

## Risk Factors Comparison 2025-03-21 to 2024-03-21 Form: 10-K

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Any investment in our common stock involves a high degree of risk. You should carefully consider the risks described below, which we believe represent certain of the material risks to our business, together with the information contained elsewhere in this Annual Report on Form 10-K, before you make a decision to invest in our common stock. Please note that the risks highlighted here are not the only ones that we may face. For example, additional risks presently unknown to us or that we currently consider immaterial or unlikely to occur could also impair our operations. If any of the following events occur or any additional risks presently unknown to us actually occur, our business, financial condition and operating results may be materially adversely affected.

**Summary Risk Factors**

- We have incurred losses since our inception and anticipate that we will continue to incur increasing losses for the foreseeable future.
- **Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.**
- We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of THIO.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.
- We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.
- We are heavily dependent on the success of THIO, our most advanced candidate, which is still under clinical development, and if this drug does not receive regulatory approval or is not successfully commercialized, our business may be harmed.
- Clinical trials are expensive, time consuming, difficult to design and implement, and involve uncertain outcomes.
- Our product candidates are based on novel technologies, which make it difficult to predict the timing, results and cost of product candidate development and likelihood of obtaining regulatory approval.
- We may find it difficult to enroll patients in our clinical trials given the limited number of patients who have the diseases for which our product candidates are being studied which could delay or prevent the start of clinical trials for our product candidates.
- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, expensive, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for THIO or any other candidates, our business will be substantially harmed.
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.
- Results of preclinical studies, early clinical trials or analyses may not be indicative of results obtained in later trials.
- The market opportunities for THIO, if approved, may be smaller than we anticipate.
- Development of THIO could take longer, be more expensive, or become impractical if the FDA requires the use of an FDA-approved companion diagnostic test in conjunction with treatment with THIO.
- If we are unable to obtain FDA approval for our IND application for the planned THIO Phase 2 trial, our clinical development of THIO may be significantly delayed and our business may be substantially harmed.
- Even if we obtain FDA approval for THIO or any other candidates in the United States, we may never obtain approval for or commercialize THIO or any other development candidate in any other jurisdiction, which would limit our ability to realize their full global market potential.
- The successful commercialization of THIO and any other candidate we develop will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels, and pricing policies.
- Even if THIO or any candidate we develop receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.
- If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing THIO, if approved.
- A variety of risks associated with operating internationally could materially adversely affect our business.
- Our employees and independent contractors, including principal investigators, clinical trial sites, contract research organizations (“CROs”), consultants, vendors, and any third parties we may engage in connection with development and commercialization, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.
- We currently rely on third-party contract manufacturing organizations, or CMOs, for the production of clinical supply of THIO and intend to rely on CMOs for the production of commercial supply of THIO, if approved. Our dependence on CMOs may impair the development and commercialization of the drug, which would adversely impact our business and financial position.
- We intend to rely on third parties to conduct, supervise and monitor our clinical trials. If those third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, it may harm our business.
- We depend on license agreements with the University of Texas Southwestern, or UTSW, to permit us to use patents and patent applications, as well as to exploit specific technological know-how. Termination of these rights or the failure to comply with obligations under these agreements could materially harm our business and prevent us from developing or commercializing our product candidates.
- We have been granted licenses of use to patent applications. There can be no assurance that any of the patent applications that we have licenses to will result in issued patents. As a result, our ability to protect our proprietary technology in the marketplace may be limited.
- Our patents may be challenged in courts or in patent offices which could result in the invalidation, narrowing or unenforceability of our patents and our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.
- Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. • Intellectual property rights do not address all potential threats to our competitive advantage. • Our reliance on third parties requires us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information. • If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. • We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. • We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties. • We expect to expand our development, regulatory, and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. • The price of our common stock may be volatile and you could lose all or part of your investment. • We do not intend to pay dividends for the foreseeable future, and our ability to pay dividends to our stockholders is restricted by applicable laws and regulations. • We may, in the future, issue additional capital stock, which would reduce investors' percent of ownership and may dilute our share value. • Our failure to meet the continued listing requirements of NYSE American could result in a delisting of our common stock. • Our failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business, financial condition, and results of operations. • The limited public company experience of our management team could adversely impact our ability to comply with the reporting requirements of U. S. securities laws, which could have a materially adverse effect on our business. • Our shares of common stock are currently listed on NYSE American. If we are unable to maintain listing of our securities on NYSE American or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our stockholders to sell their securities.

**Risks Related to Our Financial Position and Need for Additional Capital**

We have incurred losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We are not currently profitable, and we may never achieve or sustain profitability. We are a clinical stage biopharmaceutical company with a limited operating history and have incurred losses since our formation. We incurred net losses of \$ **23,254,656** and \$ **19,772,905** and \$ **15,769,279** for the years ended December 31, **2024** and **2023** and **2022**, respectively. As of December 31, **2023-2024**, we had an accumulated deficit of \$ **63-87,980-234,177-833**. We have not commercialized any products and have never generated revenue from the commercialization of any product. To date, we have devoted most of our financial resources to research and development, including our preclinical and clinical work, and to intellectual property. We expect to incur significant additional operating losses for the next several years, at least, as we advance THIO and any other candidates through clinical development, complete clinical trials, seek regulatory approval and commercialize the drug or any other candidates, if approved. The costs of advancing candidates into each clinical phase tend to increase substantially over the duration of the clinical development process. Therefore, the total costs to advance any of our candidates to marketing approval in even a single jurisdiction will be substantial. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of any products or achieve or maintain profitability. Our expenses will also increase substantially if and as we: • conduct clinical trials for any other indications or other candidates; • establish sales, marketing, distribution, and compliance infrastructures to commercialize our drug, if approved, and for any other candidates for which we may obtain marketing approval; • maintain, expand and protect our intellectual property portfolio; • hire additional clinical, scientific and commercial personnel; • add operational, financial and management information systems and personnel, including personnel to support our development and planned future commercialization efforts, as well as to support our transition to a public reporting company; and • acquire or in-license or invent other candidates or technologies. Furthermore, our ability to successfully develop, commercialize and license any candidates and generate product revenue is subject to substantial additional risks and uncertainties, as described under “ — Risks Related to Development, Clinical **Testing Trials**, Manufacturing and Regulatory Approval ” and “ — Risks Related to Commercialization. ” As a result, we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. The amount of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If we are unable to develop and commercialize one or more product candidates, either alone or through collaborations, or if revenues from any product that receives marketing approval are insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain profitability or meet outside expectations for our profitability. If we are unable to achieve or sustain profitability or to meet outside expectations for our profitability, the value of our common stock will be materially and adversely affected. Our **financial statements as of December 31, 2024 have been prepared under the assumption that we will continue as a going concern for the next twelve months. Our independent registered public accounting firm included in its opinion for the year ended December 31, 2024 an explanatory paragraph referring to our recurring losses, negative cash flow from operations and has accumulated a deficit of \$ 87,234,833 from the Company' s inception through December 31, 2024 and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to create new business opportunities and eventually attain profitable operations. Our financial statements as of December 31, 2024 did not include any adjustments that might result from the outcome of this uncertainty. The reaction of investors to the inclusion of a going concern statement by our auditors, and our potential inability to continue as a going concern, in future years could materially adversely affect our share price and our ability to raise new capital or enter into strategic**

**alliances.** Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical development of THIO and launch and commercialize THIO, if we receive regulatory approval. We will require additional capital for the further development and potential commercialization of THIO and may also need to raise additional funds sooner to pursue a more accelerated development of THIO. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. Based on our cash reserves at December 31, 2023-2024 of \$ 7-9. 15-60 million and current financial condition as of the date of this Annual Report on Form 10- K, there is substantial doubt about our ability to continue as a going concern. (See — Item 7. Management’ s Discussion and Analysis of Financial Condition and Results of Operations — Capital Resources — Our Ability to Continue as a Going Concern ” for further information.) Our future funding requirements, both near and long- term, will depend on many factors, including, but not limited to the: • initiation, progress, timing, costs and results of preclinical studies and clinical trials, including patient enrollment in such trials, for THIO or any other future candidates; • clinical development plans we establish for THIO and any other future candidates; • obligation to make royalty and non- royalty sublicense receipt payments to third- party licensors, if any, under our licensing agreements; • number and characteristics of candidates that we discover or in- license and develop; • outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect; • costs of filing, prosecuting, defending and enforcing any patent claims and maintaining and enforcing other intellectual property rights; • effects of competing technological and market developments; • costs and timing of the implementation of commercial- scale manufacturing activities; and • costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval. If we are unable to expand our operations or otherwise capitalize on our business opportunities due to a lack of capital, our ability to become profitable will be compromised. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, to fund our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate candidate development or future commercialization efforts. We were incorporated in Delaware and began our operations in August 2018. Our operations to date have been limited to financing and staffing our company, licensing candidates, conducting preclinical studies, manufacturing clinical supply, and preparing for and executing clinical studies of THIO. We have not yet demonstrated the ability to successfully complete a large- scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product, arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will eventually need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition and, as a result, our business may be adversely affected. As we continue to build our business, we expect our financial condition and operating results may 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 particular quarterly or annual period as indications of future operating performance. We do not have any products that have gained regulatory approval. Currently, our lead clinical stage candidate is THIO. As a result, our business is dependent on our ability to successfully complete clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize THIO in a timely manner. We cannot commercialize THIO in the United States without first obtaining regulatory approval from the FDA; similarly, we cannot commercialize THIO outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of THIO for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and clinical trials, generally including two adequate and well- controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA, that THIO is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Even if we were to successfully obtain approval of THIO from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post- approval study or risk management requirements. If we are unable to obtain regulatory approval for THIO in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of any other candidate that we may in- license, develop or acquire in the future. Furthermore, even if we obtain regulatory approval for THIO, we will still need to develop a commercial organization, establish commercially viable pricing and obtain approval for adequate reimbursement from third- party and

