Risk Factors Comparison 2025-03-05 to 2024-03-13 Form: 10-K

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~~Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $ 1. 2 trillion for fiscal years 2012 through 2021, triggering the legislation' s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2031 unless additional Congressional action is taken. However, COVID- 19 pandemic relief legislation suspended the 2 % Medicare sequester from May 1, 2020 through March 31, 2021. Under current legislation, the actual reduction in Medicare payments varied from 1 % in 2022 to up to 3 % in the final fiscal year of this sequester. Additionally, in March 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminated the statutory Medicaid drug rebate cap, which was previously set at 100 % of a drug' s average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U. S. Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, in July 2020 and September 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration' s proposals. The FDA also released a final rule and guidance implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, in November 2020, the Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule was delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also created a new safe harbor for price reductions reflected at the point- of- sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which also was delayed until January 1, 2023. In January 2024, the FDA authorized the state of Florida to import certain prescription drugs from Canada, and future authorizations may occur. In July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to Biden' s executive order, in September 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022, which, among other things, contains substantial drug pricing reforms that will reduce drug spending by the federal government. For example, the Inflation Reduction Act of 2022 limits the prices paid by Medicare for various prescription drugs and requires drug manufacturers to pay rebates to Medicare if they increase prices faster than inflation for drugs used by Medicare beneficiaries. Although the effect of the Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known, the Inflation Reduction Act of 2022 could affect the prices we can charge and the reimbursement we can receive for our product candidates, if approved, thereby reducing our profitability. We also expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates if approved or additional pricing pressures. The Foreign Corrupt Practices Act The Foreign Corrupt Practices Act, or the FCPA, prohibits any U. S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Additional Regulation In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations. Other Regulations We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental~~

protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future. Employees As of December 31, 2023, we had 27 employees, 26 of whom were full- time employees and one of whom was a temporary employee. As of December 31, 2023, 17 of our employees were engaged in research and development activities and 10 of our employees were engaged in business development, legal, finance, market development, information systems, facilities, human resources or administrative support. As of December 31, 2023, all of our employees were located in the United States. None of our United States employees are represented by any collective bargaining agreements. We believe that we maintain good relations with our employees. Corporate Information On January 9, 2020, Protara Therapeutics, Inc. (formerly ArTara Therapeutics, Inc., formerly Proteon Therapeutics, Inc., or the Company or Protara), and privately- held ArTara Subsidiary, Inc., or Private ArTara, completed the merger and reorganization, or the Merger, in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated September 23, 2019, or the Merger Agreement, by and among the Company, Private ArTara and REM 1 Acquisition, Inc., a wholly owned subsidiary of the Company, or Merger Sub, whereby Merger Sub merged with and into Private ArTara, with Private ArTara surviving as a wholly owned subsidiary of the Company. The Merger was structured as a reverse merger and Private ArTara was determined to be the accounting acquirer based on the terms of the Merger and other factors. We were originally incorporated in Delaware in March 2006, and at that time, acquired Proteon Therapeutics, LLC, the predecessor of Protara, which was formed in June 2001. Our principal executive offices are located at 345 Park Avenue South, 3rd Floor, New York, New York 10010, our telephone number is (646) 844- 0337 and our website address is www. protaratx. com. The contents of our website are not incorporated into this Annual Report on Form 10- K and our reference to the URL for our website is intended to be an inactive textual reference only. The information contained on, or that can be accessed through, our website is not a part of this document. Unless the context requires otherwise, references in this Annual Report on Form 10- K to " Protara ", " TARA ", " we ", " us ", the " Company " and " our " refer to Protara Therapeutics, Inc. (formerly ArTara Therapeutics, Inc., formerly Proteon Therapeutics, Inc.) and our subsidiaries. Available Information Annual Reports on Form 10- K, Quarterly Reports on Form 10- Q, Current Reports on Form 8- K, and amendments to reports filed pursuant to Sections 13 (a) and 15 (d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, will be made available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Item 1A. Risk Factors. You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report on Form 10- K and in our other public filings, in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations, and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline. Risks Related to Our Financial Condition We have a limited operating history and have never generated any revenues. We are a clinical stage biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. Our operations have been limited to organizing and staffing the Company, business planning, raising capital, developing our pipeline assets (TARA- 002 and IV Choline Chloride), identifying product candidates, and other research and development. Although our employees have made regulatory submissions and conducted successful clinical trials in the past across many therapeutic areas while employed at other companies, we have not yet demonstrated an ability to successfully complete any clinical trials and have never completed the development of any product candidate, nor have we ever generated any revenue from product sales or otherwise. Consequently, we have no meaningful operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products. We expect to incur significant expenses and significant losses for the foreseeable future and may never generate revenue or achieve or maintain profitability. