reached clinical development. If we are unable to advance our therapeutic candidates to clinical development, obtain regulatory approval and ultimately commercialize our therapeutic candidates or experience significant delays in doing so, our business will be materially harmed. We have very limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA, and, as a company, we have no experience in obtaining approval of any product- candidate. The time required to obtain FDA and other approvals is unpredictable but typically takes one or more years following completion of clinical trials, depending upon the type, complexity and novelty of the product- candidate. We may encounter delays or rejections during any stage of regulatory review and approval process based

upon the failure of clinical or laboratory data to demonstrate compliance with, or upon the failure of a product- candidate to meet, FDA requirements for safety, efficacy and quality. The standards that the FDA and its foreign counterparts use when regulating us are not always applied predictably or uniformly and can change. Because the therapeutic candidates we are developing may represent a new class of drug, the FDA and its foreign counterparts have not yet established any definitive relevant policies, practices or guidelines in relation to these therapeutic candidates. The lack of policies, practices or guidelines may hinder or slow review by the FDA of regulatory filings that we may submit. Moreover, the FDA may respond to these submissions by defining requirements we may not have anticipated. Such responses could lead to significant delays in and added costs for the clinical development of our therapeutic candidates. Any analysis of data from preclinical and clinical activities that we perform is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. In addition, the FDA may delay, limit, or deny approval of an IND or a product- candidate for many reasons, including: Ødisagreement with the design or implementation of clinical trials; Øwe may be unable to demonstrate to the satisfaction of the FDA that a product-candidate is safe and effective for any indication; Øwe may be unable to demonstrate that a product- candidate' s clinical and other benefits outweigh its safety risks; ~~72Øthe~~ **70Øthe** FDA may disagree with our interpretation of data from manufacturing results, preclinical studies or clinical trials; Øthe results of our clinical trials may not demonstrate the safety or efficacy required by the FDA for approval; orØthe FDA may find deficiencies in our manufacturing processes or facilities; and the FDA' s approval policies or regulations may significantly change in a manner rendering our clinical data insufficient for approval. After submission of a New Drug Application, or NDA, the FDA may refuse to review the application, deny approval of the application, require additional testing or data or, if the NDA is filed and later approved, require post- marketing testing and surveillance to monitor the safety or efficacy of a product. Under the Prescription Drug User Fee Act, or PDUFA, the FDA has agreed to certain performance goals in the review of NDAs. The FDA' s timelines are flexible and subject to change based on workload and other potential review issues which may delay FDA' s review of an NDA ~~. For example, during the COVID- 19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications~~ . FDA may not be able to continue its current pace and review timelines could be extended. Further, the terms of approval of any NDA, including the product labeling, may be more restrictive than we desire which could affect the marketability of our products. Even if we comply with all FDA regulatory requirements, we may not obtain regulatory approval for any of our product- candidates. If we fail to obtain regulatory approval for any of our product-candidates, we will have no commercialized products for sale and therefore have no ability to general significant, if any, revenue. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular therapeutic candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or the labeling or other restrictions. In addition, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy, or REMS, plan as part of or after approval, which may impose further requirements or restrictions on the distribution or use of an approved product, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe- use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may limit the size of the market for the product and affect reimbursement by third- party payors. We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third- party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa. If we or any collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our products successfully and could harm our reputation and lead to reduced acceptance of our products by the market. Enforcement actions can include, among others: Øadverse regulatory inspection findings; Øwarning letters; Øvoluntary or mandatory product recalls or public notification or medical product safety alerts to healthcare professionals; Ørestrictions on, or prohibitions against, marketing our products; Ørestrictions on, or prohibitions against, importation or exportation of our products; Øsuspension of review or refusal to approve pending applications or supplements to approved applications; ~~73Øexclusion~~ -- **Øexclusion** from participation in government- funded healthcare programs; ~~Øexclusion~~ **71Øexclusion** from eligibility for the award of government contracts for our products; Øsuspension or withdrawal of product approvals; Øproduct seizures; Øinjunctions; andØcivil and criminal penalties and fines. In addition, if any of our products cause serious or unexpected side effects or are associated with other safety risks after receiving marketing approval, a number of potential significant negative consequences could result, including: Øregulatory authorities may withdraw their approval of the product; Øwe may be required to recall the product, change the way it is administered, conduct additional clinical trials or change the labeling of the product; Øthe product may be rendered less competitive and sales may decrease; Ølitigation or class action lawsuits; Øour reputation may suffer generally both among clinicians and patients; orØregulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use or impose restrictions on distribution in the form of a REMS in connection with approval, if any. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants or if preliminary data demonstrate that our products are unlikely to receive regulatory approval or unlikely to be successfully commercialized. We have received Orphan

Drug Designations for TTX- **MC138** ~~siPDL1 for pancreatic cancer~~ and TTX- ~~MC138~~ **siPDL1** for pancreatic cancer, and may in the future seek Orphan Drug Designation for TTX- MC138 in other indications and for some of our other current and future therapeutic candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced. Under the Orphan Drug Act, the FDA may grant orphan designation to a therapeutic candidate or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200, 000 in the United States, or a patient population greater than 200, 000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan Drug Designation must be requested before submitting an NDA. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user- fee waivers. After the FDA grants Orphan Drug Designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. ~~74If~~ **If** a therapeutic candidate that has obtained Orphan Drug Designation subsequently receives the first FDA approval for a particular active ingredient for the disease 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, including an NDA, to market the same biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with Orphan Drug Exclusivity or if the FDA finds that the holder of the Orphan Drug Exclusivity has not shown it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our therapeutic candidates receives Orphan Drug Exclusivity, the FDA can still approve other drugs that have a different active ~~ingredient~~ **72ingredient** for use in treating the same indication or disease. Furthermore, the FDA can waive Orphan Drug Exclusivity if we are unable to manufacture sufficient supply of the approved product. We have received two Orphan Drug Designations in the U. S. and may pursue additional Designations for other current or future therapeutic candidates in additional orphan indications in which there is a medically plausible basis for the use of these products. Even when we obtain Orphan Drug Designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we intend to seek Orphan Drug Designation for other therapeutic candidates, we may never receive such designations. For example, the FDA has expressed concerns regarding the regulatory considerations for Orphan Drug Designation as applied to tissue agnostic therapies, and the FDA may interpret the Federal Food, Drug and Cosmetic Act, or FD & C Act, and regulations promulgated thereunder in a way that limits or blocks our ability to obtain Orphan Drug Designation or Orphan Drug Exclusivity, if our therapeutic candidates are approved, for our targeted indications. On August 3, 2017, Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified FDA' s pre- existing regulatory interpretation to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive Orphan Drug Exclusivity. The legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. Moreover, in the Consolidated Appropriations Act of 2021, Congress did not further change this interpretation when it clarified that the interpretation codified in FDARA would apply in cases where FDA issued an orphan designation before the enactment of FDARA, but where product approval came after the enactment of FDARA. FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how FDA may change orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. A Breakthrough Therapy designation by FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval. We may seek Breakthrough Therapy designation for some or all of our current and future product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life- threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic 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 product candidates that have been designated as breakthrough therapies, interaction and communication between FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by FDA may also be eligible for other expedited approval programs, including Accelerated Approval. ~~75Designation~~ -- **Designation** as a breakthrough therapy is within the discretion of FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to candidate products considered for approval under non- expedited FDA review procedures and does not assure ultimate approval by FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we intend to seek Breakthrough Therapy designation for some or all of our current and future product candidates, there can be no assurance that we will receive Breakthrough Therapy designation. ~~A~~ **73A** Fast Track designation by the FDA, even if granted for any of 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. 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 drug sponsor may apply for FDA Fast Track designation for a particular indication. We may seek Fast Track designation for some or all of our current and future product candidates, but there is no assurance that the FDA will grant this status to any of our current or future product candidates. Marketing applications filed by sponsors of products in Fast Track development may qualify for Priority Review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance 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, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time. Accelerated approval by FDA, even if granted for TTX- MC138 or any other future therapeutic candidate, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our therapeutic candidates will receive marketing approval. We may seek approval of TTX- MC138 and may seek approval of future therapeutic candidates using the FDA' s accelerated approval pathway. A therapeutic candidate may be eligible for accelerated approval if it treats a serious or life- threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well- controlled post- marketing clinical trials. These confirmatory trials must be completed with due diligence. In addition, unless it determines otherwise, FDA currently requires pre- approval of promotional materials for products receiving accelerated approval, which could adversely affect the timing of the commercial launch of the product. Thus, even if we seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval and, even if we do, we may not experience a faster development, regulatory review or approval process for that therapeutic candidate. In addition, receiving accelerated approval does not assure that the product' s accelerated approval will eventually be converted to a traditional approval. A variety of factors, including inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of 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, accept payments of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result of these and other factors. In particular, it has been reported that FDA' s planned expansion of its oncology division is delayed. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. ~~76Disruptions~~ -- **Disruptions** at FDA and other agencies may also slow the time necessary for new therapeutic candidates to be reviewed and / or approved by necessary government agencies, which would 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 FDA and the SEC, have had to furlough critical employees and stop critical activities ~~. Separately, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold in connection with the COVID- 19 pandemic, FDA has been working to resume pre- pandemic levels of inspections, including routine surveillance, bioresearch monitoring and pre- approval inspections on a prioritized basis~~ . Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel or for other reasons, and FDA does not determine that a remote interactive evaluation will be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. ~~During the COVID- 19 public health emergency, a number of companies announced receipt of complete response letters due to FDA' s inability to complete required inspections for their applications.~~ Regulatory authorities outside the U. S. may adopt similar restrictions or other policy measures in response to a pandemic and may experience delays in their regulatory activities. ~~If~~ **74If** a prolonged government shutdown occurs, or if global health concerns prevent FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Even if we receive regulatory approval of TTX- MC138 or any of our other therapeutic candidates, we will be subject to ongoing regulatory requirements and continued regulatory review, which may result in significant additional expense. We may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our therapeutic candidates. Any regulatory approvals that we receive for TTX- MC138 or another product- candidate may require post- marketing surveillance to monitor the safety and efficacy of the product and may require us to conduct post- approval clinical studies. The FDA may also require a REMS in order to approve our therapeutic candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our therapeutic candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our therapeutic candidates will be subject to extensive and ongoing regulatory requirements. These requirements can include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with cGMP and GCP, for any clinical trials that we conduct post- approval and