government payors. If we are unable to successfully commercialize THIO, we may not be able to earn sufficient revenue to continue our business. Pandemics, such as COVID- 19, may adversely impact our business, results of operations, financial condition, liquidity and cash flows and that of our clients. The COVID- 19 pandemic and efforts to control its spread had an impact on our operations. For example, one of our initial clinical studies is taking place in Australia, which previously imposed one of the strictest COVID- 19- related measures, including lock- downs, and may do so again in the future. Pandemics, such as COVID- 19, may have a material economic effect on our business because our research and development may be affected as a result of delays in study monitoring and data analysis; some participants and clinical investigators may not be able to comply with clinical trial protocols; any quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, resulting in our inability to conduct our research activities, including our clinical trials; and infections and deaths related to a pandemic may disrupt the United States' healthcare and healthcare regulatory systems which could divert healthcare resources away from, or materially delay FDA review and / or approval of our product candidates. While the potential economic impact brought by such pandemics may be difficult to assess or predict, it has caused, and may result in further significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from a health pandemic could materially and adversely affect our business and the value of our common stock. The spread of an infectious disease, including COVID- 19, may also result in the inability of our suppliers to deliver components or raw materials on a timely basis or materially and adversely affect our collaborators and out- license partners' ability to perform preclinical studies and clinical trials. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business and manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. The extent to which the coronavirus impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. Clinical trials are expensive, time- consuming and difficult to design and implement, and involve an uncertain outcome. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Because the results of preclinical studies and early clinical trials are not necessarily predictive of future results, THIO and our other compounds may not have favorable results in later preclinical and clinical studies or receive regulatory approval. We may experience delays in initiating and completing any clinical trials that we intend to conduct, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, or at all. Clinical trials can be delayed for a variety of reasons, including delays related to: • the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies; • obtaining regulatory approval to commence and continue to conduct a trial; • reaching an agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • obtaining Institutional Review Board, or IRB, approval at each site, or Independent Ethics Committee, or IEC, approval at sites outside the United States; • recruiting suitable patients to participate in a trial in a timely manner and in sufficient numbers; • having patients complete a trial or return for post- treatment follow- up; • imposition of a clinical hold by regulatory authorities, or IRBs, including as a result of unforeseen safety issues or side effects or failure of trial sites to adhere to regulatory requirements or follow trial protocols; • clinical sites deviating from trial protocol, failing to adequately enroll study subjects, committing fraud or other violations of regulatory requirements, or dropping out of a trial, which can render data from that site unusable in support of regulatory approval; • addressing patient safety concerns that arise during the course of a trial; • adding a sufficient number of clinical trial sites; or • manufacturing sufficient quantities of THIO for use in clinical trials. We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs or IECs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board, or DSMB, for such trial or the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we have agreements governing their committed activities, we have limited influence over their actual performance, as described in “ — Risks Related to Our Dependence on Third Parties. ” Treatment of cancer patients with our oncology product candidates may be used in combination with other cancer drugs, such as other immuno- oncology agents, monoclonal antibodies or other protein- based drugs or small molecule anti- cancer agent such as targeted agents or chemotherapy, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. Additionally, our product candidates could potentially cause adverse events. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using. As described above, any of these events could prevent us from obtaining regulatory approval or achieving or maintaining market acceptance of our product candidates and impair our ability to commercialize our products. Because all of our product candidates are derived from our platform technologies, a clinical failure of one of our product candidates may also increase the actual or perceived likelihood that our other product candidates will experience similar failures. Of the large number of products in development, only a small percentage successfully complete the FDA or comparable foreign regulatory authorities' approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial

condition, results of operations and prospects. Even if we eventually complete clinical testing and receive approval of a biologics license application (BLA) or foreign marketing application for our product candidates, the FDA or the comparable foreign regulatory authorities may grant approval contingent on the performance of costly additional clinical trials, including post-market clinical trials. The FDA or the comparable foreign regulatory authorities also may approve a product candidate for a more limited indication or patient population than we originally request, and the FDA or comparable foreign regulatory authorities may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would adversely impact our business and prospects. In addition, the FDA or comparable foreign regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter and use of our platform technologies may not ever result in marketable products. We may also experience delays in developing a sustainable, reproducible, and scalable manufacturing process or transferring that process to commercial partners or establishing our own commercial manufacturing capabilities, which may prevent us from completing our clinical trials or commercializing any products on a timely or profitable basis, if at all. Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate. As we develop our product candidates and initiate clinical trials of our additional product candidates, serious adverse events, or SAEs, undesirable side effects, relapse of disease or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the SAEs or undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective or in which efficacy is more pronounced or durable. Should we observe SAEs in our clinical trials or identify other undesirable side effects or other unexpected findings depending on their severity, our trials could be delayed or even stopped and our development programs may be halted entirely. Even if our product candidates initially show promise in early clinical trials, the side effects of biological products are frequently only detectable after they are tested in larger, longer and more extensive clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications. If serious adverse or unexpected side effects are identified during development or after approval and are determined to be attributed to our product candidate, we may be required to develop a REMS to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. Product-related side effects could also result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or ADA caused by such products, a number of potentially significant negative consequences could result, including: • regulatory authorities may suspend, withdraw or limit approvals of such product, or seek an injunction against its manufacture or distribution; • regulatory authorities may require additional warnings on the label, including “boxed” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product; • we may be required to create a medication guide outlining the risks of such side effects for distribution to patients; • we may be required to change the way a product is administered or conduct additional clinical trials; • the product may become less competitive, and our reputation may suffer; • we may decide to remove the product from the marketplace; and • we may be subject to fines, injunctions or the imposition of civil or criminal penalties. Interim, topline and preliminary data from our clinical trials may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary, interim or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change as patient enrollment and treatment continues and more patient data become available. Adverse differences between previous preliminary or interim data and future interim or final data could significantly harm our business prospects. We may also announce topline data following the completion of a preclinical study or clinical trial, which may be subject to change following a more comprehensive review 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, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, topline and preliminary 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 based on what is typically extensive information, and you or others may not agree with what we determine to be material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed. Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, or approved or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Separately, in response to the global COVID- 19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products, and on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on- site inspections of domestic manufacturing facilities subject to a risk- based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID- 19 or similar pandemics. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus our discovery and development on select product candidates and indications. Correctly prioritizing our research and development activities is particularly important for us due to the breadth of potential product candidates and indications that we believe could be pursued using our platform technologies. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may also relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. We may not be successful in our efforts to identify or discover additional product candidates in the future. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including: • our inability to design such product candidates with the properties that we desire; or • potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable additional candidates for preclinical and clinical development, our opportunities to successfully develop and commercialize therapeutic products will be limited. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that we will never obtain regulatory approval for THIO or any other candidates. We are not permitted to market any of our product candidates in the United States until we receive regulatory approval of a NDA from the FDA. Our ability to obtain approval by the FDA or other regulatory authorities can be adversely impacted for various reasons including: • we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a candidate is safe and effective for its proposed indication; • serious and unexpected drug- related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our candidates, or other products containing the active ingredient in our candidates; • negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; • we may be unable to demonstrate that a candidate's clinical and other benefits outweigh its safety risks; • the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • the data collected from clinical trials of our development candidates may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or

elsewhere, and we may be required to conduct additional clinical trials; • the FDA or comparable foreign authorities may disagree regarding the formulation, labeling and / or the specifications of our candidates; • the FDA or comparable foreign regulatory authorities may fail to approve or find deficiencies with the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; • the FDA or comparable foreign regulatory authorities may inspect and find deficiencies at the clinical trial sites we use to conduct our clinical studies; and • the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Prior to obtaining approval to commercialize a candidate in the United States or abroad, we must demonstrate with substantial evidence from well- controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The THIO- 101 Phase 2 trial is intended to be a proof- of- concept trial that may be expanded depending on interim results and includes both primary and secondary endpoints consistent with previously approved medicines. If THIO achieves its intended effects and does not exhibit unacceptable safety risks, we plan to seek **filing for** accelerated approval of THIO based on positive results of the expanded Phase 2 THIO- 101 trial **in 2026**, followed by full approval based on the results of a single phase 3 clinical study, as opposed to the traditional approach of conducting two or more phase 3 studies. Even if granted, accelerated approval status does not guarantee an accelerated review or marketing approval by the FDA. A single- study approach is permissible in certain circumstances, particularly in oncology, but such circumstances are exceptional and FDA may not agree with that proposed approach, and thus we may be required to conduct two phase 3 trials. The FDA or any foreign regulatory bodies can delay, limit or deny approval of our candidates or require us to conduct additional preclinical or clinical testing or abandon a program for many reasons, including: • the FDA or comparable foreign regulatory authorities may disagree with the adequacy of the design or implementation of our clinical trials; • the FDA or comparable foreign regulatory authorities may disagree with our safety interpretation of our drug; • the FDA or comparable foreign regulatory authorities may disagree with our efficacy interpretation of our drug; or • the FDA or comparable foreign regulatory authorities may regard our CMC package as inadequate, and more particularly: • if our NDA does not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; • if the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; • if the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; • if the FDA determines that it has insufficient information to determine whether such drug is safe for use under such conditions; • if based on information we submit and any other information before the FDA, the FDA determines there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or • if the FDA determines that our labeling is false or misleading in any particular way. Of the large number of drugs that enter clinical development, only a small percentage successfully complete the regulatory approval processes and are approved and commercialized. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market THIO or any other candidates, which would significantly harm our business, results of operations and prospects. In addition, the FDA or an applicable foreign regulatory agency also may approve a product candidate for a more limited indication or patient population than we originally requested, the FDA or foreign regulatory agency may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, or may require warnings, other safety- related labeling information, or impose post- market safety requirements, including distribution restrictions, that negatively impact the commercial potential of the drug. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including: • the patient eligibility criteria defined in the protocol; • the size of the patient population required for analysis of the trial' s primary endpoints; • the nature of the trial protocol; • the existing body of safety and efficacy data with respect to the product candidate; • the proximity of patients to clinical sites; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating; • competing clinical trials being conducted by other companies or institutions; • our ability to maintain patient consents; • the risk that patients enrolled in clinical trials will drop out of the trials before completion; and The results of preclinical studies, early clinical trials or analyses of our product candidates may not be predictive of the results of later- stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. In addition, conclusions based on promising data from analyses of clinical results may be shown to be incorrect when implemented in prospective clinical trials. Even if our clinical trials for THIO are completed as planned, we cannot be certain that their results will support the safety and efficacy sufficient to obtain regulatory approval. Serious adverse events or undesirable side effects caused by THIO or any other candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of any clinical