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have never generated any revenues, and cannot estimate with precision the extent of our future losses. We expect to incur increasing levels of operating losses for the foreseeable future as we execute on the plan to continue research and development activities, including the ongoing and planned clinical development of our product candidates, potentially acquire new products and / or product candidates, seek regulatory approvals of and potentially commercialize any approved product candidates, hire additional personnel, protect our intellectual property, and incur the additional costs of operating as a public company. We expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital. To become and remain profitable, we must develop or acquire and eventually commercialize a product with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval, manufacturing, marketing and selling any product candidate for which we obtain marketing approval, and satisfying post- marketing requirements, if any. We may never succeed in these activities and, even if we succeed in obtaining approval for and commercializing one or more products, we may never generate revenues that are significant enough to achieve profitability. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. Furthermore, because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and may continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable would decrease the value of us and could impair our ability to raise capital, maintain our research and development efforts, expand the business or continue operations. A decline in our value could also cause you to lose all or part of your investment. We will need to raise additional financing in the future to fund our operations, which may not be available to

us on favorable terms or at all. We will require substantial additional funds to conduct the costly and time- consuming preclinical studies and clinical trials necessary to pursue regulatory approval of each potential product candidate and to continue the development of TARA- 002 and IV Choline Chloride in new indications or uses. Our future capital requirements will depend upon a number of factors, including: the number and timing of future product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete preclinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; and the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance. Raising additional capital may be costly or difficult to obtain and could significantly dilute stockholders' ownership interests and divert our management' s focus on achieving our business objectives. As a result of economic conditions, general global economic uncertainty, U. S. and foreign political conditions, and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. Further, rising inflation has, in part, caused a disruption in the capital markets and an increase in interest rates, which may lead to a recession or market correction that could impact our access to capital, increase the cost of capital, and could in the future negatively affect our liquidity. A recession or market correction, inflation and / or further increases in interest rates could materially affect our business and the value of our common stock. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interests of our common stockholders will be diluted. In addition, any debt financing may subject us to fixed payment obligations and 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 capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. Even if we were to obtain sufficient funding, there can be no assurance that it will be available on terms acceptable to us or our stockholders. Our ability to use our net operating loss carryforwards and certain other tax attributes to offset future taxable income or taxes may be limited. Under current law, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020 is limited to 80 % of taxable income. It is uncertain if and to what extent various states and localities will conform to federal tax laws. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an " ownership change " which is generally defined as a greater than 50 % change in its equity ownership value over a three- year period, the corporation' s ability to use its pre- change net operating loss carryforwards and other pre- change tax attributes to offset its post- change income or taxes may be limited. We have experienced ownership changes in the past and we may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows. Risks Related to Drug / Biologics Development and Commercialization Our business depends on the successful clinical development and regulatory approval of our product candidates, including TARA- 002 and IV Choline Chloride. The success of our business, including our ability to finance our operations and generate revenue in the future, primarily depends on the successful development and regulatory approval of our product candidates, including of TARA- 002 and IV Choline Chloride. The clinical success of TARA- 002 and IV Choline Chloride depend on a number of factors, including the following: ● the timely and successful completion of planned and ongoing preclinical studies and clinical trials, including our ongoing Phase 1 and 2 clinical trials of TARA- 002 in NMIBC and our ongoing Phase 2 clinical trial of TARA- 002 in LMs, which may be significantly slower or costlier than we currently anticipate and / or produce results that do not achieve the endpoints of the trials; ● our prevalence study and our enhanced understanding of the PN patient population as part of our IV Choline Chloride program; ● whether we are required by the FDA or similar foreign regulatory agencies to conduct additional studies beyond those planned to support the approval and commercialization of TARA- 002 and IV Choline Chloride; ● achieving and maintaining, and, where applicable, ensuring that our third- party contractors achieve and maintain compliance