applicable product tracking and tracing requirements. Compliance with ongoing and changing requirements takes substantial resources and, should we be unable to remain in compliance, our business could be materially and adversely affected. In addition, if we pursue, and ultimately obtain, accelerated approval of TTX- MC138 based on a surrogate endpoint, the FDA would require us to conduct a confirmatory trial to verify the predicted clinical benefit as well as additional safety studies. The results from the confirmatory trial may not support the clinical benefit, which would result in the approval being withdrawn. Manufacturers and their facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control. ~~77Any~~ -- **Any** regulatory approvals that we receive for our therapeutic candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the therapeutic candidate. The FDA may also require a REMS as a condition of approval of our therapeutic candidates, which could entail requirements for long- term patient follow- up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our therapeutic candidates, we will have to comply with requirements including submissions of safety and other post- marketing information and reports and registration. Later discovery of previously unknown problems with our therapeutic candidates, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, or the making of unsupported claims, may result in revisions to the approved labeling to add new safety information; imposition of post- market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things: Ørestrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or product recalls; Øfines, warning letters or holds on clinical trials; Ørefusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or withdrawal of approvals; ~~Øproduct~~ **75Øproduct** seizure or detention or refusal to permit the import or export of our therapeutic candidates; andØconsent decrees or injunctions or the imposition of civil or criminal penalties. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is not inconsistent with the labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses and a company that is found to have improperly promoted off- label uses may be subject to significant liability. The policies of the FDA and of other regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our therapeutic candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. We may develop, or enter into a collaboration or partnership to develop, in vitro diagnostics, including potentially complementary diagnostics and / or companion diagnostics, for our current or future therapeutic candidates. If we, or our future collaborators, are unable to successfully develop such diagnostics, or experience significant delays in doing so, we may not realize the full commercial potential of our future therapeutic candidates. We have little experience in the development of in vitro diagnostics and, as such, we may rely on future collaborators in developing appropriate in vitro diagnostics to pair with our current or future therapeutic candidates. We have not yet begun discussions with any potential partners with respect to the development of complementary diagnostics and / or companion diagnostics and may be unsuccessful in entering into collaborations for the development of any complementary and / or companion diagnostics for our programs and our current or future therapeutic candidates. In vitro diagnostics are subject to regulation by the FDA and similar regulatory authorities outside the United States as medical devices and require separate regulatory approval or clearance prior to commercialization. If we, our collaborators, or any third- parties that we engage to assist us, are unable to successfully develop complementary diagnostics and / or companion diagnostics for our therapeutic candidates and any future therapeutic candidates, or experience delays in doing so: Øthe development of our therapeutic candidates and any other future therapeutic candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials; ~~and78Øwe~~ -- **andØwe** may not realize the full commercial potential of our therapeutic candidates and any other future therapeutic candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify, or it takes us longer to identify, patients who are likely to benefit from therapy with our products, if approved. If any of these events were to occur, our business would be harmed, possibly materially. ~~Our~~ **76Our** relationships with customers and third- party payors will be subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings. Although we do not currently have any drugs on the market, if we begin commercializing our current or future therapeutic candidates, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and third- party payors play a primary role in the recommendation and prescription of any current or future therapeutic candidates for which we obtain marketing approval. Our future arrangements with 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

market, sell and distribute our current or future therapeutic candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following: Øthe 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 either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. The Anti- Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other hand. The term remuneration has been interpreted broadly to include anything of value. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; Øthe federal False Claims Act imposes criminal and civil penalties, including through civil whistle- blower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to " cause " the submission of false or fraudulent claims. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties. Government enforcement agencies and private whistle- blowers have investigated pharmaceutical companies for or asserted liability under the False Claims Act for a variety of alleged promotional and marketing activities, such as providing free products to customers with the expectation that the customers would bill federal programs for the products; providing consulting fees and other benefits to physicians to induce them to prescribe products; engaging in promotion for " off- label " uses; and submitting inflated best price information to the Medicaid Rebate Program. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti- Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act; Øthe federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; ~~79Øthe~~ -- **Øthe** federal physician payment transparency requirements, sometimes referred to as the " Sunshine Act " under the ACA require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children' s Health Insurance Program to report to the Department of Health and Human Services information related to physician payments and other transfers of value and the ownership and investment interests of such physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non- physician providers such as physician assistants and nurse practitioners; ØHIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, ~~security~~ **77security** and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions; andØanalogous state laws and regulations, such as state anti- kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not pre- empted by HIPAA, thus complicating compliance efforts. Ensuring that our future business arrangements with third- parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do 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, including anticipated activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Obtaining and maintaining regulatory approval for our therapeutic candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval for that or of any of our other therapeutic candidates in other jurisdictions. Obtaining and maintaining regulatory approval for our therapeutic candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval for TTX- MC138, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product- candidate in those countries. Approval procedures vary among

jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as preclinical studies and clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product- candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we charge for our product is also subject to regulatory approval. ~~80We~~ **We** may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of therapeutic candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and / or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our therapeutic candidates will be harmed. Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, **(1)** changes to our manufacturing **and supply** arrangements; **(2)** additions or modifications to product labeling; **(3)** the recall or discontinuation of our products; **(4) modifications to pricing and costs;** or **(5)** additional record- keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. ~~In~~ **See the section titled " Business- Current and Future Healthcare Reform Legislation. " 78In** the United States, there have been and likely will continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U. S. biotechnology and biopharmaceutical industries. The ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70 % point- of- sale discounts from the negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D. Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. On December 14, 2018, a U. S. District Court Judge in Texas ruled that the ACA is unconstitutional in its entirety because the " individual mandate " was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U. S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U. S. Supreme Court granted the petitions for writs of certiorari to review this case. On June 17, 2021, the Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business. In addition, the ~~former~~ **then** Trump administration issued various Executive Orders which eliminated cost sharing subsidies and included provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Additionally, Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. On December 20, 2019, ~~former~~ **then** President Trump signed into law the Further Consolidated Appropriations Act (H. R. 1865), which repealed the so called " Cadillac " tax, the health insurance provider tax, and the medical device excise tax. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business. ~~81Other~~ -- **Other** legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation' s automatic reduction to several government programs, including aggregate reductions of Medicare payments to providers of 2 % per fiscal year. These reductions went into effect on April 1, 2013, and subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, or BBA, will remain in effect through 2030, unless additional congressional action is taken ~~. However, these Medicare sequester reductions were suspended from May 1, 2020, through December 31, 2020, due to the COVID- 19 pandemic~~ . The BBA also amended the ACA, effective January 1, 2019, by increasing the point- of- sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the " donut hole. " On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Moreover, increasing efforts by governmental and third- party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our therapeutic candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies

for drugs. **On** ~~At the federal level, the former Trump administration' s budget for fiscal year 2021 included a $ 135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out- of- pocket drug costs for patients, and increase patient access to lower- cost generic and biosimilar drugs. 82On~~ March 10, 2020, the ~~former~~ **then** Trump administration sent " principles " for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out- of- pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out- of- pocket expenses, and place limits on pharmaceutical price increases. The ~~former~~ **then** Trump administration previously released a " Blueprint " to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers ~~to~~ **79to** lower the list price of their products and reduce the out- of- pocket costs of drug products paid by consumers. The U. S. Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule that would allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS' s policy change that was effective January 1, 2019. On July 24, 2020, ~~former~~ **then** President Trump signed four Executive Orders aimed at lowering drug prices. The Executive Orders direct the Secretary of HHS to: (1) eliminate protection under an AKS safe harbor for certain retrospective price reductions provided by drug manufacturers to sponsors of Medicare Part D plans or pharmacy benefit managers that are not applied at the point- of- sale; (2) allow the importation of certain drugs from other countries through individual waivers, permit the re- importation of insulin products, and prioritize finalization of the proposed rule to permit the importation of drugs from Canada; (3) ensure that payment by the Medicare program for certain Medicare Part B drugs is not higher than the payment by other comparable countries (depending on whether pharmaceutical manufacturers agree to other measures); and (4) require Federally Qualified Health Centers, or FQHCs, participating in the 340B drug program to provide insulin and injectable epinephrine to certain low- income individuals at the discounted price paid by the FQHC, plus a minimal administrative fee. On October 1, 2020, the FDA issued the final rule allowing importation of certain prescription drugs from Canada. On August 6, 2020, ~~former~~ **then** President Trump signed an additional Executive Order directing U. S. government agencies to encourage the domestic procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs, which include among other things, active pharmaceutical ingredients and drugs intended for use in the diagnosis, cure, mitigation, treatment, or prevention of COVID- 19. The FDA has been directed to release a full list of Essential Medicines, Medical Countermeasures, and Critical Inputs affected by this Order by November 5, 2020. On September 13, 2020, ~~former~~ **then** President Trump signed an Executive Order directing HHS to implement a rulemaking plan to test a payment model, pursuant to which Medicare would pay, for certain high- cost prescription drugs and biological products covered by Medicare Part B, no more than the most- favored- nation price (i. e., the lowest price) after adjustments, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organization for Economic Cooperation and Development that has a comparable per- capita gross domestic product. Although a number of these and other measures may require additional authorization to become effective, Congress **at the time** and **the** ~~the~~ **then** Trump administration have each indicated that it will continue to seek new legislative and / or administrative measures to control drug costs. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. Additionally, on July 9, 2021, **then** President Biden issued an executive order directing the FDA to, among other things, continue to clarify and improve the approval framework for generic drugs and identify and address any efforts to impede generic drug competition. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing **. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product and any future products or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations and prospects** . These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our therapeutic candidates for which we may obtain regulatory approval or the frequency with which any such therapeutic candidate is prescribed or used. Additionally, we expect to experience pricing pressures in connection with the sale of any future approved therapeutic candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes. ~~83We~~ **We** are subject to certain U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations. Among other matters, U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, ~~soliciting~~ **80soliciting** , or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We plan to engage third- parties for clinical trials and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals, and we could be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we