trial we conduct could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. THIO has been previously evaluated in at least 19 clinical studies both as monotherapy and in combination with other therapies in multiple solid tumors and hematologic malignancies. A classic treatment strategy was used where patients were treated to maximum tolerated dose (MTD). Dose-limiting reversible toxicities were mainly hematologic (leukopenia, thrombocytopenia), gastrointestinal (nausea, vomiting) and generalized skin rashes; increases in blood urea nitrogen, creatinine, aspartate aminotransferase, alanine transaminase, and bilirubin were also recorded (Douglass, 1979; Gagliano, 1981; Higgins, 1985). The available data provides substantial information on the safety profile of THIO in over 600 subjects (adult and pediatric) at doses significantly higher than those intended for investigation in the current program. If unacceptable side effects arise in the development of our candidates, we, the FDA or the IRBs at the institutions in which our studies are conducted, or the DSMB, if constituted for our clinical trials, could recommend a suspension or termination of our clinical trials, or the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. In addition, drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our development candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly. Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw approvals of such product; • regulatory authorities may require additional warnings on the label, such as a “black box” warning or contraindication; • additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof; • we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients; • we could be sued and held liable for harm caused to patients; • the product may become less competitive; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, if approved, and could significantly harm our business, results of operations and prospects. We expect to initially seek approval for THIO for use as a priming treatment in combination with the immune checkpoint inhibitor cemiplimab in non-small cell lung cancer (“NSCLC”) in the United States. Our estimates of market potential have been derived from a variety of sources, including scientific literature, patient foundations and primary and secondary market research, and may prove to be incorrect. Even if we obtain significant market share for any product candidate, if approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications. We have never obtained marketing approval for a development candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our development candidates. We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our development candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our development candidates. If the FDA does not accept or approve our NDAs for our development candidates, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA that we submit may be delayed or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs. Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our development candidates, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business. THIO is active in cells that are telomerase positive (TERT). The status of a tumor as being TERT can only be established by use of an in vitro test of the tumor cells. While experimental versions of such tests currently exist, none to date have received FDA approval. Under current FDA Guidances, for drugs and therapeutic biologics where the use of a specific diagnostic test is essential for the safe and effective use of the therapeutic product, such as when the use of a product is limited to a specific patient subpopulation that can be identified by using the test, the FDA generally will not approve the therapeutic product if a relevant “companion diagnostic” test is not also approved or cleared for the appropriate indication. As stated in its Guidances, the FDA may decide that it is appropriate to approve such a therapeutic product without an approved or cleared in vitro companion diagnostic device when the drug or therapeutic biologic is intended to treat a serious or life-threatening condition for which no satisfactory alternative treatment exists and the FDA determines that the benefits from the use of a product with an unapproved or uncleared in vitro companion diagnostic device are so pronounced as to outweigh the risks from the lack of an approved or cleared in vitro companion diagnostic device. Although the vast majority of cancers are TERT, the FDA may determine that THIO can only be approved (if at all) for patients whose cancer has been confirmed to be TERT through use of an FDA-approved companion diagnostic. If the FDA were to take such a position, the development and potential approval and commercialization of THIO would take longer, be more expensive, and could become impractical. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval

could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized. Even if we obtain regulatory approval for THIO or any development candidate, we will still face extensive and ongoing regulatory requirements and obligations and any development candidates, if approved, may face future development and regulatory difficulties. Any candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and Good Clinical Practice, or GCP, requirements for any clinical trials that we conduct post-approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product candidate may be marketed or to the conditions of approval, including a requirement to implement a REMS. If any of our product candidates receive marketing approval, the accompanying label may limit the approved indicated use of the product candidate, which could limit sales of the product candidate. The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we market our products for uses beyond their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes or failure to comply with regulatory requirements, may yield various results, including: • restrictions on manufacturing such products; • restrictions on the labeling or marketing of products; • restrictions on product distribution or use; • requirements to conduct post-marketing studies or clinical trials; • warning letters or untitled letters; • withdrawal of the products from the market; • refusal to approve pending applications or supplements to approved applications that we submit; • recall of products; • fines, restitution or disgorgement of profits or revenues; • suspension or withdrawal of marketing approvals; • refusal to permit the import or export of our products; • product seizure; and • injunctions or the imposition of civil or criminal penalties. Further, the FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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, which would adversely affect our business, prospects and ability to achieve or sustain profitability. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We may seek a Breakthrough Therapy designation for THIO from the FDA. However, we might not seek such designation or be granted the designation by the FDA if sought, and even if we are granted the designation, it may not lead to a faster development or regulatory review or approval process. We may seek a Breakthrough Therapy designation for THIO or one or more of our other candidates. Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint (s). For purposes of Breakthrough Therapy designation, clinically significant endpoint generally refers to an endpoint that measures an effect on irreversible morbidity or mortality (IMM) or on symptoms that represent serious consequences of the disease. A clinically significant endpoint can also refer to findings that suggest an effect on IMM or serious symptoms. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for fast track designation (under a separate request), priority review, or accelerated approval, if supported by clinical data at the time the NDA is submitted to the FDA. FDA encourages a Breakthrough Therapy designation request to be submitted, and received by FDA, no later than the end-of-phase-2 meetings. Even if granted, accelerated approval status does not guarantee an accelerated review or marketing approval by the FDA. Designation as a Breakthrough Therapy is within the discretion of the FDA both at the time of the submission of such a request, and during FDA's review of the drug and supporting data. Even if we believe that one of our candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation or may grant such a designation and subsequently rescind the designation prior to approval. Even if we receive and maintain Breakthrough Therapy designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period

for FDA review or approval will not be shortened. Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop. The use of THIO or any other candidates we may develop in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in: • impairment of our business reputation and significant negative media attention; • withdrawal of participants from our clinical trials; • significant costs to defend the litigation; • distraction of management's attention from our primary business; • substantial monetary awards to patients or other claimants; • inability to commercialize THIO or any other product candidate; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • decreased market demand for any product; and • loss of revenue. The product liability insurance coverage we plan to acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. We intend to acquire insurance coverage to include larger clinical studies, different countries and the potential sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim, or series of claims, brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect the results of our operations and business, including preventing or limiting the commercialization of any product candidates we develop. We face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively. The biopharmaceutical and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to acquire, develop, and obtain marketing approval for new products on a cost-effective basis and to market them successfully. If THIO is approved, we will face intense competition from a variety of businesses, including large, fully integrated pharmaceutical companies, specialty pharmaceutical companies and biopharmaceutical companies in the United States and other jurisdictions. These organizations may have significantly greater resources than we do and may conduct similar research; seek patent protection; and establish collaborative arrangements for research, development, manufacturing and marketing of products that may compete with us. Our competitors may, among other things: • have significantly greater name recognition, financial, manufacturing, marketing, drug development, technical, and human resources than we do, and future mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors; • develop and commercialize products that are safer, more effective, less expensive, more convenient, or easier to administer, or have fewer or less severe effects; • obtain quicker regulatory approval; • implement more effective approaches to sales and marketing; or • form more advantageous strategic alliances. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel; establishing clinical trial sites and patient registration; and 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 more effective, have fewer or less severe side effects, or are more convenient or are less expensive than THIO. Our competitors may also obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for THIO, which could result in our competitors establishing or strengthening their market position before we are able to enter the market. We may face early generic competition for THIO or our other products. Pharmaceutical companies developing novel products face intense competition from generic drug manufacturers who aggressively seek to challenge patents and non-patent exclusivities for branded products, and who are able to use much less-onerous product development and FDA approval pathways for their generic products. The active ingredient of THIO was extensively tested as early as the 1970s and we intend to rely in part on the clinical data previously developed for the drug in support of an NDA for THIO. Generic drug applicants and other competitors may be able to similarly rely upon the prior clinical data in support of efforts to gain approval of competing products using the same active ingredient as THIO. If one or more such competitors complete development and seek and obtain regulatory approval before we do, our ability to obtain approval of and market THIO may be delayed. Under the FDA's generic drug approval processes, described in more detail in the section titled "Hatch-Waxman and Generic Competition," we believe that THIO, if approved before any other application for a drug containing the same active ingredient, may be eligible for a five-year regulatory exclusivity period known as new chemical entity, or NCE Exclusivity, which would delay FDA review and approval of a competing product application that relies in whole or in part upon the FDA's approval of THIO, but such exclusivity is only determined by the FDA after a drug is approved and the FDA may determine that THIO is not eligible for NCE Exclusivity, or that approval of THIO must be delayed due to another applicant's relevant exclusivity. A new drug may, upon approval of its initial NDA or approval of supplemental NDAs, qualify for a three-year exclusivity period during which no generic version could be approved for the specific conditions of use covered by such exclusivity. Three-year exclusivity does not prevent FDA approval of another drug with the same active ingredient for a different indication or other conditions of use not protected by the exclusivity. Even if a competing version of THIO was approved with a different indication or condition of use, physicians would be free to prescribe such drug for uses that are covered by our regulatory exclusivity, if any. The successful commercialization of THIO and any other candidate we develop will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels, and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue. The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as THIO, if approved. Our ability