with their contractual obligations and with all regulatory requirements applicable to TARA- 002 and IV Choline Chloride; ● the ability of third parties with whom we contract to manufacture adequate clinical trial and commercial supplies of TARA- 002 and IV Choline Chloride, to remain in good standing with regulatory agencies and to develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP; ● a continued acceptable safety profile during clinical development and following approval of TARA- 002 and IV Choline Chloride; and ● the existence of a regulatory environment conducive to the successful development of TARA- 002 and IV Choline Chloride, including in the event of a potential or actual government shutdown affecting Federal agencies such as the FDA, which could impact the FDA' s ability to timely review and process regulatory submissions. If any one of these factors is not present, many of which are beyond our control, we could experience significant delays or an inability to obtain regulatory approval of TARA- 002 or IV Choline Chloride. Our clinical trials may take longer to enroll than anticipated due to competing trials or otherwise or may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during their development, which could increase our costs or necessitate the abandonment or limitation of the

development of the product candidate. We have never completed a clinical trial or made a BLA or NDA submission and may be unable to successfully do so for TARA- 002 or IV Choline Chloride. The conduct of a clinical trial is a long, expensive, complicated and highly regulated process. Although our employees have conducted successful clinical trials and made regulatory submissions in the past across many therapeutic areas while employed at other companies, we, as a company, have not completed any clinical trials, or submitted a BLA or NDA and as a result may require more time and incur greater costs than we anticipate. Failure to commence or complete, or delays in clinical trials or planned regulatory submissions would prevent us from, or delay us, in obtaining regulatory approval of and commercializing TARA- 002 or IV Choline Chloride, which would adversely impact our financial performance. We rely, and expect to continue to rely, on third- party CROs and other third parties to conduct and oversee our clinical trials. If these third parties do not meet our requirements or otherwise conduct the trials as required, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, our product candidates. We rely, and expect to continue to rely, on third- party CROs to conduct and oversee our TARA- 002 and IV Choline Chloride clinical trials and studies and other aspects of product development. We also rely on various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA' s regulations and cGCP, requirements, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and record- keeping for drug and biologic products. These CROs and other third parties have and will continue to play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. We will rely heavily on these parties for the execution of our clinical trials and preclinical studies and will control only certain aspects of their activities. We and our CROs and other third- party contractors will be required to comply with cGCP and cGLP, requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities. Regulatory authorities enforce these cGCP and cGLP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCP and cGLP requirements, or reveal non- compliance from an audit or inspection, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authorities may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials or preclinical studies comply with applicable cGCP and cGLP requirements. In addition, our clinical trials generally must be conducted with product candidate produced under cGMP regulations. Our failure to comply with these regulations and policies may require us to repeat clinical trials, which would delay the regulatory approval process. If any of our CROs or clinical trial sites fail to comply with their contractual commitments or terminate their involvement in one of our clinical trials for any reason, we may not be able to enter into arrangements with alternative CROs or clinical trial sites or do so on commercially reasonable terms. In addition, if our relationship with clinical trial sites is terminated, we may experience the loss of follow- up information on patients enrolled in our clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and could receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA. 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. Preliminary, interim, or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the data we previously published. Accordingly, preliminary, interim, and topline data should be viewed with caution until the final data are available. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is 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. Our clinical development of our product candidates includes clinical trial sites outside the United States, and the FDA and applicable foreign regulatory authorities may not accept data from such sites. Our clinical development of TARA- 002 in NMIBC includes clinical trial sites outside the United States and we may in the future choose to conduct one or more of our full clinical trials outside of the United States. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the United States or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions or exclusions. Where data from foreign clinical trials or clinical trial sites are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless such data are applicable to the U. S. population and U. S. medical practice; the studies