do not explicitly authorize or have prior knowledge of such activities. Healthcare reform in the U. S. and other countries may materially and adversely affect us. In the U. S. and in many foreign jurisdictions, the legislative landscape continues to evolve. Our revenue prospects could be affected by changes in healthcare spending and policies in our target markets. We operate in a highly regulated industry and new laws or judicial decisions, or new interpretations of existing laws or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could materially and adversely affect us. There is significant interest in promoting healthcare reform, as evidenced by the enactment in the U. S. of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act in 2010, or together, the ACA. It is likely that many governments will continue to consider new healthcare legislation or changes to existing legislation. We cannot predict the initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified, or how they may affect us. The continuing efforts of governments, insurance companies, managed care organizations and other third- party payors to contain or reduce healthcare costs may adversely affect: Øthe demand for any products for which we may obtain regulatory approval; Øour ability to set a price that we believe is fair for our products; Øour ability to generate revenues and achieve or maintain profitability; andØthe level of taxes that we are required to pay. Under the ACA, there are many programs and requirements for which details or consequences are still not fully understood. We are unable to predict what healthcare programs and regulations will ultimately be implemented at any level of government in or outside the U. S., but any changes that decrease reimbursement for our approved products, reduce volumes of medical procedures or impose new cost- containment measures could adversely affect us. Prescription Drug Pricing Reduction ActOn August 16, 2022, the Inflation Reduction Act of 2022 was passed, which among other things, allows for CMS to negotiate prices for certain single- source drugs and biologics reimbursed under Medicare Part B and Part D, beginning with ten high- cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. The legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated " maximum fair price " under the law or for taking price increases that exceed inflation. The legislation also caps Medicare beneficiaries' annual out- of- pocket drug expenses at $ 2, 000. The effect of Inflation Reduction Act of 2022 on our business and the healthcare industry in general is not yet known. ~~84We~~ **We** are subject to geopolitical risks, economic volatility, anti- corruption laws, export and import restrictions, local regulatory authorities and the laws and medical practices in foreign jurisdictions. The costs of healthcare internationally have risen significantly over the past decade. Numerous initiatives and reform by legislators, regulators and third- party payers to curb these costs have reduced reimbursement rates. One outcome of these dynamics is that hospitals and others are consolidating into larger integrated delivery networks and group purchasing organizations in an effort to reduce administrative costs and increase purchasing power. This consolidation has resulted in greater pricing pressure on suppliers, decreased average selling prices and changes in medical practices. If we secure marketing approval for our therapeutic candidates, our ~~commercial~~ **81commercial** success will be determined by, among other things, our ability to obtain acceptable pricing for approved products which will be subject to, among other things, the factors described above. The expansion of group purchasing organizations, integrated delivery networks and large single accounts among hospitals could also put price pressure on our approved products. We expect that market demand, government regulation, third- party reimbursement policies, government contracting requirements and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers and competitors. The result may be further downward pressure on the prices we are able to obtain, thus adversely affecting us. Even if we obtain regulatory approval of our therapeutic candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community. Risks related to commercializationWe currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third- parties to market and sell any products for which we obtain regulatory approval, we may not be able to generate product revenue. We have no sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our therapeutic candidates ultimately receives regulatory approval, we expect to establish a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming. We have no prior experience as a company in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may also choose to collaborate with third- parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of building our own sales force and distribution systems. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third- parties for these functions than if we were to market, sell and distribute any products that we develop and for which we receive regulatory approval ourselves. We likely will have little control over such third- parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third- parties, we may not be able to generate any future product revenue and we would incur significant additional losses. Coverage and reimbursement may be limited or unavailable in certain market segments for our therapeutic candidates, if approved, which could make it difficult for us to sell any therapeutic candidates profitably. In the United States and in other countries, patients who are prescribed treatment for their conditions generally rely on third- party payors to reimburse all or part

of the costs associated with their treatment. ~~85Significant~~ -- **Significant** uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any products for which we may receive regulatory marketing approval will depend, in part, on the availability of coverage and reimbursement from third-party payors. Third- party payors include government authorities such as Medicare, Medicaid, TRICARE, and the Veterans Administration, managed care providers, private health insurers, and other organizations. Patients who are provided medical treatment for their conditions generally rely on third- party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use our therapeutic candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our therapeutic candidates or assure that coverage and reimbursement will be available for any product that we may develop. ~~Government~~ **82Government** authorities and other third- party payors decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third- party payor may depend upon a number of factors, including the third- party payor' s determination that use of a product is: Øa covered benefit under its health plan; Øsafe, effective and medically necessary; Øappropriate for the specific patient; Øcost- effective; andØneither experimental nor investigational. Our ability to commercialize any products successfully will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third- party payors, including government health care programs and private health insurers. Moreover, a payor' s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our therapeutic candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors. Therefore, coverage and reimbursement for our products can differ significantly from payor to payor. As a result, obtaining coverage and reimbursement approval of a product from a government or other third- party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost- effectiveness data for the use of our products on a payor- by- payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co- payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long- term follow- up evaluations required following the use of therapeutic candidates, once approved. It is difficult to predict at this time what third- party payors will decide with respect to the coverage and reimbursement for our therapeutic candidates, if approved. ~~86The~~ -- **The** Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug and biologic benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs and biologics. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs and biologics, and each drug plan can develop its own formulary that identifies which drugs and biologics it will cover, and at what tier or level. However, Part D prescription drug formularies must include products within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs and biologics in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs and biologics may increase demand for products for which we obtain marketing approval. Any negotiated prices for any of our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non- governmental payors. For a drug or biologic product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U. S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the average manufacturer price, or AMP, and Medicaid rebate amounts reported by the manufacturer. As of 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, expanded the types of entities eligible to receive ~~discounted~~ **83discounted** 340B pricing, although under the current state of the law these newly eligible entities (with the exception of children' s hospitals) will not be eligible to receive discounted 340B pricing on orphan drugs. As the required 340B discount is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. The Centers for Medicare & Medicaid Services, or CMS, has previously and may in the future implement reductions in Medicare Part B reimbursement for 340B drugs through notice and comment rulemaking. It is unclear how such reimbursement reductions could affect covered hospitals who might purchase our products in the future, and affect the rates we may charge such facilities for our approved products. Changes to these current laws and state and federal healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any therapeutic candidates for which we may obtain regulatory approval or the frequency with which any such therapeutic candidate is prescribed or used. We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. The development and commercialization of new oncology drug products is highly competitive. We may face competition with respect to any therapeutic candidates that we seek to develop or commercialize in the future from major

biotechnology and biopharmaceutical companies, specialty biotechnology and biopharmaceutical companies, and other biotechnology and biopharmaceutical companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization. ~~87Not~~ -- **Not** only must we compete with other companies that are focused on therapeutics that treat cancer, but also any therapeutic candidates that we successfully develop and commercialize will compete with existing and new therapies that may become available in the future. Our competitors may develop more successful products similar to ours sooner than we can commercialize ours, which may negatively impact our results. Companies that we are aware of with targeted therapeutics in the treatment of various cancers include Ionis, Moderna, Alnylam, BioNTech, Dicerna, Siranomics, among others which have therapeutic candidates in various stages of preclinical and clinical developments. Arrowhead Pharmaceuticals is a clinical stage company with a pipeline of investigational RNAi therapeutics. However, we know of no other companies currently in clinical development with miRNA therapeutics targeting metastatic disease. For additional information regarding our competition, see " Business- Competition. " Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, more convenient, or less expensive than any products that we may develop. Furthermore, products currently approved for other indications could be discovered to be effective treatments of the biological processes that drive cancers as well, which could give such products significant regulatory and market timing advantages over TTX- MC138 or other therapeutic candidates that we may identify. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we do, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential therapeutic candidates uneconomical or obsolete and we may not be successful in marketing any therapeutic candidates we may develop against competitors. The availability of competitive products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize. ~~If~~ **84If** , in the future, we are unable to establish sales and marketing and patient support capabilities or enter into agreements with third- parties to sell and market our current or future therapeutic candidates, we may not be successful in commercializing our current or future therapeutic candidates if and when they are approved, and we may not be able to generate any revenue. We do not currently have a sales or marketing infrastructure and have no experience in the sales, marketing, patient support or distribution of drugs. We currently intend to partner with a larger commercial organization to market any of our therapeutic candidates, if approved, though our intentions may change in the future. To achieve commercial success for any approved therapeutic candidate for which we retain sales and marketing responsibilities, we must build our sales, marketing, patient support, managerial and other non- technical capabilities or make arrangements with third- parties to perform these services. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our current or future therapeutic candidates if and when they are approved. There are risks involved with both establishing our own sales and marketing and patient support capabilities and entering into arrangements with third- parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any drug launch. If the commercial launch of a therapeutic 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. This may 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 current or future therapeutic candidates on our own include: Øour inability to recruit and retain adequate numbers of effective sales and marketing personnel; Øthe inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future drugs, if approved; ~~88Øthe~~ -- **Øthe** lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; andØunforeseen costs and expenses associated with creating an independent sales and marketing organization. If we enter into arrangements with third- parties to perform sales, marketing, patient support and distribution services, our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any current or future therapeutic candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third- parties to sell and market our current or future therapeutic candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third- parties, and any of them may fail to devote the necessary resources and attention to sell and market our current or future therapeutic candidates effectively. 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 our current or future therapeutic candidates. Further, our business, results of operations, financial condition and prospects will be materially adversely affected. Sales of our products may involve a lengthy sales cycle. Many factors are expected to influence the sales cycle for our approved products. These factors include the future state of the market, the perceived value of our therapeutic candidates, the evolution of competing technologies, insurance coverage or prior authorization requirements and changes in medical practices. Any of these may adversely affect our sales cycles and the rate of market acceptance of our approved products. ~~Risks~~ **85Risks** related to third- parties and suppliersWe expect to rely on third- party manufacturing and supply vendors, and our supply of research and

development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality. We have very limited manufacturing facilities and personnel. We currently rely, and expect to continue to rely, primarily on third- parties for the manufacture of TTX- MC138 and any future potential therapeutic candidates that we may develop. There can be no assurance that our preclinical and clinical development product supplies will not be limited or interrupted, or that they will be of satisfactory quality or continue to be available at acceptable prices ~~. For example, the extent to which the COVID- 19 pandemic impacts our ability to procure sufficient supplies for the development of our therapeutic candidates will depend on the severity and duration of the spread of the virus and the actions undertaken to contain COVID- 19 or treat its effects. Since the beginning of the COVID- 19 pandemic, several vaccines for COVID- 19 have received Emergency Use Authorization by the FDA, some of which later received marketing approval. Additional vaccines may be authorized or approved in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials~~ . Any replacement of our manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements. We may be unable to establish additional agreements, or extend existing agreements, with third- party manufacturers or to do so on terms acceptable to us. Even if we are able to establish agreements with third- party manufacturers, reliance on third- party manufacturers entails additional risks, including: Øreliance on the third- party for sufficient quantity and quality at acceptable costs which could delay, prevent or impair our development or commercialization efforts; Øthe possible breach of the manufacturing agreement by the third- party; Øfailure to meet our manufacturing specifications; Øfailure to meet our manufacturing schedule; Ømisappropriation of our proprietary information, including our trade secrets and know- how; ~~89Øthe~~ -- **Øthe** possible termination or nonrenewal of the agreement by the third- party at a time that is costly or inconvenient for us; Ødisruptions to the operations of our manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of a manufacturer or supplier; andØreliance on the third- party for regulatory compliance, quality assurance and safety reporting. Our reliance on others for our manufacturing will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all applicable regulations regarding manufacturing. Our therapeutic candidates and any products that we may develop may compete for access to manufacturing facilities with other therapeutic candidates and products. There are a limited number of manufacturers that operate in accordance with cGMP regulations that might be capable of manufacturing for us which could restrict our ability to supply products and, as a result, have a material adverse effect on us. Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or could otherwise adversely affect our ability to commercialize our approved products. Some of these events could be the basis for costly FDA action, including injunction, recall, seizure or total or partial suspension of production. We will have limited control over the day- to- day manufacturing and quality operations of our contract manufacturers. While we intend to ensure vendor management oversight and exercise commercially reasonable efforts to oversee operations and embed our quality system standards and controls in our manufacturing agreements, we will remain subject to the performance of our contract manufacturers. We will be dependent on our suppliers for proper oversight and control of their operations while we will be deemed the responsible party. Our outside manufacturers may themselves rely on other parties that they do not control. Our suppliers might fail to obtain, or experience delays in obtaining, regulatory approvals applicable to the aspects of their business that pertains to us. As a result, the development and commercialization of our products may be delayed. If this occurs, we may need to identify alternative sources of supply which may not be feasible, or which may adversely affect our timelines and financial results. Our dependence upon others for the manufacture of our therapeutic candidates or products may adversely affect our ability to commercialize any products that receive marketing approval on a timely and competitive basis. Thus, our current and anticipated ~~future~~ **86future** dependence upon others for manufacturing may adversely affect our timelines, our future profit margins or our ability to commercialize any therapeutic candidates that receive marketing approval on a timely and competitive basis. We rely on third- parties to conduct certain aspects of our preclinical studies and clinical trials. If these third- parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential therapeutic candidates. We depend, or may depend in the future, upon third- parties to conduct certain aspects of our preclinical studies and clinical trials, under agreements with universities, medical institutions, CROs, strategic collaborators and others. We expect to have to negotiate budgets and contracts with such third- parties, which may result in delays to our development timelines and increased costs. We will rely especially heavily on universities, medical institutions, CROs and other third- parties for the conduct of our clinical trials. While we are obligated to ensure compliance by third- parties with clinical trial protocols and other aspects of our clinical trials, and to have mechanisms in place to monitor our clinical trials, the sites at which they are conducted, and the investigators and other personnel involved in our clinical trials, we have limited control over these entities and individuals and limited visibility into their day- to- day activities, including with respect to their compliance with the approved clinical protocol. Our reliance on third- parties does not relieve us of our regulatory responsibilities for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. We and these third- parties are required to comply with GCP requirements for therapeutic candidates in clinical development. Regulatory authorities enforce GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third- parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with GCP requirements. ~~90Our~~ -- **Our** failure or any failure by these third- parties to comply with these regulations or to recruit a sufficient number of patients meeting requirements for enrollment in the trial may require us to repeat clinical trials, which would delay the regulatory