to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our drug and any other product candidates we develop. Assuming we obtain coverage for our product candidates by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third- party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third- party payors may require pre- approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third- party payors will decide with respect to the coverage and reimbursement for our product candidates. No uniform policy for coverage and reimbursement for products exists among third- party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely. Third- party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third- party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when a comparable alternative drug, an equivalent generic drug, a biosimilar, or a less expensive therapy is available. It is possible that a third- party payor may consider our product candidates as alternatives to less expensive drugs and offer to reimburse patients only for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our product candidates. We may also be subject to extensive governmental price controls and other market regulations outside of the United States, and we believe the increasing emphasis on cost- containment initiatives in other countries have and will continue to put pressure on the pricing and usage of medical products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. Moreover, increasing efforts by governmental and third- party payors in the United States 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 product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. If THIO or any candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenues or become profitable. The degree of market acceptance of our product candidates, if approved, will depend on a number of factors, including but not limited to: • the efficacy and potential advantages compared to alternative treatments; • effectiveness of sales and marketing efforts; • the cost of treatment in relation to alternative treatments, including any similar generic treatments; • our ability to offer our products for sale at competitive prices; • the convenience and ease of administration compared to alternative treatments; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • the strength of marketing and distribution support; • the availability of third- party coverage and adequate reimbursement; • the prevalence and severity of any side effects; and • any restrictions on the use of our product together with other medications. Because we expect sales of our product candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing. We do not have any infrastructure for the sales, marketing or distribution of THIO, or compliance functions related to such activities, and the cost of establishing and maintaining such an organization may exceed the cost- effectiveness of doing so. In order to market and successfully commercialize our drug or any product candidate we develop, if approved, we must build our sales, distribution, marketing, managerial, compliance, and other non- technical capabilities or make arrangements with third parties to perform these services. We expect to build a focused sales, distribution and marketing infrastructure to market THIO, if approved, in the United States, with expected licenses in other countries and regions, including large markets such as Japan and Europe. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate

training to sales and marketing personnel, oversee the compliance of sales and marketing functions, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing, distribution and compliance capabilities could delay any product launch, which would adversely impact the commercialization of that product. For example, if the commercial launch of THIO 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 product candidates on our own include, but are not limited to: • our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to prescribe our products; and • unforeseen costs and expenses associated with creating an independent sales and marketing organization. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our product candidates, if approved, in certain markets overseas. Therefore, our future success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in a product and such collaborator's ability to successfully market and sell the product. We intend to pursue collaborative arrangements regarding the sale and marketing of THIO, if approved, for certain markets overseas; however, we cannot assure you that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of THIO, we may be forced to delay the potential commercialization of the drug or reduce the scope of our sales or marketing activities. If we need to increase our expenditures to fund commercialization activities for THIO we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. We may also have to enter into collaborative arrangements for THIO at an earlier stage than otherwise would be ideal and we may be required to relinquish rights to it or otherwise agree to terms unfavorable to us. Any of these occurrences may have an adverse effect on our business, operating results and prospects. If we are unable to establish adequate sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates and may never become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies. In July 2021, we established a wholly owned Australian subsidiary, MAIA Biotechnology Australia Pty Ltd, to conduct various pre-clinical and clinical activities for the development of our product candidates and in April 2022, we established a wholly owned Romanian subsidiary, MAIA Biotechnology Romania S. R. L. to conduct various preclinical and clinical activities for the development of our product candidates. Additionally, our business strategy includes potentially expanding further internationally if any of our product candidates receive regulatory approval. Doing business internationally involves a number of risks, including but not limited to: • multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses; • failure by us to obtain and maintain regulatory approvals for the use of our products in various countries; • additional potentially relevant third-party patent rights; • complexities and difficulties in obtaining protection and enforcing our intellectual property; • difficulties in staffing and managing foreign operations; • complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems; • limits in our ability to penetrate international markets; • financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations; • natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; • the expansion of the Russian military invasion of Ukraine; • the expansion of the Israel and Hamas conflict; • certain expenses including, among others, expenses for travel, translation and insurance; and • regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U. S. Foreign Corrupt Practices Act, its books and records provisions, or its anti-bribery provisions. Any of these factors could significantly harm any future international expansion and operations and, consequently, our results of operations. Our employees and independent contractors, including principal investigators, clinical trial sites, consultants, vendors and any third parties we may engage in connection with development and commercialization of our product candidates, could engage in misconduct, including intentional, reckless or negligent conduct or unauthorized activities that violate: the laws and regulations of the FDA or other similar regulatory requirements of other authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; manufacturing standards; data privacy, security, fraud and abuse and other healthcare laws and regulations; or laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations 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 could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. 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 from a failure to comply with such laws or regulations. Additionally, we are

subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U. S. federal healthcare programs or healthcare programs in other jurisdictions, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations. We have limited personnel with experience in manufacturing, and we do not own facilities for manufacturing. Instead, we rely on and expect to continue to rely on CMOs for the supply of cGMP grade clinical trial materials and commercial quantities of THIO and any candidates we develop, if approved. Reliance on CMOs may expose us to more risk than if we were to manufacture our product candidates ourselves. We intend to have manufactured a sufficient clinical supply of THIO drug substance to enable us to complete our clinical trials, and we have also engaged a CMO to provide clinical and commercial supply of the drug product. The facilities used to manufacture our product candidates must be inspected by the FDA and comparable foreign authorities. While we provide oversight of manufacturing activities, we do not and will not control the execution of manufacturing activities by, and are or will be essentially dependent on, our CMOs for compliance with cGMP requirements for the manufacture of our product candidates. As a result, we are subject to the risk that our product candidates may have manufacturing defects that we have limited ability to prevent. If a CMO cannot successfully manufacture material that conforms to our specifications and the regulatory requirements, we will not be able to secure or maintain regulatory approval for the use of our product candidates in clinical trials, or for commercial distribution of our product candidates, if approved. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval or finds deficiencies in the future, we may need to find alternative manufacturing facilities, which would delay our development program and significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacture of our product candidates or that obtained approvals could be revoked. Furthermore, CMOs may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate CMO or another acceptable solution in time, our clinical trials could be delayed, or our commercial activities could be harmed. We rely on and will continue to rely on CMOs to purchase from third- party suppliers the raw materials necessary to produce our product candidates. We do not and will not have control over the process or timing of the acquisition of these raw materials by our CMOs. Moreover, we currently do not have any agreements for the production of these raw materials. Supplies of raw material could be interrupted from time to time and we cannot be certain that alternative supplies could be obtained within a reasonable timeframe, at an acceptable cost, or at all. In addition, a disruption in the supply of raw materials could delay the commercial launch of our product candidates, if approved, or result in a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. Growth in the costs and expenses of raw materials may also impair our ability to cost effectively manufacture our product candidates. There are a limited number of suppliers for the raw materials that we may use to manufacture our product candidates and we may need to assess alternative suppliers to prevent a possible disruption of the manufacture of our product candidates. Finding new CMOs or third- party suppliers involves additional cost and requires our management' s time and focus. In addition, there is typically a transition period when a new CMO commences work. Although we generally have not, and do not intend to, begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates. As part of their manufacture of our product candidates, our CMOs and third- party suppliers are expected to comply with and respect the proprietary rights of others. If a CMO or third- party supplier fails to acquire the proper licenses or otherwise infringes the proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third- party suppliers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved. We intend to continue to rely on third parties to conduct, supervise and monitor our clinical trials. If those third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, it may harm our business. We rely, and will continue to rely, on CROs, CRO- contracted vendors and clinical trial sites to ensure the proper and timely conduct of our clinical trials, including our Phase 2 trials of THIO. Our reliance on CROs for clinical development activities limits our control over these activities, but we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards. We and our CROs will be required to comply with the good laboratory practice requirements for our preclinical studies and GCP requirements for our clinical trials, which are regulations and guidelines enforced by the FDA and are also required by comparable foreign regulatory authorities. Regulatory authorities enforce GCP requirements through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with 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 perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Accordingly, if our CROs fail to comply with these requirements, we may be required to repeat clinical trials, which would delay the regulatory approval process. Our CROs are not our employees, and we do not control whether or not they devote sufficient time and resources to our clinical trials. Our CROs may also have

relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities, which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed. If our relationship with any CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects. The number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers and the loss of, or a disruption in our relationship with, any one or more collaborators could harm our business. If any collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research and development funding or milestone or royalty payments under such collaborations. If we do not receive the funding we expect under these agreements, our continued development of our product candidates could be delayed, and we may need additional resources to develop additional product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K also apply to the activities of any collaborators and there can be no assurance that our collaborations will produce positive results or successful products on a timely basis or at all. In addition, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination or otherwise changes its business priorities, the collaborator might deemphasize or terminate the development or commercialization of our product candidates. If a collaborator terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of our business and our stock price could be adversely affected. We may in the future collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our programs, and our business may be materially and adversely affected. Risks Related to Healthcare Laws and Other Legal Compliance Matters Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our development candidates, if approved, and may affect the prices we may set. In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U. S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, has substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following: • an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs; • a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off 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; • requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members; • an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; • a methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and biologics that are inhaled, infused, instilled, implanted, or injected; • extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; • expansion of eligibility criteria for Medicaid programs thereby potentially increasing a manufacturer's Medicaid rebate liability; • a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; • establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or

CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; • expansion of the entities eligible for discounts under the Public Health Service program; and • a licensure framework for follow on biologic products. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. It is uncertain the extent to which any such changes may impact our business or financial condition. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011, resulted in aggregate reductions of Medicare payments to providers of 2 % per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional action is taken by Congress. In January 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. Additionally, the orphan drug tax credit was reduced as part of a broader tax reform. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations. In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been Congressional inquiries and proposed federal and state legislation designed to 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. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. We expect that additional U. S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U. S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, results of operations, financial condition 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 candidates or put pressure on our product pricing. In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability. Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third- party payors, patient organizations, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third- party payors, patient organizations, and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include: • the U. S. federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, any good, facility, item, or service, for which payment may be made, in whole or in part, under U. S. federal and state healthcare programs such as Medicare and Medicaid. 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. The U. S. federal 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 U. S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, or FCA, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U. S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U. S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U. S. federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. A claim includes “ any request or demand ” for money or property presented to the federal government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “ cause ” the submission of false or fraudulent claims; • the U. S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private) and 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 U. S. 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; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure 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; • the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices; • the U. S. federal legislation commonly referred to as the Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children' s Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and • analogous U. S. state laws and regulations, including: state anti- kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by any third- party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U. S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; 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 preempted by HIPAA, thus complicating compliance efforts. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our consulting agreements and other relationships with physicians and other healthcare providers, some of whom receive stock or stock options as compensation for their services, could be subject to challenge under one or more of such laws. Ensuring that our current and future internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time- consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Any clinical trial programs we conduct or research collaborations we enter into in the European Economic Area may subject us to the General Data Protection Regulation. If we conduct clinical trial programs or enter into research collaborations in the European Economic Area, or EEA, we may be subject to the General Data Protection regulation, or GDPR. The GDPR applies extraterritorially and implements stringent operational requirements for processors and controllers of personal data, including, for example, high standards for obtaining consent from individuals to process their personal data, robust disclosures to individuals, a comprehensive individual data rights regime, data export restrictions governing transfers of data from the EEA / European Union, or EU, to other jurisdictions, short timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to health data, other special categories of personal data and coded data and additional obligations if we contract third- party processors in connection with the processing of personal data. The United Kingdom has implemented its own version of the GDPR, which contains similar requirements. The GDPR provides that EU member states may establish their own laws and regulations limiting the processing of personal data, including genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs to increase. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and / or fines of up to 20 million Euros or up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill. We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities. Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled

use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions. As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third-party manufacturers or our development efforts may be interrupted or delayed. Recent legislation may materially adversely affect our financial condition, results of operations and cash flows. Recently enacted U. S. tax legislation has significantly changed the U. S. federal income taxation of U. S. corporations, including by reducing the U. S. corporate income tax rate, limiting interest deductions, and revising the rules governing NOLs. Many of these changes are effective immediately, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service, or the IRS, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U. S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. The reduction of the corporate tax rate under the legislation may cause a reduction in the economic benefit of deferred tax assets available to us. Furthermore, under the legislation, although the treatment of tax losses generated before December 31, 2017, has generally not changed, tax losses generated in calendar year 2018 and beyond will only be able to offset 80 % of taxable income. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years. While some of the changes made by the tax legislation may adversely affect us in one or more reporting periods and prospectively, other changes may be beneficial on a going-forward basis. We intend to work with our tax advisors and auditors to determine the full impact that the recent tax legislation as a whole will have on us. We urge our investors to consult with their legal and tax advisors with respect to such legislation.

#### Risks Related to Our Intellectual Property

We are a party to license agreements with UTSW under which we were granted rights to patents and patent applications, as well as proprietary technologies, that are important and necessary to our business. Our rights to use these patents and patent applications and employ the inventions claimed in these licensed patents, as well as the exploitation of proprietary technology, are subject to the continuation of, and our compliance with, the terms of our license agreements. Our license agreements impose upon us various diligence, payment and other obligations, including the following:

- our obligation to pay UTSW various milestone payments;
- our obligation to pay UTSW royalties based on net sales; and
- our obligation to pay UTSW fees associated with the prosecution, maintenance, or filing of the patents and patent applications we have licensed.

If we fail to comply with any of our obligations under the license agreements, or we are subject to a bankruptcy or dissolution, UTSW may have the right to terminate their respective license agreements, in which event we would not be able to market any product candidates covered by the licenses. We do not currently own any patents, and we are heavily reliant upon licenses from UTSW to certain patent rights that are important or necessary to the development of our technology and product candidates. As a result, we may be limited in our ability to prevent competitors from developing and commercializing competitive products. We do not control the prosecution, maintenance, or filing of the patents and patent applications that are licensed to us under the license agreements. Thus, these patents and patent applications were not drafted by us or our attorneys, and we do not directly control the prosecution of these patents and patent applications. We cannot be certain that drafting or prosecution of the patents and patent applications licensed to us has been conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. UTSW directly controls the preparation, filing and prosecution of patent applications, and is responsible for maintaining the patents, covering technology that we license. If we fail to comply with the obligations under our license agreement, including as a result of COVID-19 impacting our operations or due to lack of funds, or if we use the licensed intellectual property in an unauthorized manner, we may be required to pay damages and our licensors may have the right to terminate the license. If our license agreement is terminated, we may not be able to develop, manufacture, market or sell the product candidates covered by our agreement. Such an occurrence could materially adversely affect the value of the product candidates being developed under any such agreement. Disputes may arise regarding intellectual property subject to, and any of our rights and obligations under, any license or other strategic agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or violate the intellectual property of the licensor that is not subject to the license agreement;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the sublicensing of patent and other rights to third parties under any such agreement or collaborative relationships;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. Our business also would suffer if any current or future licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual

property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating or otherwise violating the licensor's rights. In addition, if we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to seek alternative options, such as developing new product candidates with design-around technologies, which may require more time and investment, or abandon development of the relevant research programs or product candidates and our business, financial condition, results of operations and prospects could suffer. We have been granted licenses of use to patent applications in many countries worldwide. These applications cover a range of treatment methods. Unless and until the pending patent applications are issued, their protective scope is impossible to determine. It is also impossible to predict whether or how many of the patent applications will result in issued patents. Even if pending applications are issued, they may be issued with coverage significantly narrower than what is currently sought. Our proprietary position for our product candidates currently depends in part upon licenses to patents protecting methods of use, which may not prevent a competitor or other third party from using the same product candidate for another use. Composition of matter patent claims on the active pharmaceutical ingredient, or API, in pharmaceutical drug products are generally considered to be the favored form of intellectual property protection for pharmaceutical products, as such patents generally provide protection without regard to any particular method of use, manufacture or formulation of the API used. Method of use patent claims protect the use of a product for the specified method. These types of patent claims do not prevent a competitor or other third party from making and marketing an identical API for an indication that is outside the scope of the method claims. Moreover, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute. There is no assurance that all the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents further cover THIO or any future product candidate, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to any patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period during which we could market a product candidate under patent protection could be reduced. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U. S. law does. However, in certain instances, the laws of the United States are more restrictive than those of foreign countries. For example, a recent series of Supreme Court Cases has narrowed the types of subject matter considered eligible for patenting. Accordingly, certain diagnostic methods are considered ineligible for patenting because they are directed to a "law of nature." Further, publications of discoveries in scientific literature often lag the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated, held unenforceable, in whole or in part, or reduced in term. Such a result could limit our ability to stop others from using or commercializing similar or identical technology and products. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. While various extensions may be available, the life of a patent is limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. 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. We may become subject to third parties' claims alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to protect or enforce our patents, which could be costly and / or time consuming, delay or prevent the development and commercialization of our product candidates or put our patents and other proprietary rights at risk. Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell our product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical and biotechnology industries is common, including patent infringement lawsuits, inter partes review, interferences, oppositions and reexamination proceedings before the U. S. Patent and Trademark Office, or USPTO, and corresponding foreign patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous U. S., EU and foreign issued patents and pending patent

applications, which are owned by third parties, exist in the fields in which we are developing product candidates. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties. We may be subject to third- party claims including infringement, interference, or derivation proceedings before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Even if we believe third party infringement claims are without merit, a court of competent jurisdiction could hold that the third- party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Proceedings challenging our patents or those that we license may also result in our patent claims being invalidated or narrowed in scope. Similarly, if our patents or patent applications are challenged during interference or derivation proceedings, a court may hold that a third- party is entitled to certain patent ownership rights instead of us. Further, if any third- party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, methods of manufacture, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. Defending such claims would cause us to incur substantial expenses and, if unsuccessful, could cause us to pay substantial damages if we are found to be infringing a third party' s patent rights. If we are found to have infringed such rights willfully, the damages may be enhanced and may include attorneys' fees. Further, if a patent infringement suit is brought against us or our third- party service providers, our development, manufacturing or sales activities relating to the product or product candidate that is the subject of the suit may be delayed or terminated. As a result of patent infringement claims, or in order to avoid potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which may require us to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if a license can be obtained on acceptable terms, the rights may be nonexclusive, which could give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we could be prevented from commercializing one or more of our product candidates, forced to modify such product candidates, or to cease some aspect of our business operations, which could harm our business significantly. Modifying our product candidates to design around third- party intellectual property rights may result in significant cost or delay to us and could prove to be technically infeasible. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. In addition, if the breadth or strength of protection provided the patents and patent applications we own or in- license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. If we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of eligibility, lack of novelty, obviousness or non- enablement. Third parties might allege unenforceability of our patents because someone connected with prosecution of the patent withheld relevant information, or made a misleading statement, during prosecution. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Furthermore, our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing on our patents or other intellectual property rights. Additionally, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors view these announcements in a negative light, the price of our common stock could be adversely affected. Finally, 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 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 view these announcements in a negative light, the price of our common stock could be adversely affected. Such litigation or proceedings 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 proceedings could have an adverse effect on our ability to compete in the marketplace. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which might adversely affect our ability to develop, manufacture and market our product candidates. We cannot guarantee that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the United States, Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, in the United States, applications filed before