were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on- site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable home country. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time- consuming and delay aspects of our business plan. TARA- 002 is an immunopotentiator, and one indication that we are pursuing is the treatment of LMs. There are no FDA- approved therapies for the treatment of LMs and it is difficult to predict the timing and costs of clinical development for TARA- 002 for LMs. To date, there are no FDA- approved therapies for the treatment of LMs. The regulatory approval process for novel product candidates such as TARA- 002 can be more expensive and take longer than for other, better known or extensively studied therapeutic approaches. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring TARA- 002 to market in LMs could decrease our ability to generate sufficient revenue to maintain our business. Our product candidates may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in post- approval regulatory action. Unforeseen side effects from TARA- 002 or IV Choline Chloride could arise either during clinical development or, if approved, after the product has been marketed. Undesirable side effects could cause us, any partners with which we may collaborate, or regulatory authorities to interrupt, extend, modify, delay or halt clinical trials and could result in a more restrictive or narrower label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities. Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. Any side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may harm our business, financial condition, operating results and prospects. Additionally, if we or others identify undesirable side effects, or other previously unknown problems, in connection with a product after obtaining U. S. or foreign regulatory approval, a number of potentially negative consequences could result, which could prevent us or our potential partners from achieving or maintaining market acceptance of the product and could substantially increase the costs of commercializing such product. A fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process for IV Choline Chloride. The FDA has granted fast track designation to IV Choline Chloride for the treatment of IFALD. If a drug is intended for the treatment of a serious or life- threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for fast track designation. We may not experience a faster development process, review or approval for the treatment of IFALD or any other indication. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Although the FDA has granted Rare Pediatric Disease Designation for TARA- 002 for the treatment of LMs, a BLA for TARA- 002, if approved, may not meet the eligibility criteria for a priority review voucher. Rare Pediatric Disease Designation has been granted for TARA- 002 for the treatment of LMs. In 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This provision is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a " rare pediatric disease " may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U. S. within one year following the date of approval. For the purposes of this program, a " rare pediatric disease " is a (a) serious or life- threatening disease in which the serious or life- threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and (b) rare disease or conditions within the meaning of the Orphan Drug Act. Congress has only authorized the Rare Pediatric Disease Priority Review Voucher program until September 30, 2024. However, if a drug candidate received Rare Pediatric Disease Designation before September 30, 2024, it is eligible to receive a voucher if it is approved before September 30, 2026. TARA- 002 for the treatment of LMs may not be approved by that date, or at all, and, therefore, we may not be in a position to obtain a priority review voucher prior to expiration of the program, unless Congress further reauthorizes the program. Additionally, designation of a drug for a rare pediatric disease does not guarantee that a BLA will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Finally, a Rare Pediatric Disease Designation does not lead to faster development or regulatory review of the product or increase the likelihood that it will receive marketing approval. We may or may not realize any benefit from receiving a voucher. Even if a product candidate obtains regulatory approval, it may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success. The commercial success of both TARA- 002 and IV Choline Chloride, if approved, will depend significantly on the broad adoption and use of them by physicians and patients for approved indications, and neither may be commercially successful even though the product is shown to be safe and effective. The degree and rate of physician and patient adoption of a product, if approved, and successful commercialization will depend on a number of factors, including but not limited to: ● patient demand for approved products that treat the indication for which a product is approved; ● the safety and effectiveness of the product compared to other available therapies; ● the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors; ● the cost of treatment in relation to alternative treatments

and willingness to pay on the part of patients; ● in the case of TARA- 002 for LMs, overcoming physician or patient biases toward alternative treatments for LMs; ● insurers' willingness to see the applicable indication as a disease worth treating; ● proper administration; ● patient satisfaction with the results, administration and overall treatment experience; ● the ability to successfully commercialize TARA- 002 and IV Choline Chloride in the United States and internationally, if either is approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others; ● our ability and our partners' ability to establish and enforce intellectual property rights in and to TARA- 002 and IV Choline Chloride; ● limitations or contraindications, warnings, precautions or approved indications for use different than those sought by us that are contained in the final FDA- approved labeling for the applicable product; ● any FDA requirement to undertake a Risk Evaluation and Mitigation Strategy; ● the effectiveness of our sales, marketing, pricing, reimbursement and access, government affairs, and distribution efforts; ● adverse publicity about a product or favorable publicity about competitive products; ● new government regulations and programs, including price controls and / or limits or prohibitions on ways to commercialize drugs, such as increased scrutiny on direct- to- consumer advertising of pharmaceuticals; and ● potential product liability claims or other product- related litigation. If either TARA- 002 or IV Choline Chloride is approved for use but fails to achieve the broad degree of physician and patient adoption necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business. Further, even if regulatory approvals are obtained, we may never be able to successfully commercialize TARA- 002 or IV Choline Chloride, or the FDA or comparable foreign regulatory authorities may require labeling changes or impose significant restrictions on a product' s indicated uses or marketing or impose ongoing requirements for potentially costly post- approval studies or post- market surveillance. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of TARA- 002 or IV Choline Chloride to continue our business. Before obtaining marketing approvals for the commercial sale of any product candidate, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that such product candidate is both safe and effective for use in the applicable indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety and are associated with side effects or have characteristics that are unexpected. Based on the safety profile seen in clinical testing, we may need to abandon development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more tolerable from a risk- benefit perspective. The FDA or an institutional review board may also require that we suspend, discontinue, or limit clinical trials based on safety information. Such findings could further result in regulatory authorities failing to provide marketing authorization for the product candidate. Many pharmaceutical candidates that initially showed promise in early stage testing and which were efficacious have later been found to cause side effects that prevented further development of the drug candidate and, in extreme cases, the side effects were not seen until after the drug was marketed, causing regulators to remove the drug from the market post- approval. Any adverse developments that occur in patients undergoing treatment with OK- 432 / Picibanil or in patients participating in clinical trials conducted by third parties may affect our ability to obtain regulatory approval or commercialize TARA- 002. Chugai Pharmaceutical, over which we have no control, has the rights to commercialize TARA- 002 and the originator therapy to TARA- 002, OK- 432, which is currently marketed under the name Picibanil, in Japan and Taiwan for various indications. In addition, clinical trials using Picibanil are currently ongoing in various countries around the world. If serious adverse events occur with patients using Picibanil or during any clinical trials of Picibanil conducted by third parties, the FDA may delay, limit or deny approval of TARA- 002 or require us to conduct additional clinical trials as a condition to marketing approval, which would increase our costs. If we receive FDA approval for TARA- 002 and a new and serious safety issue is identified in connection with use of Picibanil or in clinical trials of Picibanil conducted by third parties, the FDA may withdraw the approval of the product or otherwise restrict our ability to market and sell TARA- 002. In addition, treating physicians may be less willing to administer TARA- 002 due to concerns over such adverse events, which would limit our ability to commercialize TARA- 002. We may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate the potential return on investment for those product candidates. At any time, we may decide to discontinue the development of any of our product candidates for a variety of reasons, including the appearance of new technologies that make our product candidates obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses. Other Risks Related to Our Business Our product candidates, if approved, will face significant competition and their failure to compete effectively may prevent them from achieving significant market penetration. The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition, uncertain and complex patent terms, and a strong emphasis on developing newer, fast- to- market proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing and marketing of healthcare products competitive with those that we are developing, including TARA- 002 and IV Choline Chloride. We will face competition from a number of sources, such as pharmaceutical companies, biotechnology companies, generic drug companies, consumer products companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, regulatory expertise, clinical trial expertise, intellectual property portfolios, international reach, experience in obtaining patents and regulatory approvals for product candidates and other resources than we have. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long- term customer relationships with our target physicians, which could inhibit our market penetration efforts. With respect to our lead product candidate, TARA- 002, for the treatment of NMIBC and LMs, the active ingredient in TARA- 002 is a genetically distinct strain of Streptococcus pyogenes (group A, type 3) Su strain. TARA- 002 is produced through a proprietary manufacturing process. We anticipate that, if approved by the FDA, TARA- 002 will be protected by 12 years of biologic exclusivity. There are no approved

pharmacotherapies currently available for the treatment of LMs and the current treatment options include a high- risk surgical procedure and off- label use of sclerosants, including doxycycline, bleomycin, ethanol and sodium tetradecyl sulfate. There are a number of drug development companies and academic researchers exploring oral formulations of various agents including macrolides, phosphodiesterase inhibitors, and calcineurin / mTOR inhibitors. These are in early development. TARA- 002, if approved for the treatment of NMIBC, would be subject to competition from existing treatment methods of surgery, chemotherapy and immunomodulatory therapy. For example, the current standard of care for NMIBC includes intravesical BCG TICE (manufactured by Merck & Co. Inc.). Other products approved for the treatment of NMIBC include Merck & Co., Inc.' s Keytruda, Endo International plc' s Valstar, and Ferring B. V.' s Adstiladrin. Additional product candidates in development include but may not be limited to Japanese BCG Laboratory' s BCG Tokyo, Pfizer Inc.' s Sasanlimab in combination with BCG, ImmunityBio, Inc.' s VesAnktiva in combination with BCG, CG Oncology Inc.' s CG0070, enGene Inc.' s, EG- 70, Seagen Inc.' s PADCEV, Janssen' s TAR200 combined with gemcitabine plus or minus Cetrelimab, Urogen Pharma Ltd.' s Jelmyto, Theralase Technologies Inc.' s Ruvidar, and Auro BioSciences, Inc.' s Aura- 0011. Additional pharmaceutical and biotechnology companies with product candidates in development for the treatment of NMIBC include but may not be limited to Verity, AstraZeneca PLC, Bristol- Myers Squibb Company, Roche Group, Asieris