approval process. Moreover, our business may be implicated if any of these third- parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. Any third- parties conducting aspects of our preclinical studies or clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third- parties, we cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical programs. These third- parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other therapeutic development activities, which could affect their performance on our behalf. If these third- parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons or if, due to federal or state orders ~~or absenteeism due to the COVID- 19 pandemic,~~ they are unable to meet their contractual and regulatory obligations, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our therapeutic candidates. As a result, our financial results and the commercial prospects for our therapeutic candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. If any of our relationships with these third- party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third- parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. ~~Parties~~ **87Parties** conducting some or all of our product manufacturing may not perform satisfactorily. Outside manufacturers may not be able to or may not comply with cGMP regulations or similar regulatory requirements outside the U. S. Our failure, or the failure of our manufacturers, to comply with applicable regulations could delay clinical development or marketing approval or result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of therapeutic candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. We may not have arrangements for redundant supply or a second source for key materials, components or our products and therapeutic candidates. If our contract manufacturers cannot perform as expected, we may be required to replace such manufacturers. There may be only a small number of potential alternative manufacturers who could manufacture our therapeutic candidates. We may incur added costs and delays in identifying, gaining access to and qualifying any such replacement. We are highly dependent on others to provide services for certain core aspects of our business. To conserve financial resources, we utilize consultants, advisors and other parties for certain functions including regulatory affairs, clinical trials, medical practice issues, product management and human resources. If other parties are not available to provide services through completion of our programs at the time we require their services, or if the expertise we require is not readily available, the development and commercialization of our therapeutic candidates may be delayed. ~~91If~~ **If** our third- party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages. Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials, by our third- party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the U. S. governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations. We may not be successful in establishing and maintaining strategic partnerships, which could adversely affect our ability to develop and commercialize products. A part of our strategy is to seek, evaluate and, when strategically attractive, enter into development and commercial partnerships. Potential partners may include larger medical products companies. These potential partners often have their own internal development programs and priorities which may be a potential source of competition for our therapeutic candidates. We must develop technologies of value and then demonstrate the value of our technologies and therapeutic candidates if we are to be successful in arranging strategic partnerships on terms that will be attractive. There are no assurances that we will succeed in arranging any partnerships. Identifying appropriate partners for our therapeutic candidates and the negotiation process is lengthy, time- consuming and complex and we have limited resources to do this. In order for us to successfully partner our therapeutic candidates, potential partners must view these therapeutic candidates as economically and technologically valuable with features or benefits that are superior to existing products or therapeutic candidates in development. We may not be able to maintain such strategic partnerships if, for example, development or approval of a product is delayed or sales of an approved product are disappointing. Any delay in entering into strategic partnership agreements related to our therapeutic candidates could delay their development and commercialization and reduce their competitiveness even if they reach the market. In addition, strategic partners may not perform as we expect or may breach their agreements with us. We may not be able to adequately protect our rights under these agreements and attempting to do so is likely to be time- consuming and expensive. ~~Furthermore~~ **88Furthermore** , our strategic partners will likely seek to control certain decisions regarding the development and commercialization of our therapeutic candidates and may not conduct

those activities in the manner or time we would like. If we fail to establish and maintain strategic partnerships related to our therapeutic candidates, we will bear all of the risk and costs related to the development and commercialization of our therapeutic candidates. This may require us to seek additional financing, hire additional employees and otherwise develop expertise which we do not have. These factors could materially and adversely affect the development or commercial success of any product-candidate for which we do not arrange a strategic partnership. ~~92Risks --~~ **Risks** related to managing our business and operationsWe face risks related to health epidemics, pandemics and other widespread outbreaks of contagious disease, including a pandemic, which could significantly disrupt our operations, impact our financial results or otherwise adversely affect our business. Significant outbreaks of contagious diseases and other adverse public health developments could have a material adverse effect on our business operations and operating results. ~~For example, the spread of COVID has had, and identification of new variants of COVID- 19 could have, an adverse effect on segments of the global economy and our operations. As a result of the COVID- 19 pandemic or similar public health crises that may arise, we may experience disruptions that could adversely affect our operations, research and development, preclinical studies, clinical trials and manufacturing activities we may conduct~~ , some of which may include: Ødelays or difficulties in commencing enrollment of patients in our planned clinical trials; Øthe impact from potential delays, including potential difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff; Ødiversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials; Øinterruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures that are deemed non- essential, which may impact the integrity of subject data and clinical trial endpoints; Øinterruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines; Øinterruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems; Øinterruptions in preclinical studies due to restricted or limited operations at our laboratory facility; Ølimitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; andØinterruption or delays to our sourced discovery and clinical activities. In March 2021, we moved our laboratory operations to facilities leased from the Massachusetts Biomedical Initiatives, Inc., or MBI, in Worcester, Massachusetts. In December 2022, we signed a two- year sublease for office and lab space in Newton, Massachusetts, which commenced February 1, 2023. ~~This~~ **The Newton sublease terminated January 31, 2025. We have moved our R & D operations to space at Michigan State University, or MSU, with which we are negotiating a sponsored research agreement. We moved our business operations into** new space **in Woburn,** ~~allows both lab personnel and the rest of our~~ Massachusetts **, under a short-** ~~team~~ **term arrangement** ~~to be housed in one location~~ . While we believe we will have sufficient access to ~~the Newton facility~~ **our R & D space at MSU** , there is no assurance that this will be the case. Should access to **this** ~~the Newton~~ facility be limited, or should other ~~pandemic- related~~ restrictions be imposed, our development work would be further adversely affected. The extent of such adverse effects will depend on future developments which are highly uncertain and cannot be predicted. In addition, the ~~Newton~~ **MSU** facilities may not meet all our requirements. ~~The~~ **89The** extent to which ~~the COVID- 19 pandemic or other~~ health problems **may** ultimately affect our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. ~~93We~~ **We** will need to grow the size of our organization, and we may experience difficulties in managing this growth. As of ~~March 20~~ **April 11** , ~~2024~~ **2025** , we had ~~10~~ **seven** employees ~~including three with Ph. D.' s~~ . We also utilize various outside companies and individuals under consulting or other arrangements to support our operations. As our clinical development and commercialization plans and strategies develop, and as we continue to operate as a public company, we expect to need additional human resources in areas including management, clinical and regulatory, manufacturing, research, medical, sales, marketing, financial, and other. Future growth would impose significant added responsibilities on members of management, including: Ørecruiting, integrating, retaining and motivating additional employees; Ømanaging our development efforts effectively, including the clinical, manufacturing and quality review process for our therapeutic candidates, while complying with our contractual obligations to contractors, collaboration partners and other third- parties; andØimproving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to commercialize our therapeutic candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day- to- day activities in order to devote a substantial amount of time to managing these growth activities. We currently rely, and for the foreseeable future will continue to rely, in substantial part on third- parties, including independent organizations, advisors and consultants, to provide certain services to support and perform our operations. There can be no assurance that the services of these third- parties will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality, accuracy or quantity of the services provided is compromised for any reason, our clinical trials may be delayed or terminated, and we may not be able to obtain, or may be substantially delayed in obtaining, regulatory approval of our therapeutic candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other suitable outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully execute the tasks necessary to further develop and commercialize our therapeutic candidates and, accordingly, may not achieve our development and commercialization goals. Our

future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. Our ability to compete in the highly competitive oncology industry depends upon our ability to attract and retain highly qualified managerial, scientific and operations personnel. We are dependent on our management, scientific and medical personnel and advisors, including our ~~Executive~~ Chairman, Philippe Calais, PhD; our interim CEO, CFO, Principal Financial Officer and director, Thomas A. Fitzgerald; our co- founder and Chief Scientific Officer, Dr. Zdravka Medarova; our co- founder and advisor, Dr. Anna Moore; our board of directors and members of our scientific and business advisory boards as well as our many consultants. The loss of the services of any of these individuals or entities, and our inability to find suitable replacements, could result in delays in product development and materially harm our business. Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain ~~regulatory~~ **90regulatory** approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel. ~~94The~~ -- **The** estimates of market opportunity and forecasts of market growth included in this annual report or that we may otherwise provide may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all. Market opportunity estimates and growth forecasts included in this annual report or that we may otherwise provide are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. These estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet the size estimates and growth forecasts included herein, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties. We may be exposed to significant foreign exchange risk. We incur expenses, and may in the future derive revenues, in a variety of currencies. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. To date, we have not had significant proportions of our spending tied to foreign currencies but this may change in the future. Thus, fluctuations in currency exchange rates could affect our results as expressed in U. S. dollars. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows. Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our products. The Animal Welfare Act, or AWA, is the federal law that covers the treatment of certain animals used in research. Currently, the AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size, and feeding, watering and shipping conditions. Third- parties with whom we contract are subject to registration, inspections and reporting requirements under the AWA and comparable rules, regulations, and or obligations that may exist in many foreign jurisdictions. Furthermore, some states have their own regulations, including general anti- cruelty legislation, which establish certain standards in handling animals. Comparable rules, regulations, and / or obligations exist in many foreign jurisdictions. If we or our contractors fail to comply with regulations concerning the treatment of animals used in research, we may be subject to fines and penalties and adverse publicity, and our operations could be adversely affected. Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation. We have net operating loss carryforwards and tax credit carryforwards for U. S. federal and state income tax purposes which begin to expire in future years. Additionally, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, changes in our ownership may limit the amount of our net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50 percentage points within a three- year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. Private placements and other transactions that have occurred since our inception, as well as our initial public offering, may trigger such an ownership change pursuant to Section 382. Any such limitation, whether as the result of future securities offerings, our initial public offering, prior private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us, could have a material adverse effect on our results of operations in future years. The reduction of the corporate tax rate under the Tax Cuts and Jobs Act of 2017, or the Tax Cuts and Jobs Act, may cause a reduction in the economic benefit of our net operating loss carryforwards and other deferred tax assets available to us. Our ability to ~~utilize~~ **91utilize** those net operating loss carryforwards could be limited by an " ownership change " as described above, which could result in increased tax liability to us. ~~95Risks~~ -- **Risks** related to intellectual propertyOur success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection. Our business will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our therapeutic candidates, their respective components, synthetic intermediates, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third- party challenges. Our ability to stop unauthorized third- parties from making, using, selling, offering to sell or importing our therapeutic

candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities and whether a court would issue an injunctive remedy. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any therapeutic candidates we may develop may be adversely affected. The patenting process is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The patenting process is subject to numerous risks and there can be no assurance that we will be successful in obtaining patents for which we have applied. In addition, we may not pursue, obtain, or maintain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third- parties and are reliant on our licensors or licensees. The strength of patents in the biotechnology and biopharmaceutical fields involves complex legal and scientific questions and can be uncertain. The patent applications that we own or license may fail to result in issued patents with claims that cover our therapeutic candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third- parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our technology, including our therapeutic candidates, or prevent others from designing around the claims in our patents. If the breadth or strength of protection provided by the patent applications we hold with respect to our therapeutic candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our therapeutic candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our therapeutic candidates under patent protection would be reduced. We cannot be certain that we were the first to file any patent application related to our technology, including our therapeutic candidates, and, if we were not, we may be precluded from obtaining patent protection for our technology, including our therapeutic candidates. Some of the patents that we control were filed prior to March 16, 2013, and are thus based on the " first- inventor- to- invent " criterion. We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third- party or instituted by the United States Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Similarly, for United States applications in which at least one claim is not entitled to a priority date before March 16, 2013, derivation proceedings can be instituted to determine whether the subject matter of a patent claim was derived from a prior inventor' s disclosure. We may be required to disclaim part or all of the term of certain patents. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent or patent application claim. There also may be prior art of which we are aware, but ~~which~~ **92which** we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. ~~96No~~ **No** assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, would adequately protect our therapeutic candidates, or would be found by a court to be infringed by a competitor' s technology or product. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities and consider that we are free to operate in relation to our therapeutic candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our therapeutic candidates or our activities infringing such claims. The possibility exists that others will develop products that have the same effect as our products on an independent basis and that do not infringe our patents or other intellectual property rights or will design around the claims of patents that may issue that cover our products. Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Under the enacted Leahy- Smith America Invents Act, or the America Invents Act, after March 2013, the United States moved from a " first- to- invent " to a " first- inventor- to- file " system. Under a " first- inventor- to- file " system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U. S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post- grant review system. The effects of these changes are currently unclear, as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the " first- inventor- to- file " provisions. In addition, the courts have yet to address many of these provisions and the applicability of the America Invents Act and new regulations on specific patents discussed herein, for which issues have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example: Øothers may be able to make or use compounds that are similar to the compositions of our therapeutic candidates but that are not covered by the claims of our patents or those of our licensors; Øwe or our licensors, as the case may be, may fail to meet our obligations to the U. S. government in regards to any licensed patents and patent applications invented or developed using U. S. government funding, leading to the loss of patent rights; Øwe or our licensors, as the case may be, might not have been the first to file patent applications for these inventions; Øothers may independently develop similar or alternative technologies or duplicate any of our

technologies; Øit is possible that our pending patent applications will not result in issued patents; Øit is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents; Øit is possible that others may circumvent our owned or licensed patents; Øit is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours; Øthe laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States; Øthe claims of our owned or licensed issued patents or patent applications, if and when issued, may not cover our therapeutic candidates; ~~Øour~~ **93Øour** owned or in- licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third- parties; ~~97Øthe~~ -- **Øthe** inventors of our owned or licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors; Øit is possible that our owned or licensed patents or patent applications omit individual (s) that should be listed as inventor (s) or include individual (s) that should not be listed as inventor (s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable; Øwe have engaged in scientific collaborations in the past and expect to continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents; Øwe may not develop additional proprietary technologies for which we can obtain patent protection; Øit is possible that therapeutic candidates or diagnostic tests we develop may be covered by third- parties' patents or other exclusive rights; orØthe patents of others may have an adverse effect on our business. The patents covering the therapeutic use of our lead candidate, TTX- MC138, are currently issued only in the U. S. and there are no foreign applications pending for this invention at this time. We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world. We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on therapeutic candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third- parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to oncology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third- parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Third- party claims of intellectual property infringement may be costly and time consuming to defend, and could prevent or delay our product discovery, development and commercialization efforts. Our commercial success depends in part on our ability to develop, manufacture, market and sell our therapeutic candidates and use our proprietary technologies without infringing the proprietary rights of third- parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and biopharmaceutical industries, as well as ~~administrative~~ **94administrative** proceedings for challenging patents, including interference, derivation, inter partes review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. ~~98We~~ **We** may be exposed to, or threatened with, future litigation by third- parties having patent or other intellectual property rights alleging that our therapeutic candidates and / or proprietary technologies infringe their intellectual property rights. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third- parties, exist in the fields in which we are developing our therapeutic candidates. As the biotechnology and biopharmaceutical industries expand and more patents are issued, the risk increases that our therapeutic candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third- parties may allege they have patent rights encompassing our therapeutic candidates, technologies or methods. If a third- party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to: Øinfringement and other intellectual property claims which, regardless of merit, may be expensive and time- consuming to litigate and may divert our management' s attention from our core business; Øsubstantial damages for infringement, which we may have to pay if a court decides that the therapeutic candidate or technology at issue infringes on or violates the third- party' s rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner' s attorneys' fees; Øa court prohibiting us from developing, manufacturing, marketing or selling our therapeutic candidates, or from using our proprietary technologies, unless the third- party licenses its product rights to us, which it is not required to do; Øif a license is available from a third- party, we may have to pay substantial royalties, upfront fees and other amounts, and / or grant cross- licenses to intellectual property rights for our therapeutic candidates and any license that is available may be non-

exclusive, which could result in our competitors gaining access to the same intellectual property; andØthe need to redesign our therapeutic candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. If we are not able to obtain and enforce patent and other intellectual property protection for our technologies, development and commercialization of our therapeutic candidates may be adversely affected and our business materially harmed. Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in- licensing intellectual property rights of others, for our therapeutic candidates, methods used to manufacture our therapeutic candidates and methods for treating patients using our therapeutic candidates, as well as our ability to preserve our trade secrets, to prevent third- parties from infringing our proprietary rights and to operate without infringing the proprietary rights of others. ~~99We~~ **95We** and our current or future licensors and licensees may not be able to apply for or prosecute patents on certain aspects of our technologies at reasonable cost, in a timely fashion, or at all. The patent position of oncology companies can be highly uncertain because it involves complex legal and factual questions. There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our issued or granted patents will not later be found to be invalid or unenforceable, or that any issued or granted patents will include claims that are sufficiently broad to cover our therapeutic candidates or delivery technologies or provide meaningful protection from our competitors. If third- parties disclose or misappropriate our proprietary rights, it may materially and adversely affect us. While we will endeavor to try to protect our technologies with intellectual property rights such as patents, the process of obtaining patents is time- consuming, expensive and sometimes unpredictable. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the process of pursuing patent coverage. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than otherwise would have been the case. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in oncology patents. Moreover, changes in either the patent laws or in the interpretations of patent laws may diminish the value of our intellectual property. As such, we do not know the degree of future protection that we might have with respect to our proprietary technologies. Further, patents have a limited lifespan. In the United States and in industrialized countries generally, a patent expires 20 years after the first claim of priority (or first provisional U. S. patent application). Various limited extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our technologies, we may be more susceptible to competition, including from generic versions of our therapeutic candidates. Further, the extensive period of time between patent filing and regulatory approval for a product- candidate limits the time during which we can market a product- candidate under patent protection, which may particularly and adversely affect our profitability. Intellectual property litigation and administrative patent office patent validity challenges in one or more countries could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their regular responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. As noted above, some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third- parties, or enter into development collaborations that would help us commercialize our current or future therapeutic candidates, if approved. Any of the foregoing events would harm our business, financial condition, results of operations and prospects. ~~100Confidentiality~~ --- **Confidentiality** agreements with employees and others may not prevent unauthorized disclosure of proprietary information. Among the ways we attempt to protect our intellectual property is by entering into confidentiality agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. These agreements are intended to protect (i) proprietary know- how that may not be patentable or that we may elect not to patent, (ii) processes for which patents are difficult to enforce and (iii) other elements of our technology not covered by patents. Although we use reasonable efforts to protect our intellectual property, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our intellectual property to competitors or others. In addition, competitors may otherwise gain access to our intellectual property or independently develop substantially equivalent

information and techniques. Enforcing a claim that another party illegally obtained and is using any of our intellectual property is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U. S. ~~sometimes~~ **96sometimes** are less willing than U. S. courts to protect intellectual property. Misappropriation or unauthorized disclosure of our intellectual property could materially and adversely affect our competitive position and may have a material adverse effect on us. Third- parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets. As is common in the biotechnology and biopharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third- parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace. Patent terms may be inadequate to protect our competitive position on our therapeutic candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest claimed U. S. provisional filing date. Various extensions such as patent term adjustments and / or extensions, may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our therapeutic candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new therapeutic candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. ~~101Changes~~ --- **Changes** in patent law could diminish the value of patents in general, thereby impairing our ability to protect our current or future therapeutic candidates. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the U. S. and other countries, including the Leahy- Smith America Invents Act, or Leahy- Smith Act, signed into law on September 16, 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. In addition, the Leahy- Smith Act has transformed the U. S. patent system into a " first inventor to file " system. The first- inventor- to- file provisions, however, only became effective on March 16, 2013. Accordingly, 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 patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition. 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. Additionally, there have been recent proposals for additional changes to the patent laws of the U. S. and other countries that, if adopted, could impact our ability to obtain ~~patent~~ **97patent** protection for our proprietary technology or 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 would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. If we are unable to adequately protect and enforce our trade secrets, our business and competitive position would be harmed. In addition to the protection afforded by patents we may own or license, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know- how that may not be patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know- how, information, or technology that may not be covered by patents. Although we require all of our employees, consultants, advisors and any third- parties who have access to our proprietary know- how, information, or technology to enter into confidentiality agreements, trade secrets can be difficult to protect, and we have limited control over the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances, and 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 information. Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign

countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the U. S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U. S. and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third- parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and future prospects. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. If we choose to go to court to stop a third- party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third- parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. 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 them from using that technology or information to compete with us. ~~102Thus~~ **Thus** , we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party' s relationship with us is to be kept confidential and not disclosed to third- parties except in specific circumstances. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third- parties. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. Although we require all of our employees to assign their inventions 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. The assignment of intellectual property rights may not be self- executing, or the assignment agreements may be breached, and we may be forced to bring claims against third- parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects. ~~We~~ **98We** may initiate, become a defendant in, or otherwise become party to lawsuits to protect or enforce our intellectual property rights, which could be expensive, time- consuming and unsuccessful. Competitors may infringe any patents we may own or license. In addition, any patents we may own or license also may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that one or more of any patents we may own or license is not valid or is unenforceable or that the other party' s use of our technology that may be patented falls under the safe harbor to patent infringement under 35 U. S. C. § 271 (e) (1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that any patents we may own or license do not cover the technology in question or that such third- party' s activities do not infringe our patent applications or any patents we may own or license. An adverse result in any litigation or defense proceedings could put one or more of any patents we may own or in- license at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Depending upon the timing, duration and specifics of FDA marketing approval of our current or future therapeutic candidates, one or more of the U. S. patents we own or license may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. Different laws govern the extension of patents on approved pharmaceutical products in Europe and other jurisdictions. However, we may not be granted a patent 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. For example, we may not be granted an extension in the U. S. if all of our patents covering an approved product expire more than fourteen years from the date of NDA approval for a product covered by those patents. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our ability to generate revenues could be materially adversely affected. ~~103Post~~ **Post** - grant proceedings provoked by third- parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patent applications or any patents we may own or license. These proceedings are expensive, and an unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. In addition to potential USPTO post- grant proceedings, we may become a party to patent opposition

proceedings in the EPO, or similar proceedings in other foreign patent offices or courts where our patents may be challenged. The costs of these proceedings could be substantial and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result in a post- grant challenge proceeding may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business. Litigation or post- grant proceedings within patent offices may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U. S. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. ~~We~~ **99We** may not be able to detect infringement against any patents we may own or license. Even if we detect infringement by a third- party of any patents we may own or license, we may choose not to pursue litigation against or settlement with the third- party. If we later sue such third- party for patent infringement, the third- party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce any patents we may own or license against such third- party. General Risk FactorsOur internal computer systems, or those of our third- party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our current or future therapeutic candidates' development programs. Despite the implementation of security measures, our internal computer systems and those of our third- party CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for our current or future therapeutic candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or current or future therapeutic candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our current or future therapeutic candidates could be delayed. ~~104We~~ **We** may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure. We rely on information technology systems that we or our third- party providers operate to process, transmit and store electronic information in our day- to- day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial- of- service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e. g., state breach notification laws), federal (e. g., HIPAA, as amended by HITECH), and international law (e. g., the European Union, or EU, General Data Protection Regulation, or GDPR) and may cause a material adverse impact to our reputation, affect our ability to use collected data, conduct new studies and potentially disrupt our business. We rely on our third- party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. We also rely on our employees and consultants to safeguard their security credentials and follow our policies and procedures regarding use and access of computers and other devices that may contain our sensitive information. If we or our third- party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third- party providers could have difficulty preventing, detecting and controlling such cyber- attacks and any such attacks could result in losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third- parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of ~~such~~ **100such** security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business. Like many other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems and attempts to damage or steal our property, information or financial resources, including through malicious codes and viruses, phishing, business email compromise attacks, and attempted ransomware or other cyber- attacks. Whereas none of these

instances has had a material impact on us so far, the number and complexity of these threats continue to increase over time. For example, in July 2021, we were subject to what we believe was a phishing attack. We do not believe this incident had a material impact on our business or financial condition. However, the number and complexity of these threats continue to increase. If a material breach of our information technology systems or those of our third- party service providers occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. Such a material breach could also have a material adverse effect on our business, financial condition or results of operations. ~~105We~~ **We** or the third- parties upon whom we depend may be adversely affected by earthquakes, other natural disasters, or political and military events, and our business continuity and disaster recovery plans may not adequately protect us from any such serious disaster. Any unplanned or unexpected event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or man- made accidents or incidents that result in us being unable to fully utilize our facilities, or our third- party contract manufacturers being unable to operate their manufacturing facilities normally, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of or reduced access to these facilities or interruptions in the flow of supplies may result in increased costs, delays in the development of our therapeutic candidates or interruption of our business operations. Earthquakes or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event were to occur that prevented us from using all or a significant portion of our facilities, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third- party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. Also, Russia' s military attack on Ukraine could have a material adverse effect on our business, financial condition, results of operations and prospects. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third- party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Our employees, principal investigators, clinical trial sites, CROs and consultants 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 that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the U. S. and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing, patient support and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or 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, but it is not always possible to identify and deter misconduct by employees and other third- parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits ~~stemming~~ **101stemming** from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. ~~106Efforts~~ --- **Efforts** to ensure that our business arrangements with third- parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations, any of which could adversely affect our ability to operate our business and our results of operations. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully

defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and / or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the national anti- bribery laws of EU Member States, such as the U. K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician' s employer, his or her competent professional organization and / or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide- ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third- party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the U. S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to € 20 million or 4 % of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time- intensive process that may increase our cost of doing business or require us to change our business practices and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. ~~Unstable~~ **102Unstable** market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including periods of severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability, including most recently in connection with the novel coronavirus pandemic and inflation and potential recession concerns. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any debt or equity financing we seek to obtain more difficult, more costly, and more dilutive. ~~107Failure~~ --- **Failure** to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, scale back or discontinue the development and commercialization of one or more of our therapeutic candidates or delay our pursuit of potential licenses or acquisitions. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. Furthermore, our stock price may further decline due in part to the volatility of the stock market and general economic conditions. Current economic circumstances may harm our business, financial condition and results of operations. Our overall performance depends, in part, on worldwide economic conditions. In recent months, we have observed increased economic uncertainty in the United States and abroad. Impacts of such economic circumstances include: Øreduced credit availability; Øhigher borrowing costs; Øreduced liquidity; Øvolatility in credit, equity and foreign exchange markets; Ødeclines in equity valuations, especially in the biopharmaceutical sector; andØbankruptcies. These developments could lead to supply chain disruption, inflation, higher interest rates, and uncertainty about business continuity, which may adversely affect our business, financial condition and our results of operations. They are likely to make obtaining equity capital more difficult and more expensive. Rising inflation rates have increased our operating costs and could negatively impact our operations. In addition, inflation rates, particularly in the United States, have increased recently to levels not seen in decades. Increased inflation has resulted in increased operating costs (including our labor costs), and may result in reduced liquidity, and limitations on our ability to access capital, including by raising debt and equity capital. In addition, the United States Federal Reserve has raised interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten these risks. ~~We~~ **103We** may incur substantial costs in our efforts to comply with evolving global data protection laws and regulations, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations. The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about participants and healthcare providers in connection with clinical trials. ~~108Implementation~~ --- **Implementation** standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may (i) create uncertainty in our business, (ii) affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, (iii) result in liability or (iv) impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self- regulatory standards could result in negative publicity, diversion of management time and

effort, or proceedings against us by governmental entities or others. California passed the California Data Privacy Protection Act of 2018, or the CCPA, which went into effect in January 2020. The CCPA provides new data privacy rights for consumers and new operational requirements for companies, which may increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as for private rights of action for certain data breaches that result in the loss of personal information. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. The CCPA may lead to similar laws in other U. S. states or at a national level, which could increase our potential liability and adversely affect our business. In addition to our operations in the United States, which may be subject to healthcare and other laws relating to the privacy and security of health information and other personal information, if we establish operations or conduct clinical trials in Europe, we will be subject to European data privacy laws, regulations and guidelines. The General Data Protection Regulation, (EU) 2016 / 679, or GDPR, became effective on May 25, 2018, and deals with the collection, use, storage, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals in the European Economic Area, or EEA. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, keeping personal information secure, having data processing agreements with third- parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record- keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non- compliance, including fines of up to € 10 million or up to 2 % of our total worldwide annual turnover for certain comparatively minor offenses, or up to € 20 million or up to 4 % of our total worldwide annual turnover (i. e., revenues), whichever is greater, for more serious offenses. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross- border data transfers. Further, national laws of member states of the EU are in the process of being adapted to the requirements under the GDPR, possibly implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country. As a result, we do not expect to operate in a uniform legal landscape in the EEA. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions. European laws have historically differed quite substantially in this field, leading to additional uncertainty. The U. K.' s decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the U. K. In particular, it is unclear how data transfers to and from the U. K. will be regulated now that the U. K. has left the EU. ~~109We~~ **We** may conduct clinical trials in the EEA where the GDPR would increase our responsibility and liability in relation to personal data that we process when such processing is subject to the GDPR, and when we are required to have in place additional mechanisms and safeguards to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR is a rigorous and time- intensive process that would increase our cost of doing business or require us to change our business practices. ~~Despite~~ **104Despite** those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. We expect that we will face uncertainty as to whether our efforts to comply with any obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our business and on our ability to attract and retain new clients or biotechnology and biopharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national vendors or biotechnology and biopharmaceutical partners to use our products due to the potential risk exposure as a result of data protection obligations imposed on them by law, including the GDPR. Such vendors or biotechnology and biopharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the forgoing could materially harm our business, prospects, financial condition and results of operations. We or any future strategic partners may become subject to third- party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights. We or any future strategic partners may be subject to third- party claims for infringement or misappropriation of patent or other proprietary rights. If we, our licensors or any future strategic partners are found to infringe a third- party patent or other intellectual property rights, we could be required to pay substantial damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed. In addition, we, our licensors or any future strategic partners may choose to seek, or be required to seek, a license to technology owned by a third-party, which license may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be limited which could give our competitors access to the same technology or intellectual property rights as is licensed to us. If we fail to obtain a required license, we may be unable to effectively market certain approved products which could materially harm us. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. In addition, we may find it necessary to pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights. The cost to us in litigation or other proceedings relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and would divert our management' s attention from operating the business. Most of our competitors would be better able to sustain the costs of complex patent litigation than us