November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States, EU and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our future product candidates, or their manufacture or use may currently be unpublished. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States, the EU or elsewhere that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates. From time to time we may identify patents or applications in the same general area as our products and product candidates. We may determine these third-party patents are irrelevant to our business based on various factors including our interpretation of the scope of the patent claims and our interpretation of when the patent expires. If the patents are asserted against us, however, a court may disagree with our determinations. Further, while we may determine that the scope of claims that will issue from a patent application does not present a risk, it is difficult to accurately predict the scope of claims that will issue from a patent application, our determination may be incorrect, and the issuing patent may be asserted against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our product candidates. We might, if possible, also be forced to redesign our product candidates so that we no longer infringe on the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. As is the case with other biopharmaceutical and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical and pharmaceutical industries involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharmaceutical and pharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the America Invents Act (AIA) which was passed in September 2011, resulted in significant changes to the U. S. patent system. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions. Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent with the USPTO. This applies to all of our U. S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U. S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. Additionally, 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Similarly, the complexity and uncertainty of European patent laws has also increased in recent years. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business. Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and European and other patent agencies over the lifetime of a patent. In addition, the USPTO and European and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which such noncompliance will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our

competitive position and could impair our ability to successfully commercialize our product candidates in any indication for which they are approved. We enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our and our licensors' 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 and our licensors have patent protection, but enforcement is not as strong as that in the United States or the EU. These products may compete with our product candidates, and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, we may decide to abandon national and regional patent applications before grant. The grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of our products. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology. The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and the EU, and many companies have encountered significant difficulties in protecting and defending such rights in such 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, 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 other jurisdictions, whether or not successful, 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. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions. Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired. If we do not obtain patent term extension in the United States under the Hatch- Waxman Act and in foreign countries having similar legislation, thereby potentially extending the term of marketing exclusivity for our product candidates, our business may be materially harmed. 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 U. S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, we may be able to extend the term of a patent covering each product candidate under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments and similar legislation in the EU. The Hatch- Waxman Amendments permit a patent term extension of up to five years for a non- expired patent which claims a human drug product, a method of using the product, or a method of manufacturing the product, as compensation for effective patent term lost during product development and the FDA regulatory review process. Moreover, only one patent may be extended covering the drug product and the total patent term including the extension cannot exceed 14 years following regulatory approval. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially. Further, under certain circumstances, patent terms covering our products or product candidates may be extended for time spent during the pendency of the patent application in the USPTO (referred to as Patent Term Adjustment, or PTA). The laws and regulations underlying how the USPTO calculates the PTA is subject to change and any such PTA granted by the USPTO could be challenged by a third- party. If we do not prevail under such a challenge, the PTA may be reduced or eliminated, resulting in a shorter patent term, which may negatively impact

our ability to exclude competitors. Because PTA added to the term of patents covering pharmaceutical products has particular value, our business may be adversely affected if the PTA is successfully challenged by a third party and our ability to exclude competitors is reduced or eliminated. Intellectual property discovered through government funded programs may be subject to federal regulations such as “ march- in ” rights, certain reporting requirements and a preference for U. S.- based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non- U. S. manufacturers. We may develop, acquire, or license intellectual property rights that have been generated through the use of U. S. government funding or grants. Pursuant to the Bayh- Dole Act of 1980, the U. S. government has certain rights in inventions developed with government funding. These U. S. government rights include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non- exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as march- in rights). If the U. S. government exercised its march- in rights in our future intellectual property rights that are generated through the use of U. S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U. S. government for the exercise of such rights. The U. S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U. S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U. S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. For example, some of our intellectual property, including the intellectual property licensed from the University of Texas Southwestern Medical Center was funded in whole or in part by the United States government, the United States government has certain rights to such patent rights and technology, including a non- exclusive license authorizing the government to use the invention for non- commercial purposes and march- in rights, and impose certain reporting and domestic manufacturing requirements. These rights may permit the United States government to disclose our confidential information to third parties and to exercise march- in rights to use or allow third parties to use our licensed technology. The government can exercise its march- in rights if it determines that action is necessary because we fail to achieve practical application of the government- funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to United States industry. In addition, our rights in such inventions are and may be subject to certain requirements to manufacture products embodying such inventions in the United States. This preference for U. S. industry may limit our ability to contract with non- U. S. product manufacturers for products covered by such intellectual property. Any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations and prospects. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative: • others may be able to make products that are similar to THIO or our future product candidates but that are not covered by the claims of the patents that we own or license from others; • others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our intellectual property rights; • we or any of our collaborators might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license; • we or any of our collaborators might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license; • it is possible that our pending patent applications will not lead to issued patents; • issued patents that we own may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • ownership of our patents or patent applications may be challenged by third parties; and • the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business. We consider proprietary trade secrets or confidential know- how and unpatented know- how to be important to our business. We may rely on trade secrets or confidential know- how to protect our technology, especially where patent protection is believed by us to be of limited value. Because we expect to rely on third parties to manufacture THIO and any future product candidates, and we expect to collaborate with third parties on the development of THIO and any future product candidates, we must, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. However, trade secrets or confidential know- how can be difficult to maintain as confidential. To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and

confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business. We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for any other of our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks. In addition, any proprietary name we propose to use with our clinical-stage product candidates or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. The EMA may also object to our proposed proprietary product name that infringes the existing rights of third parties. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and growth prospects. A third party may hold intellectual property, including patent rights that are important or necessary to the development or commercialization of THIO or our future product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize THIO or our product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, which could materially harm our business. At this time, we are unaware of any intellectual property that interferes with ours or is complementary and needed to commercialize THIO. We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership or right to use. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Our proprietary information may be lost, or we may suffer security breaches. In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, disruption of our operations, damage to our reputation and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our clinical development of our product candidates.

**Risks Related to Our Employees, Managing Our Growth and Our Operations** Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel. We are highly dependent on the development, regulatory, commercialization and business development expertise of Vlad Vitoc as well as the other principal members of our management, scientific and clinical teams. Although we have employment agreements, offer letters or consulting agreements with our executive officers, these agreements do not prevent them from terminating their services at any time. If we lose one or more of our executive officers or key

employees, our ability to implement our business strategy successfully could be seriously harmed. 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 product candidates, gain regulatory approval, and commercialize new products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional 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. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize product candidates will be limited. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities or acquire new facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources. In the future, we may enter into transactions to acquire other businesses, products or technologies. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results. Our business and operations would suffer in the event of system failures. Our computer systems, as well as those of our CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of THIO or any other product candidate could be delayed.

**Risks Relating to Our Common Stock** **If we are unable to comply with the continued listing requirements of the NYSE American, then our Common Stock would be delisted from the NYSE American, which would limit investors' ability to effect transactions in our Common Stock and subject us to additional trading restrictions. Our common stock is currently listed on the NYSE American and the continued listing of our Common Stock on the NYSE American is contingent on our continued compliance with a number of listing requirements. If we are unable to comply with the continued listing requirements of the NYSE American, our Common Stock would be delisted from the NYSE American, which would limit investors' ability to effect transactions in our Common Stock and subject us to additional trading restrictions. In order to maintain our listing, we must maintain certain share prices, financial and share distribution targets, including maintaining a minimum amount of stockholders' equity and a minimum number of public stockholders, as well as satisfy other listing requirements of the NYSE American. In addition to these objective standards, NYSE American may delist the securities of any issuer for other reasons involving the judgment of NYSE American.** Section 1003 (a) (i) of the NYSE American Company Guide requires a listed company to have stockholders' equity of \$ 2-6 million or more if the listed company has reported sustained losses from continuing operations and / or net losses in two of its five most recent fiscal years, and Section 1003 (a) (ii) requires a listed company to have stockholders' equity of \$ 4 million or more if the listed company has reported losses from continuing operations and / or net losses in three of its four most recent fiscal years. Our stockholders' equity was approximately \$ 0-3. 48 6 million as of December 31, 2023-2024 , and we have had losses from continuing operations and / or net losses in each of our fiscal years ended December 31, 2020, 2021, 2022 and , 2023 and 2024 . Further **However** , we **do not are in compliance with NYSE American listing standards as we** currently satisfy the alternate compliance standards provided in Section 1003 (a) **which provide that the** . We expect to receive a notice from NYSE American **will** informing us that we do not **normally consider suspending dealings in** meet the foregoing continued listing requirements. If we receive such a notice, **or removing from** we expect to be afforded 30 days to submit a plan to regain compliance with the **list, the securities of an issuer which is below any** stockholders' equity requirement **for described above if the issuer is in compliance with the following of the NYSE American 's consideration, and if the plan Company Guide since: (i) total value of our market capitalization is accepted at least \$ 50 , to be granted 000, 000 or total assets an and revenue extension period of up \$ 50, 000, 000 each in its last fiscal year, or in to two 18 months from of its last the three date of fiscal years; and (ii) the deficiency notice to regain**

compliance issuer has at least 1, 100, 000 shares publicly held, a market value of publicly held shares of at least \$ 15, 000, 000 and 400 round lot shareholders. There If the plan is not accepted or if we are not in compliance with the continued listing standards by such compliance date or if we do not make progress consistent with any such plan submitted to NYSE American during the plan period, the NYSE American may commence delisting procedures. In the event of a delisting, we can provide no assurance that we will be able any action taken by us to restore regain or maintain compliance with the NYSE American continued listing standards and / requirements would be successful. If our or continue our listing on the common stock is ultimately delisted by NYSE American, in the future. If the NYSE American delists our Common Stock from trading on its exchange and we are not able to list our securities on another national securities exchange, we expect our securities the Common Stock could would qualify to be quoted on an over-the-counter market. If this were to occur, then we could face significant material adverse consequences, including: • a material reduction in the liquidity of our common stock and a corresponding material reduction in the trading price of our common stock; a more limited availability of market quotations for our securities; • reduced liquidity for our securities; • substantially impair our ability to raise additional funds; • the loss of institutional investor interest and a decreased ability to issue additional securities or obtain additional financing in the future; • a determination that our common Common stock Stock is a “ penny stock ,” that which will requires require brokers trading in our Common Stock to adhere to more stringent rules and possibly resulting result in a reduced level of trading activity in the secondary trading market for our securities; more • a limited research amount of news and analyst coverage by stock analysts; loss of reputation; more difficult and • more expensive equity financings in the future; the potential loss breaches of confidence by investors; representations or covenants of our agreements pursuant to which we made representations or covenants relating to our compliance with applicable listing requirements, which, regardless of merit, could result in costly litigation, significant liabilities and fewer diversion of our management’s time and attention and could have a material adverse effect on our financial condition, business and results development opportunities. The National Securities Markets Improvement Act of operations 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as “ covered securities .” If our Our shares of common stock remains are thinly traded, and the price may not reflect our value; there can be no assurance that there will be an active market for our shares now or in the future. We have a trading symbol for our common stock (“ MAIA ”) and our common stock is currently listed on the NYSE American, our. Our shares of common stock are thinly traded, and as such the price, if traded, may not reflect our value. There can be no assurance that there will be covered securities. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and an, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. If our securities were no longer listed on NYSE American and therefore not “ covered securities ,” we would be subject to regulation in each state in which we offer our securities. An active, liquid trading market for our shares of common stock either now or in the future. The market liquidity will be dependent on, among other things, the perception of our operating business and any steps that our management might take to bring us to the awareness of investors. There can be no assurance given that there will be any awareness generated or, if given, that it will be positive. Consequently, investors may not be able to liquidate their investment or may be able to liquidate it only at a price that does not reflect the value of the business. If a more active market should develop, the price may be highly volatile. Our Due to the possibility of our common stock being priced lower than its actual value was listed and began trading on the NYSE American on July 28, many brokerage firms may 2022 under the symbol “ MAIA .” Prior to the listing, there was no not public market for be willing to effect transactions in the securities. Even if an investor finds a broker willing to effect a transaction in the shares of our common stock, the combination An active trading market for shares of brokerage commissions, transfer fees, taxes, if our common stock may never develop or be sustained. If an any active trading market does not develop, and any other you may have difficulty selling costs may exceed the selling price any of our shares that you purchase. The price of our common stock may be volatile. Securities markets worldwide have experienced in the past, and are likely to experience in the future, significant price and volume fluctuations. This market volatility, as well as general economic, market, or political conditions could reduce the market price of our common stock regardless of our results of operations. The trading price of our common stock has been and is likely to continue to be volatile and could be subject to wide price fluctuations in response to various factors including, among other things, the risk factors described herein and other factors beyond our control. Factors affecting the trading price of our common stock could include, but are not limited to: • market conditions in the broader stock market; • actual or anticipated variations in our quarterly results of operations; • developments in our industry in general; • results from our ongoing clinical trials and future clinical trials with our current and future product candidates or of our competitors; • adverse results or delays in clinical trials; • failure to commercialize our product candidates; • unanticipated serious safety concerns related to the use of our product candidates; • changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock; • any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority’s review of such filings, including without limitation the FDA’s issuance of a “ refusal to file ” letter or a request for additional information; • regulatory or legal developments in the United States and other countries; • the level of expenses related to future product candidates or clinical development programs; • our failure to achieve product development goals in the timeframe we announce; • issuance of new, negative or changed securities analysts’ reports or recommendations or estimates; • sales, or anticipated sales, of our stock, including sales by our officers, directors and significant stockholders; • additions or departures of key personnel; • regulatory or political developments; • the public’s response to press releases or other public announcements by us or third parties, including our filings with the SEC; • announcements, media reports or other public forum comments related to litigation, claims or reputational charges against us; • guidance, if any, that we provide to the public, any changes in this guidance, or our failure to