Pharmaceuticals, BeiGene, Ltd, NanOlogy, LLC, Linton Pharm Co., Ltd., Lindis Biotech GmbH, Taizhou Hanzhong biomedical co. Ltd., Shionogi & Co. Ltd., Rapamycin Holdings, Inc., Vaxiion Therapeutics Inc., Incyte Corporation, LiPac Oncology, Inc., Anika Therapeutics Inc., Surge Pharmaceuticals Pvt. Ltd., and Istari Oncology, Inc. There are no treatments currently available for patients on PN who are choline- deficient. IV Choline Chloride is the only sterile injectable form of choline chloride that can be combined with parenteral nutrition. Further, the U. S. Patent and Trademark Office, or USPTO, issued to us Patent No. US 11, 311, 503 claiming a sterile aqueous choline salt composition with a term expiring in 2041. TARA- 002 and any future product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA- licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12- year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor' s own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when such processes are intended to be implemented, the BPCIA may be fully adopted by the FDA, and any such processes could have a material adverse effect on the future commercial prospects for our biological products. We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12- year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. We currently have limited marketing capabilities and no sales organization. If we are unable to grow our sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our product candidates, if approved, or generate product revenue. We currently have limited marketing capabilities and no sales organization. To commercialize our product candidates, if approved, in the United States, Canada, the European Union, Latin America and other jurisdictions we may seek to enter, we must build our marketing, sales, distribution, managerial and other non- technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. Although our employees have experience in the marketing, sale and distribution of pharmaceutical products, and business development activities involving external alliances, from prior employment at other companies, we, as a company, have no prior experience in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing, distribution and pricing / reimbursement / access capabilities would impact adversely the commercialization of these products. We have only received the exclusive rights to the materials required to commercialize TARA- 002 in territories other than Japan and Taiwan until June 17, 2030, or an earlier date if Chugai Pharmaceutical terminates the agreement with us for any number of reasons, following which such rights become non- exclusive. Pursuant to an agreement with Chugai Pharmaceutical dated June 17, 2019, as amended on July 14, 2020 (effective as of June 30, 2020), Chugai Pharmaceutical agreed to provide us with exclusive access to the starting material necessary to manufacture TARA- 002 as well as technical support necessary for us to develop and commercialize TARA- 002 anywhere in the world other than Japan and Taiwan. However, this agreement does not prevent Chugai from providing such materials and support to any third- party for medical, compassionate use and / or non- commercial research purposes and this agreement is exclusive only through June 17, 2030 or, the earlier termination of the agreement by either party. Once our rights to the materials and technology necessary to manufacture, develop and commercialize TARA- 002 are not exclusive, third parties, including those with greater expertise and greater resources, could obtain such materials and technology and develop a competing therapy, which would adversely affect our ability to generate revenue and achieve or maintain profitability. Even if

we obtain regulatory approval to begin commercializing any of our products, we would remain subject to ongoing regulatory review, which could subsequently result in a suspension or termination of sale of these products. Even after we achieve U. S. regulatory approval for a product candidate, if any, we will be subject to continued regulatory review and compliance obligations. For example, with respect to our product candidates, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. A product candidate' s approval may contain requirements for potentially costly post- approval studies and surveillance, including Phase 4 clinical trials, to monitor the safety and efficacy of the product. We will also be subject to ongoing FDA obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, pharmacovigilance and adverse event reporting, storage, advertising, promotion and recordkeeping for our product candidates. In addition, manufacturers of drug and biologic products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the manufacturing, processing, distribution or storage facility where, or processes by which, the product is made, a regulatory agency may impose restrictions on that product or us, including requesting that we initiate a product recall, or requiring notice to physicians or the public, withdrawal of the product from the market, or suspension of manufacturing. We face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate. We face an inherent risk of product liability or similar causes of action as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority and notwithstanding that we comply with applicable laws on promotional activity. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our product candidates could result in injury to a patient or potentially even death. We cannot offer any assurance that we will not face product liability suits in the future, nor can we assure you that our insurance coverage will be sufficient to cover our liability under any such cases. In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates, among others, and under some circumstances even government agencies. If we cannot successfully defend ourselves against product liability or similar claims, we will incur substantial liabilities, reputational harm and possibly injunctions and punitive actions. In addition, regardless of merit or eventual outcome, product liability claims may result in: ● withdrawal or delay of recruitment or decreased enrollment rates of clinical trial participants; ● termination or increased government regulation of clinical trial sites or entire trial programs; ● the inability to commercialize our product candidates; ● decreased demand for our product candidates; ● impairment of our business reputation; ● product recall or withdrawal from the market or labeling, marketing or promotional restrictions; ● substantial costs of any related litigation or similar disputes; ● distraction of management' s attention and other resources from our primary business; ● significant delay in product launch; ● substantial monetary awards to patients or other claimants against us that may not be covered by insurance; ● withdrawal of reimbursement or formulary inclusion; or ● loss of revenue. We have obtained product liability insurance coverage for our clinical trials. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects. Our insurance coverage may not be sufficient to cover all of our product liability- related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, restrictive and narrow, and, in the future, we may not be able to maintain adequate insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability or other similar legal actions. We will need to increase our product liability coverage if any of our product candidates receive regulatory approval, which will be costly, and we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all and for all geographies in which we wish to launch. A successful product liability claim or series of claims brought against us, if judgments exceed our insurance coverage, could decrease our cash and harm our business, financial condition, operating results and future prospects. Our employees, independent contractors, principal investigators, other clinical trial staff, consultants, vendors, CROs and any partners with whom we may collaborate may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, principal investigators, other clinical trial staff, consultants, vendors, CROs and any partners with which we may collaborate may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless, gross or negligent misconduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; anticorruption laws, anti- kickback and Medicare / Medicaid rules, or laws that require the true, complete and accurate reporting of financial information or data, books and records. If any such or similar actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative and punitive penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, debarments, contractual damages, imprisonment, reputational harm, diminished profits and future earnings, injunctions, and curtailment or cessation of our operations, any of which could adversely affect our ability to operate our business and our operating results. We may be subject to risks related to off- label use of our product candidates, if approved. The FDA strictly regulates the advertising and promotion of drug products, and drug products may only be marketed or promoted for their FDA approved uses, consistent with the product' s approved labeling. Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice,

the Office of Inspector General of the Department of Health and Human Services, state attorneys general, members of Congress and the public. For example, the FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses, and a company that is found to have improperly promoted off- label uses may be subject to significant liability. Although physicians may prescribe products for off- label uses as the FDA and other regulatory agencies do not regulate a physician' s choice of drug treatment made in the physician' s independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off- label uses of products for which marketing clearance has not been issued. Companies may only share truthful and not misleading information that is otherwise consistent with a product' s FDA approved labeling. Violations, including promotion of our products for unapproved or off- label uses, are subject to enforcement letters, inquiries and investigations, and civil, criminal and / or administrative sanctions by the FDA. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by relevant foreign regulatory authorities. In the United States, engaging in impermissible promotion of our product candidates for off- label uses can also subject us to false claims litigation under federal and state statutes, which can lead to significant civil, criminal and / or administrative penalties and fines and agreements, such as a corporate integrity agreement, that materially restrict the manner in which we promote or distribute our product candidates. If we do not lawfully promote our products once they have received regulatory approval, we may become subject to such litigation and, if we are not successful in defending against such actions, those actions could have a material adverse effect on our business, financial condition and operating results and even result in having an independent compliance monitor assigned to audit our ongoing operations for a lengthy period of time. If we or any partners with which we may collaborate are unable to achieve and maintain coverage and adequate levels of reimbursement for TARA- 002 or IV Choline Chloride following regulatory approval, their commercial success may be hindered severely. If TARA- 002 or IV Choline Chloride only becomes available by prescription, successful sales by us or by any partners with which we may collaborate depend on the availability of coverage and adequate reimbursement from third- party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third- party payors to reimburse most or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and private third- party payors is often critical to new product acceptance. Coverage decisions may depend on clinical and economic standards that disfavor new drug products when more established or lower- cost therapeutic alternatives are already available or subsequently become available, or may be affected by the budgets and demands on the various entities responsible for providing health insurance to patients who will use TARA- 002 or IV Choline Chloride. Even if we obtain coverage for our products, the resulting reimbursement payment rates might not be adequate or may require co- payments that patients find unacceptably high. Patients are unlikely to use a product unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost. In addition, the market for our products will depend significantly on access to third- party payors' drug formularies or lists of medications for which third- party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies and there may be time limitations on when a new drug may even apply for formulary