because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could materially delay our research and development efforts and significantly limit our ability to continue our operations. We incur significant costs as a result of operating as a public company, and our management devotes substantial time to compliance activities and investor relations. As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes- Oxley Act of 2002, as amended, or Sarbanes- Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes- Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd- Frank Wall Street Reform and Consumer Protection Act, or the Dodd- Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd- Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as " say on pay " and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of an initial public offering. We intend to continue to take advantage of this legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. ~~110In~~ **In** addition to substantially increasing our legal and financial compliance costs, we expect the rules and regulations applicable to public companies to continue to make some of our activities more time- consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, or increase our costs, they could have a material adverse effect on our business, financial condition and results of operations and may require us to reduce costs in other areas of our business or ~~increase~~ **105increase** the prices of any products or services we may offer in the future. For example, we expect these rules and regulations to 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 the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to comply with 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 increasing use of social media platforms presents new risks and challenges. Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our therapeutic candidates, if any. Social media practices in the biotechnology and biopharmaceutical industries continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off- label marketing or other prohibited activities and heightened scrutiny by the FDA, the SEC and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public' s legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our therapeutic candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. In addition, we may encounter attacks on social media regarding our company, management, therapeutic candidates or products. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business. Risks related to our Common StockIf you purchase our securities, you may be subject to substantial dilution in the book value of your shares of common stock. You may suffer substantial dilution in the net tangible book value of the common stock you purchase as a result of future offerings of equity or equity- related securities. There is no public market for any of our pre- funded warrants or our common stock purchase warrantsThere is no established public trading market for ~~the~~ pre- funded warrants or common stock purchase warrants we have issued. We will not list the pre- funded warrants or common stock purchase warrants on any securities exchange or nationally recognized trading system, including the Nasdaq Capital Market. Therefore, we do not expect a market to ever develop for the pre- funded warrants or common stock purchase warrants. Without an active market, the liquidity of ~~the~~ **our** pre- funded warrants and common stock purchase warrants will be limited. **Pre** ~~The pre-~~ funded warrants and common stock purchase warrants are speculative in nature. **Pre** ~~The pre-~~ funded warrants and common stock purchase warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but merely represent the right to acquire shares of common stock at a fixed price. Commencing on the date of issuance, holders of pre- funded warrants and common stock purchase warrants may exercise their right to acquire the underlying common stock and pay the respective stated warrant exercise price per share. ~~111Until~~ --- **Until** holders of pre- funded warrants and common stock purchase warrants acquire shares of our common stock upon exercise thereof, such holders will have no rights with respect to shares of our common stock, except as provided in the pre- funded warrants and common stock purchase warrants, respectively. Upon exercise of the pre- funded warrants and common stock purchase warrants, such holders will be entitled to the rights of a common stockholder only as to matters for which the record date occurs after the exercise date. ~~The~~ **106The** price of our common stock may be volatile or may decline regardless of our operating performance, shareholders may not be able to resell their shares at or above the price at which they purchase those shares. Trading volume in shares of our common stock on the Nasdaq Capital Market has been limited. You may not be able to sell your shares quickly or at the market price if trading in

shares of our common stock is not active. An active or liquid market in our common stock may not develop or, if it does develop, it may not sustain. As a result of these and other factors, shareholders may not be able to resell their shares of our common stock at or above the price at which they purchase those shares in this offering. Further, 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. The price of our common stock may fluctuate substantially, which could result in substantial losses for purchasers of our common stock. Our stock price has been volatile since our initial public offering. The stock market in general, and the market for the stocks of many smaller biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations often unrelated or disproportionate to the operating performance of particular companies. We believe that this has occurred for numerous reasons including as a result ~~of the COVID- 19 pandemic~~ , economic events and expectations, the war in the Ukraine and the current armed conflict in Israel and the Gaza Strip, with Israel having declared of war on Hamas, a U. S. designated Foreign Terrorist Organization, due to recent attacks. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. As a result of the foregoing, shareholders may not be able to sell their common stock at or above the price at which they purchase those shares in this offering or otherwise. The market price for our common stock may be influenced by many factors, including: Øthe success of competitive drugs or technologies; Øresults of clinical trials of our current or future therapeutic candidates or those of our competitors; Øregulatory or legal developments in the U. S. and other countries; Ødevelopments or disputes concerning patent applications, issued patents or other proprietary rights; Øthe recruitment or departure of key personnel; Øthe level of expenses related to any of our current or future therapeutic candidates or clinical development programs; Øthe results of our efforts to discover, develop, acquire or license additional current or future therapeutic candidates or drugs; Øactual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; Øvariations in our financial results or those of companies that are perceived to be similar to us; Øchanges in the structure of healthcare payment systems; Ømarket conditions in the pharmaceutical and biotechnology sectors; Øgeneral economic, industry and market conditions; ~~112Øpotential~~ --- **Øpotential** delisting from Nasdaq; andØthe other factors described in this " Risk Factors " section. ~~If~~ **107If** the market price of our common stock declines, you may not realize any return on your investment in us and further you may lose some or all of your investment. Additionally, in the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company' s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management' s attention and resources. Securities sales practice requirements may limit a stockholder' s ability to buy and sell our securities. Effective June 30, 2020, the SEC implemented Regulation Best Interest requiring that " A broker, dealer, or a natural person who is an associated person of a broker or dealer, when making a recommendation of any securities transaction or investment strategy involving securities (including account recommendations) to a retail customer, shall act in the best interest of the retail customer at the time the recommendation is made, without placing the financial or other interest of the broker, dealer, or natural person who is an associated person of a broker or dealer making the recommendation ahead of the interest of the retail customer. " This is a significantly higher standard for broker- dealers to recommend securities to retail customers than under prior FINRA suitability rules. FINRA suitability rules still apply to institutional investors and require that in recommending an investment to a customer, a broker- dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending securities to their customers, broker- dealers must make reasonable efforts to obtain information about the customer' s financial status, tax status, investment objectives and other information, and, for retail customers, determine that the investment is in the customer' s " best interest, " and meets other SEC requirements. Both SEC Regulation Best Interest and FINRA' s suitability requirements may make it more difficult for broker- dealers to recommend that their customers buy speculative, low- priced securities. They may affect investing in our common stock, which may have the effect of reducing the level of trading activity in our securities. As a result, fewer broker- dealers may be willing to make a market in our common stock, reducing a stockholder' s ability to resell shares of our common stock. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or current or future therapeutic candidates. Until such time, if ever, as we can generate the cash we need from operations, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of common stock or securities convertible into or exchangeable for common stock, the ownership interest of our shareholders will be diluted, and the terms of these new securities may include liquidation or other preferences that materially adversely affect the rights of our shareholders. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third- parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or current or future therapeutic candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, scale back or discontinue the development and commercialization of one or more of our therapeutic candidates, delay our pursuit of potential licenses or acquisitions, grant rights to develop and market current or future therapeutic candidates that we would otherwise prefer to develop and market ourselves, or restrict or curtail our operations. ~~113We~~ **We** will need to raise substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, scale back or discontinue some of our therapeutic candidate development programs or commercialization efforts. The development of pharmaceutical drugs is capital intensive. We are currently advancing clinical development of TTX- MC138. Our ~~current~~ cash resources **at December 31, 2024,** are insufficient to fund our planned operations or development plans beyond sometime in the **middle of the second** ~~late third or early fourth~~

quarter ~~of 2024~~ **2025** . We may not be able to complete our ~~planned~~ **Phase I / II** clinical trial, we may only be able to complete the trial in a small subset of patients and in only one tumor type. Even if completed, we will require additional funds to advance further. If we are capital constrained, we may not be able to meet our obligations. If we are unable to meet our obligations, or we experience a disruption in our cash flows, it could limit or halt our ability to continue to develop our therapeutic candidates or even to continue operations, either of which occurrence would have a material adverse effect on us and our shareholders. We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we continue the research and development of, advance the preclinical and clinical activities of, and seek marketing approval for, our current or future ~~therapeutic~~ **108therapeutic** candidates. In addition, if we obtain marketing approval for any of our current or future therapeutic candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution to the extent that such sales, marketing, product manufacturing and distribution are not the responsibility of our collaborators. We may also need to raise additional funds sooner if we choose to pursue additional indications and / or geographies for our current or future therapeutic candidates or otherwise expand more rapidly than we presently anticipate. Furthermore, we expect to continue to incur significant costs associated with operating as a public company. If we are unable to raise capital when needed, we would be forced to delay, scale back or discontinue the development and commercialization of one or more of our therapeutic candidates, delay our pursuit of potential licenses or acquisitions, or significantly reduce our operations. Our future capital requirements will depend on and could increase significantly as a result of many factors, including: Øthe scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our current or future therapeutic candidates ~~; Øthe potential additional expenses attributable to adjusting our development plans (including any supply- related matters) to the COVID- 19 pandemic~~ ; Øthe scope, prioritization and number of our research and development programs; Øthe costs, timing and outcome of regulatory review of our current or future therapeutic candidates; Øour ability to establish and maintain collaborations on favorable terms, if at all; Øthe achievement of milestones or occurrence of other developments that trigger payments under any additional collaboration agreements we obtain; Øthe extent to which we are obligated to reimburse, or are entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any; Øthe costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property- related claims; Øthe extent to which we acquire or license other current or future therapeutic candidates and technologies; Øthe costs of securing manufacturing arrangements for clinical and commercial production; andØthe costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our current or future therapeutic candidates. ~~114Identifying~~ --- **Identifying** potential current or future therapeutic candidates and conducting preclinical testing and clinical trials is a time- consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve drug sales. In addition, our current or future therapeutic candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to continue to rely on additional funding to achieve our business objectives. Any additional fundraising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our current or future therapeutic candidates. Disruptions in the financial markets in general, and those due ~~to the COVID- 19 pandemic and~~ geopolitical events in particular, have made equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms favorable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness could result in fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations ~~on~~ **109on** our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or current or future therapeutic candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. If we are unable to obtain funding on a timely basis, we may be required to significantly delay, scale back or discontinue one or more of our research or development programs, the commercialization of any therapeutic candidates, be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, or restrict or curtail operations, any of which could materially affect our business, financial condition and results of operations ~~. We could lose our listing on the Nasdaq Capital Market, including if we do not meet the Nasdaq rule regarding the level of stockholders' equity. The loss of our Nasdaq listing would in all likelihood make our common stock significantly less liquid and adversely affect its value. As initially disclosed on our Current Report on Form 8- K filed with the SEC on May 18, 2023, we received a letter from the Listing Qualifications Department, or the Staff, of The Nasdaq Stock Market LLC, or Nasdaq, on May 16, 2023, that we are not in compliance with the stockholders' equity requirement for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550 (b) (1) requires that companies listed on the Nasdaq Capital Market maintain stockholders' equity of at least $ 2, 500, 000, or the Stockholders' Equity Requirement, or that they meet one of the alternative listing standards, market value of listed securities of at least $ 35 million or net income of $ 500, 000 from continuing operations in the most recently completed fiscal year, or in two of the three most recently completed fiscal years. We were given 45 calendar days, or until June 30, 2023, to submit a plan to Nasdaq describing how we intend to seek to regain compliance with the Stockholders' Equity Requirement, or the Compliance Plan. If the Compliance Plan was determined to be acceptable to the Staff, the Staff would have the discretion to grant the Company an extension of 180 calendar days from the date of the Staff notification to regain compliance with the Stockholders' Equity~~