meet this guidance; • the development and sustainability of an active trading market for our common stock; • investor perceptions of the investment opportunity associated with our common stock relative to other investment alternatives; • other events or factors, including those resulting from system failures and disruptions, earthquakes, hurricanes, war, acts of terrorism, global outbreaks or pandemic, other natural disasters or responses to these events; • changes in accounting principles; • litigation and governmental investigations; and • changing economic conditions. These and other factors may cause the market price and demand for shares of our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. We could be subject to securities class action litigation. In the past, when the market price of a stock has been volatile, holders of that stock sometimes have instituted securities class action litigation against the company that issued the stock following a decline in the market price of their securities. This risk is especially relevant for us because biotechnology companies have experienced significant share price volatility in recent years. Securities litigation against us, regardless of the merits or outcome, could result in substantial costs and divert the time and attention of our management from our business, which could have a material adverse effect on our business, financial condition, and results of operations. Future sales of our common stock, or the perception in the public markets that these sales may occur, could cause the market price for our common stock to decline. At the time of this date of this Annual Report on Form 10-K, **we have 1,773,912 shares of Common Stock issuable upon exercise of options outstanding under the MAIA Biotechnology, Inc. 2018 Stock Option Plan (the “MAIA 2018 Plan”) with a weighted-average exercise price of \$ 1.80 per share; 3,863,503, 928,589 shares of Common Stock issuable upon exercise of options outstanding under the MAIA Biotechnology, Inc. Amended and Restated 2020 Equity Incentive Plan (the “MAIA 2020 Plan”) with a weighted-average exercise price of \$ 2.49 per share; 5,427,326 shares of Common Stock issuable upon exercise of options outstanding under our 2021 Equity Incentive Plan (the “MAIA 2021 Plan”) with a weighted-average exercise price of \$ 2.49 per share; 673,673 shares of Common Stock reserved for future issuance under the MAIA 2021 Plan and 9,299,143 shares issuable upon the exercise of warrants to purchase shares of common stock at a weighted average exercise price of \$ 2.23 per share and 14,039,559 shares of common stock are reserved for issuance under our 2021 Equity Incentive Plan and 436,690 shares of common stock are reserved for issuance under our At-the-Market Offering Agreement dated February 14, 2024 with H. C. Wainwright and Co., LLC.** We cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock prevailing from time to time. Sales of substantial amounts of shares of our common stock in the public market, or the perception that those sales will occur, could cause the market price of our common stock to decline. Of the shares of common stock outstanding, **5,455,727, 010,844** are restricted securities within the meaning of Rule 144 under the Securities Act and subject to certain restrictions on resale. Restricted securities may be sold in the public market only if they are registered under the Securities Act, or are sold pursuant to an exemption from registration such as Rule 144 or Rule 701. We may retain future earnings, if any, for future operations, expansion and debt repayment and have no current plans to pay any cash dividends for the foreseeable future. As a result of our current dividend policy, you may not receive any return on an investment in our common stock unless you sell our common stock for a price greater than that which you paid for it. Any future determination to declare and pay cash dividends will be at the discretion of our board of directors and will depend on, among other things, our financial condition, results of operations, cash requirements, contractual restrictions and such other factors as our board of directors deems relevant. Our ability to declare and pay dividends to our stockholders is subject to certain laws, regulations, and policies, including minimum capital requirements and, as a Delaware corporation, we are subject to certain restrictions on dividends under the Delaware General Corporation Law (the “DGCL”). Under the DGCL, our board of directors may not authorize payment of a dividend unless it is either paid out of our surplus, as calculated in accordance with the DGCL, or if we do not have a surplus, it is paid out of our net profits for the fiscal year in which the dividend is declared and / or the preceding fiscal year. Our ability to pay dividends depends on our receipt of cash dividends from our operating subsidiaries, which may further restrict our ability to pay dividends as a result of the laws of their jurisdiction of organization or agreements of our subsidiaries, including agreements governing our indebtedness. For more information, see “Dividend Policy.” Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us. Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case, to the fullest extent permitted by Delaware law. Pursuant to our amended and restated bylaws and the DGCL, our directors will not be liable to the Company or any stockholders for damages for any breach of fiduciary duty, except (i) acts that breach his or her duty of loyalty to the Company or its stockholders; (ii) acts or omissions without good faith or involving intentional misconduct or knowing violation of the law; (iii) pursuant to Section 174 of the DGCL regarding director liability for unlawful payment of a dividend or unlawful stock purchase or redemption; or (iv) for any transaction from which the director derived an improper personal benefit. In addition, we have entered into indemnification agreements with each of our executive officers and directors. The indemnification agreements provide the executive officers and directors with contractual rights to indemnification, expense advancement and reimbursement, to the fullest extent permitted under the DGCL. The bylaws also require us, if so requested, to advance expenses that such director or officer incurred in defending or investigating a threatened or pending action, suit or proceeding, provided that such person will return any such advance if it is ultimately determined that such person is not entitled to indemnification by us. Any claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us. We have the right to raise additional capital or incur borrowings from third parties to finance our business. The issuance of additional equity securities, whether pursuant to that certain At-the-Market (“ATM”) Offering Agreement dated February 14, 2024 with H. C. Wainwright & Co., LLC pursuant to each of which we may also sell **an amount up to \$ 1,445,000 million** of shares of our common stock **that does not exceed the number or dollar amount of shares of common stock that would cause the Company or the**

**offering of the Shares to not satisfy the eligibility and transaction requirements for use of Form S- 3, including, if applicable, General Instruction I. B. 6 of Registration Statement on Form S- 3**, as more fully described elsewhere in this Annual Report on Form 10- K ) or otherwise, will dilute the holdings of existing stockholders and may reduce the share price of our common stock. We may also implement public or private mergers, business combinations, business acquisitions and similar transactions pursuant to which it would issue substantial additional capital stock to outside parties, causing substantial dilution in the ownership of the Company by our existing stockholders. Our Board of Directors has the authority, without the consent of any of the stockholders, to cause us to issue more shares of common stock and / or preferred stock at such price and on such terms and conditions as are determined by the Board of Directors in its sole discretion. The issuance of additional shares of capital stock by us will dilute your ownership percentage in the Company and could impair our ability to raise capital in the future through the sale of equity securities. Certain stockholders who are also officers and directors of the Company may have significant control over our management. Our directors and executive officers own as of March 21, ~~2024~~ **2025**, an aggregate of ~~3-4~~, ~~844~~ **504**, ~~565~~ **706** shares of our common stock, which constitutes ~~19-15~~. 2 % of our issued and outstanding common stock. As a result, our directors and executive officers may have a significant influence on our affairs and management, as well as on all matters requiring stockholder approval, including electing and removing members of our Board of Directors, causing us to engage in transactions with affiliated entities, causing or restricting our sale or merger, and certain other matters. Such concentration of ownership and control could have the effect of delaying, deferring or preventing a change in control of us even when such a change of control would be in the best interests of our stockholders. Anti- takeover protections in our amended and restated certificate of incorporation and our amended and restated bylaws, or our contractual obligations may discourage or prevent a takeover of our Company, even if an acquisition would be beneficial to our stockholders. Provisions contained in our amended and restated certificate of incorporation and our amended and restated bylaws, as well as provisions of the DGCL, could delay or make it more difficult to remove incumbent directors or could impede a merger, takeover or other business combination involving us or the replacement of our management, or discourage a potential investor from making a tender offer for our common stock, which, under certain circumstances, could reduce the market value of our common stock, even if it would benefit our stockholders. Among other things, these provisions: • do not permit cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates; • delegate the sole power of a majority of the board of directors to fix the number of directors; • provide the power to our board of directors to fill any vacancy on our board of directors, whether such vacancy occurs as a result of an increase in the number of directors or otherwise; • generally limit stockholders ability to call special meetings of stockholders and generally prohibit stockholder action to be taken by written consent; and • establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings. Our amended and restated bylaws designate the Court of Chancery of the State of Delaware 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, employees, agents or other stockholders. Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for any (i) derivative action or proceeding brought on our behalf, (ii) action asserting a claim of breach of a fiduciary duty or other wrongdoing by any current or former director, officer, employee, agent or stockholder to us or our stockholders, (iii) any action or proceeding asserting a claim against us or any current or former director, officer or other employee of the company, arising out of or pursuant to arising under any provision of the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or (iv) action asserting a claim governed by the internal affairs doctrine of the law of the State of Delaware, except for, as to each of (i) through (iv) above, any action as to which the Court of Chancery of the State of Delaware determines that there is an indispensable party not subject to the personal jurisdiction of the Court of Chancery of the State of Delaware (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery of the State of Delaware within ten (10) days following such determination), in which case the United States District Court for the District of Delaware or other state courts of the State of Delaware, as applicable, shall, to the fullest extent permitted by law, be the sole and exclusive forum for any such claims. However, the exclusive forum provisions shall not apply to suits brought to enforce a duty or liability created by the Securities Act, the Securities Exchange Act of 1934, as amended (the “ Exchange Act ”) or any other claim for which the federal courts have exclusive jurisdiction, for which the federal district courts of the District of Delaware shall be the sole and exclusive forum unless the Company consents in writing to the selection of an alternative forum. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. To the fullest extent permitted by law, any person or entity purchasing or otherwise acquiring or holding any interest in any shares of our capital stock shall be deemed to have notice of and consented to the forum provision in our amended and restated bylaws. This choice of forum provision may limit a stockholder's ability to bring a claim in a different judicial forum, including one that it may find favorable or convenient for a specified class of disputes with us or our directors, officers, other stockholders, or employees, which may discourage such lawsuits, make them more difficult or expensive to pursue, and result in outcomes that are less favorable to such stockholders than outcomes that may have been attainable in other jurisdictions. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on our business, financial condition and results of

operations. We are considered a “ smaller reporting company ” and are exempt from certain disclosure requirements, which could make our stock less attractive to potential investors. Rule 12b- 2 of the Exchange Act defines a “ smaller reporting company ” as an issuer that is not an investment company, an asset- backed issuer, or a majority- owned subsidiary of a parent that is not a smaller reporting company and that: • Had a public float of less than \$ 250 million as of the last business day of its most recently completed fiscal quarter, computed by multiplying the aggregate number of worldwide number of shares of its voting and non- voting common equity held by non- affiliates by the price at which the common equity was last sold, or the average of the bid and asked prices of common equity, in the principal market for the common equity; or • In the case of an initial registration statement under the Securities Act or the Exchange Act for shares of its common equity, had a public float of less than \$ 250 million as of a date within 30 days of the date of the filing of the registration statement, computed by multiplying the aggregate worldwide number of such shares held by non- affiliates before the registration plus, in the case of a Securities Act registration statement, the number of such shares included in the registration statement by the estimated offering price of the shares; or • In the case of an issuer who had annual revenue of less than \$ 100 million during the most recently completed fiscal year for which audit financial statements are available, had a public float as calculated under paragraph (1) or (2) of this definition that was either zero or less than \$ 700 million. As a “ smaller reporting company ” we are not required and may not include a Compensation Discussion and Analysis section in our proxy statements; we provide only 3 years of business development information; provide fewer years of selected data; and have other “ scaled ” disclosure requirements that are less comprehensive than issuers that are not “ smaller reporting companies ” which could make our stock less attractive to potential investors, which could make it more difficult for you to sell your shares. We are considered an “ emerging growth company, ” and the reduced reporting requirements applicable to emerging growth companies may make our common stock less attractive to investors. We are an “ emerging growth company, ” as defined in the Jumpstart Our Business Startups Act, or JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (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 means the market value of our common stock held by non- affiliates exceeds \$ 700 million as of the end of our prior second fiscal quarter, and (2) the date on which we have issued more than \$ 1. 0 billion in non- convertible debt during the prior three- year period. In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We intend to take advantage of the extended transition period for adopting new or revised accounting standards under the JOBS Act as an emerging growth company. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile. General Risk Factors Changes in accounting standards and subjective assumptions, estimates and judgments by management related to complex accounting matters may materially impact reporting of our financial condition and results of operations. Accounting principles generally accepted in the United States and related accounting pronouncements, implementation guidelines, and interpretations we apply to a wide range of matters that are relevant to our business, such as accounting for long- lived asset impairment and share- based compensation, are complex and involve subjective assumptions, estimates and judgments by our management. Changes in these rules or their interpretation or changes in underlying assumptions, estimates or judgments by our management could significantly change or add significant volatility to our reported or expected financial performance. Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U. S. generally accepted accounting principles (“ GAAP ”). Under standards established by the Public Company Accounting Oversight Board (“ PCAOB ”) and the Exchange Act, a deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or personnel, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. The PCAOB and Rule 12b- 2 of the Exchange Act define a material weakness as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented, or detected and corrected, on a timely basis. We are required, pursuant to Section 404 of the Sarbanes- Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the first fiscal year beginning after the effective date of our IPO and in each year thereafter. Our auditors will also need to attest to the effectiveness of our internal control over financial reporting upon losing our Emerging Growth Company status and becoming an accelerated filer or a large accelerated filer. If we are unable to assert that our internal control over financial reporting is effective , or when required in the future or, if our independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be adversely affected, and we could become subject to litigation or investigations by the stock exchange on which our common stock are listed, the SEC or other regulatory authorities, which could require additional financial and management resources and could have a material adverse effect on our business, financial condition, and results of operations. The lack of public company experience of our management team could adversely impact our ability to comply with the reporting requirements of U. S.

securities laws, which could have a materially adverse effect on our business. Our officers have limited public company experience, which could impair our ability to comply with legal and regulatory requirements such as those imposed by Sarbanes-Oxley Act. Such responsibilities include complying with federal securities laws and making required disclosures on a timely basis. Any such deficiencies, weaknesses or lack of compliance could have a materially adverse effect on our ability to comply with the reporting requirements of the Exchange Act, which is necessary to maintain our public company status. If we were to fail to fulfill those obligations, our ability to continue as a U. S. public company would be in jeopardy in which event you could lose your entire investment in our Company. Unanticipated changes in the insurance market or factors affecting self- insurance reserve estimates could have a material adverse effect on our business, financial condition and results of operations. We use a combination of insurance and self- insurance coverage to provide for potential liabilities for workers' compensation, general liability, property losses, auto liability, directors and officers liability, pharmacy liability and employee health care benefits. However, there are types of losses we may incur but against which we cannot be insured or which we believe are not economically reasonable to insure, such as losses due to acts of war, employee and certain other crime, certain wage and hour and other employment- related claims, including class actions, actions based on certain customer protection laws, certain cyber events and some natural and other disasters or similar events. If we incur these losses and they are material, our business could suffer. Liabilities associated with the risks that are retained by us are determined, based in part, by considering historical claims experience, severity factors, inflation, and other actuarial assumptions. Our determination of the risk we retain is subject to a high degree of variability related to, among other things, future interest and inflation rates, future economic conditions, litigation trends and benefit- level changes. Any deviation of actual claims and other expenses related to these and other risks in excess of our assumptions, estimates, and historical trends, may have a material adverse effect on our business, financial condition and results of operations. We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability due to the ongoing military conflict between Russia and Ukraine and Israel and Hamas. U. S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine. In February 2022, Russia launched a full- scale military invasion of Ukraine. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets. Additionally, Russia' s prior annexation of Crimea, recent recognition of two separatist republics in the Donetsk and Luhansk regions of Ukraine and subsequent military interventions in Ukraine have led to sanctions and other penalties being levied by the United States, European Union and other countries against Russia, Belarus, the Crimea Region of Ukraine, the so- called Donetsk People' s Republic, and the so- called Luhansk People' s Republic, including agreement to remove certain Russian financial institutions from the Society for Worldwide Interbank Financial Telecommunication (SWIFT) payment system. Additional potential sanctions and penalties have also been proposed and / or threatened. Russian military actions and the resulting sanctions could adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds. On October 7, 2023, Hamas launched a series of attacks on civilian and military targets in Southern and Central Israel, to which the Israel Defense Forces have responded. In addition, Hezbollah has attacked military and civilian targets in Northern Israel, to which Israel has responded. How long and how severe the current conflict in Gaza becomes is unknown at this time and any continued clash among Israel, Hamas or Hezbollah or other countries or militant groups in the region may escalate in the future into a greater regional conflict. Any of the abovementioned factors could affect our business, prospects, financial condition, and operating results. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this Annual Report on Form 10- K. Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non- performance by financial institutions or transactional counterparties, could adversely affect our business, financial condition and results of operations. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past led and may in the future lead to market- wide liquidity problems. On March 10 and March 12, 2023, the Federal Deposit Insurance Corporation (“ FDIC ”) took control and was appointed receiver of Silicon Valley Bank (“ SVB ”) and Signature Bank, respectively, after each bank was unable to continue its operations. We are unable to predict the extent or nature of the impacts of the failures of SVB and Signature Bank and related circumstances at this time. Similarly, we cannot predict the impact that the high market volatility and instability of the banking sector more broadly could have on economic activity and our business in particular. The failure of other banks and financial institutions and measures taken, or not taken, by governments, businesses and other organizations in response to these events could adversely impact our business, financial condition and results of operations. Although we do not hold any of our funds at SVB or Signature Bank, if the financial institutions with which we do business enter receivership or become insolvent in the future, there is no guarantee that the Department of the Treasury, the Federal Reserve and the FDIC will intercede to provide us and other depositors with access to balances in excess of the \$ 250, 000 FDIC insurance limit, that we would be able to access our existing cash, ~~cash equivalents and investments~~, that we would be able to maintain any required letters of credit or other credit support arrangements, or that we would be able to adequately fund our business for a prolonged period of time or at all, any of which could have a material adverse effect on our business, financial condition and results of operations. In addition, if any parties with which we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to continue to fund their business and perform their obligations to us could be adversely affected, which, in turn, could have a material adverse effect on our business, financial condition and results of operations.