Requirement. The Company submitted the Compliance Plan to Nasdaq on June 30, 2023, and supplemented it with additional materials on July 24, 2023. 115On July 26, 2023, the Company received a Delisting Determination Letter from the Staff advising the Company that the Staff had determined not to accept the Company' s Compliance Plan, that the Company' s request for an extension had been denied, and that the Company' s common stock was subject to delisting from the Nasdaq Capital Market, or the Delisting Determination. In accordance with Nasdaq Listing Rule 5815 (a) (2), the Company was provided with seven calendar days, or until August 2, 2023, to request a hearing before the Nasdaq Hearings Panel, or the Panel, to appeal the Delisting Determination. The Company submitted a request for a hearing to Nasdaq, and on August 2, 2023, was notified by Nasdaq that an oral hearing, or the Hearing, by the Panel to discuss the Delisting Determination had been scheduled. The Hearing was held on October 5, 2023. On October 26, 2023, the Company received a letter from the Panel granting an extension to continue its listing on Nasdaq until January 22, 2024, subject to (1) on or before November 14, 2023, following the filing of its Form 10- Q for the period ended September 30, 2023, the Company providing a detailed update to the Panel regarding its meeting the stockholders' equity requirement (we provided this update to the Panel) and (2) on or before January 22, 2024, the Company providing an update to the Panel on how it demonstrates long- term compliance with the stockholder' s equity requirement and other listing standards. The letter stated that the Panel does not have discretion to grant continued listing on Nasdaq beyond January 22, 2024, if the Company has not regained compliance with the stockholder' s equity requirement. The letter also stated that the Panel reserves the right to reconsider the terms of this exception granting continued listing based on any event, condition or circumstance that exists or develops that would, in the opinion of the Panel, make continued listing of the Company' s securities on Nasdaq inadvisable or unwarranted. The Panel advised the Company that it is a requirement during this exception period that the Company provide prompt notification of any significant events that occur during this time that may affect the Company' s compliance with Nasdaq requirements, including prompt advance notice of any event that may call into question the Company' s ability to meet the terms of the exception granted. There can be no assurance that the Company will be able to regain compliance with the Stockholders' Equity Requirement, or that the Company' s plan to demonstrate long- term compliance with the stockholder' s equity requirement will be accepted by the Panel. In the event of a delisting from the Nasdaq Capital Market, our stock would likely be traded in the over- the- counter inter- dealer quotation system, more commonly known as the OTC. OTC transactions involve risks in addition to those associated with transactions in securities traded on the securities exchanges, such as the Nasdaq Capital Market, or Exchange- listed stocks. Many OTC stocks trade less frequently and in smaller volumes than Exchange- listed stocks. Accordingly, our stock would be less liquid than it would be otherwise. Also, the prices of OTC stocks are often more volatile than Exchange- listed stocks. Additionally, many institutional investors are prohibited from investing in OTC stocks, and it might be more challenging to raise capital when needed. We could lose our listing on the Nasdaq Capital Market if the closing bid price of our common stock does not return to above $ 1. 00 for at least ten consecutive days during the 180 days ending May 6, 2024. The loss of the Nasdaq listing would make our common stock significantly less liquid and would adversely affect its value. On November 7, 2023, we received a letter from the Listing Qualifications Department (the " Staff ") of Nasdaq notifying us that, for the 30 consecutive business day period between September 26, 2023, through November 6, 2023, our common stock had not maintained a minimum closing bid price of $ 1. 00 per share (the " Minimum Bid Price Requirement ") required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550 (a) (2). The Nasdaq letter does not result in the immediate delisting of the Company' s common stock from the Nasdaq Capital Market. In accordance with Nasdaq Listing Rule 5810 (c) (3) (A) (the " Compliance Period Rule "), we have been provided an initial period of 180 calendar days, or until May 6, 2024, (the " Compliance Date ") to regain compliance with the Minimum Bid Price Requirement. If, at any time during this 180- day period, the bid price for the Company' s common stock closes at $ 1. 00 or more per share for a minimum of 10 consecutive business days, or such longer period up to 20 consecutive business days as may be determined by the Staff in its discretion, as required under the Compliance Period Rule, the Staff will provide written notification to the Company that it complies with the Minimum Bid Price Requirement and the common stock will continue to be eligible for listing on The Nasdaq Capital Market unless other eligibility deficiencies exist. If the Company does not regain compliance with the Minimum Bid Price Requirement by the Compliance Date, the Company may be eligible for an additional 180 calendar day compliance period. To qualify, the Company would be required to meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and would need to provide written notice to Nasdaq of its intention to cure the deficiency during the additional compliance period. 116If it appears to the Staff that the Company will not be able to cure the deficiency, the Staff will provide written notice to the Company that its common stock will be subject to delisting. At that time, the Company may appeal the Staff' s delisting determination to a Nasdaq Hearing Panel (the " Panel "). The Company expects that its stock would remain listed pending the Panel' s decision, subject to the Company' s ability to regain compliance with the Stockholders' Equity Requirement (as defined below). There can be no assurance that, if the Company does appeal the Staff' s delisting determination to the Panel, such appeal would be successful. We will continue to monitor the closing bid price of our common stock and seek to regain compliance with the Minimum Bid Price Requirement within the allotted compliance period; however, there can be no assurance that we will regain compliance with the Minimum Bid Requirement or that, if we do appeal a subsequent delisting determination, such appeal would be successful. On January 10, 2024, we filed a Certificate of Amendment to our Certificate of Incorporation with the Secretary of State of the State of Delaware to effect a 1- for- 40 reverse stock split of our outstanding common stock. On January 16, 2024, we effected the reverse stock split of our common stock, shares either issued and outstanding or held by the Company as treasury stock. On January 16, 2024, our common stock had a minimum closing bid price in excess of $ 1. 00 per share, however, there can be no assurance that the bid price for our common stock will close at $ 1. 00 or more per share for a minimum of 10 consecutive business days, or such longer period up to 20 consecutive business days as may be determined by the Staff in its discretion, as required under the Compliance Period Rule. Further, while Nasdaq rules do not impose a specific

~~limit on the number of times a listed company may effect a reverse stock split to maintain or regain compliance with the Minimum Bid Price Requirement, Nasdaq has stated that a series of reverse stock splits may undermine investor confidence in securities listed on Nasdaq. Accordingly, Nasdaq may determine that it is not in the public interest to maintain our listing, even if we regain compliance with the Minimum Bid Price Requirement. In addition, Nasdaq Listing Rule 5810 (c) (3) (A) (iv) states that if a listed company that fails to meet the Minimum Bid Price Requirement after effecting one or more reverse stock splits over the prior two- year period with a cumulative ratio of 250 shares or more to one, then the company is not eligible for a Compliance Period. Since we effected a 1- for- 20 reverse stock split of our Common Stock on May 23, 2023 and a 1- for- 40 reverse stock split of our Common Stock on January 16, 2024, we have effected reverse stock splits with a cumulative ratio of one share for every 800 shares previously owned. Any subsequent reverse stock split would result in us exceeding the 1- for- 250 cumulative ratio~~ . We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors. We are an emerging growth company, or EGC, as defined in the JOBS Act, enacted in April 2012. For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, or Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an EGC for up to five years following the year in which we completed our initial public offering, although circumstances could cause us to lose that status earlier. We will remain an EGC until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering (i. e., December 31, 2026), (b) in which we have total annual gross revenue of at least $ 1. 235 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non- affiliates to exceed $ 700. 0 million as of the prior June 30th, and (ii) the date on which we have issued more than $ 1. 0 billion in non- convertible debt during the prior three- year period. We may choose to take advantage of some, but not all, of the available exemptions. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. Under the JOBS Act, EGCs can also delay adopting new or revised accounting standards until such time as those standards apply to private companies, which may make our financial statements less comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. ~~117If~~ **If** securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline. The trading market for our common stock may be influenced, in part, by the research and reports that industry or financial analysts publish about us or our business. If begun, we may lose research coverage by industry or financial analysts. If no or few analysts maintain coverage of us, the trading price of our stock would likely decrease. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock would likely decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline. We do not intend to pay cash dividends on our common stock, so any returns will be limited to the value of our stock. We currently anticipate that we will retain any future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying cash dividends for the foreseeable future. Furthermore, future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation in the value of their stock, if any, and which could decrease in value resulting in losses to our stockholders. ~~We~~ **110We** have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business. As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes- Oxley Act of 2022, or Section 404, requires that we evaluate and determine the effectiveness of our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. To date, we have had limited financial and accounting personnel to fully execute our accounting processes and address our internal control over financial reporting. In preparation of our financial statements to meet the requirements of our IPO, we determined that material weakness in our internal control over financial reporting existed during the year ended December 31, 2021. Prior to our IPO in 2021, we did not design and therefore did not have an effective control environment commensurate with our current financial reporting requirements. Specifically, we lacked a sufficient number of professionals with segregated duties with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately. In connection with the preparation of our financial statements as of and for the years ended December 31, **2024 and** 2023 ~~and 2022~~ , we identified material weaknesses in our control over financial reporting, and determined that many of these material weaknesses remained unremediated from when they were first identified during the year ended December 31, 2021, in connection with the preparation of our financial statements for our IPO. While these material weaknesses did not result in a misstatement for ~~the~~ **these** years ~~ended December 31, 2023 and 2022~~ , each ~~of the above material weaknesses~~ could have resulted in a misstatement of the aforementioned account balances or disclosures that could have resulted in a material misstatement to the annual or interim financial statements that would not have been prevented or detected. In order to remediate the material weaknesses in our internal control over financial reporting and address the material weaknesses in our accounting processes, we **have** ~~plan to establish~~ **established** more robust accounting policies and procedures,

~~and review~~ **reviewed** ~~the~~ adoption of new accounting ~~positions~~ **staff support,** and the need for financial statement disclosures. Also, in September 2022, we engaged an independent consultant to assist us in determining what personnel are needed, in evaluating new accounting policies, and in enhancing the robustness of our reporting systems and procedures. This work is ongoing. ~~118We~~ **We** began implementing and plan to continue to implement steps to address the internal control deficiencies that contributed to the material weaknesses, including the following: ~~Øwhen~~ **Øsubject to available** funding ~~allows~~, hiring ~~of~~ additional finance and accounting personnel with requisite experience and technical accounting expertise, supplemented by third- party resources; Ødocumenting and formally assessing our accounting and financial reporting policies and procedures; andØassessing significant accounting transactions and other technical accounting and financial reporting issues, preparing accounting memoranda addressing these issues and maintaining these memoranda in our corporate records. While we believe that these efforts will improve our internal control over financial reporting, implementation of these and other measures will be ongoing and will require validation and testing of the design and operating effectiveness of our internal controls over a sustained period of financial reporting cycles. We cannot reasonably estimate when these remediation measures will be completed nor can we assure you that the measures we have taken to date, and are continuing to take, will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weaknesses in a timely manner, we will be unable to conclude that we maintain effective internal controls over financial reporting. Furthermore, we may not have identified all material weaknesses, and our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Accordingly, there continues to be a reasonable possibility that these deficiencies or others could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our financial statements that would not be prevented or detected on a timely basis. ~~If~~ **111If** we continue to fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock. We will be required to disclose changes made in our internal controls and procedures on a quarterly basis, and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an EGC, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an EGC for up to five years. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management' s assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation. Anti- takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management. Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include: Øa prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders; ~~119Øa~~ **Øa** requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office; Ødvance notice requirements for stockholder proposals and nominations for election to our board of directors; Øa requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two- thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors; Øa requirement for approval by not less than two- thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; andØthe authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock. **112** ~~In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, or DGCL, which may prohibit certain business combinations with stockholders owning 15 % or more of our outstanding voting stock. These antitakeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then- current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline. Our amended and restated bylaws designate a certain court as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and~~

~~exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation and our amended and restated bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or by- laws or (v) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Unless we consent in writing to the selection of an alternate forum, the United States District Court for the District of Massachusetts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, as our principal office is located in Boston, Massachusetts. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in our shares of common stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. 120~~