inclusion. Also, third- party payors may refuse to include products in their formularies or otherwise restrict patient access to such products when a less costly biosimilar or generic equivalent or other treatment alternative is available in the discretion of the formulary. Third- party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, although private third- party payors tend to follow Medicare practices, no uniform or consistent policy of coverage and reimbursement for drug products exists among third- party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor as well as from state to state. Consequently, the coverage determination process is often a time- consuming and costly process that must be played out across many jurisdictions and different entities and that will require us to provide scientific, clinical and health economics support for the use of our products compared to current alternatives and do so to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained and in what time frame. Further, we believe that future coverage and reimbursement likely will be subject to increased restrictions both in the United States and in international markets. Third- party coverage and reimbursement for our products may not be available or adequate in either the United States or international markets, which could harm our business, financial condition, operating results and prospects. Further, coverage policies and third- party reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. Healthcare reform measures could hinder or prevent the commercial success of our product candidates. Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any future product candidates we may develop. For example, the Trump administration and certain members of the U. S. Congress sought to repeal all or part of the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, and implement a replacement program. In another example, the so- called " individual mandate " was repealed as part of tax reform legislation adopted in December 2017, informally titled the Tax Cuts and Jobs Act, or Tax Act, such that the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code was eliminated beginning in 2019. Additionally, in June 2021, the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the individual mandate was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. Further, prior to the U. S. Supreme Court ruling, in January 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that

include work requirements, and policies that create barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. For example, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. In July 2020 and September 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. The FDA also released a final rule and guidance implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, in November 2020, the Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point- of- sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of the rule has been delayed until January 1, 2026. In November 2020, the Centers for Medicare & Medicaid Services, or CMS, issued an interim final rule implementing former President Trump's Most Favored Nation, or MFN, executive order, which would tie Medicare Part B payments for certain physician- administered drugs to the lowest price paid in other economically advanced countries, and was effective as of January 1, 2021. As a result of litigation challenging the MFN model, in December 2021, CMS published a final rule that rescinded the MFN model interim final rule. Further, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, in September 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS could take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, in August 2022, President Biden signed into law the Inflation Reduction Act of 2022, which, among other things, contains substantial drug pricing reforms that will reduce drug spending by the federal government. For example, the Inflation Reduction Act of 2022 limits the prices paid by Medicare for various prescription drugs and requires drug manufacturers to pay rebates to Medicare if they increase prices faster than inflation for drugs used by Medicare beneficiaries. Although the effect of the Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known, and biopharmaceutical companies and others have filed lawsuits challenging the legality of certain parts of the statute, the Inflation Reduction Act of 2022 could affect the prices we can charge and the reimbursement we can receive for our product candidates, if approved, thereby reducing our profitability. We also expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates if approved or additional pricing pressures. There also continue to be calls to place additional restrictions on or to ban direct- to- consumer advertising of pharmaceuticals, which would limit our ability to market our product candidates. The United States is in a minority of jurisdictions that allow this kind of advertising and its removal could limit the potential reach of a marketing campaign. We are subject to strict healthcare laws, regulation and enforcement, and our failure to comply with those laws could adversely affect our business, operations and financial condition. Certain federal and state healthcare laws and regulations pertaining to fraud and abuse, privacy, transparency, and patients' rights are and will be applicable to our business. We are subject to regulation by both the federal government and the states in which we or our partners conduct business. The healthcare laws and regulations that may affect our ability to operate include but are not limited to: the federal Anti- Kickback Statute; federal civil and criminal false claims laws and civil monetary penalty laws; the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act; the Prescription Drug Marketing Act (for sampling of drug product among other things); the federal physician sunshine requirements under the Affordable Care Act; the Foreign Corrupt Practices Act as it applies to activities outside of the United States; the federal Right- to- Try legislation; and similar state laws of such federal laws, which may be broader in scope. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti- Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert management's attention from the operation of our business and result in reputational damage. If our operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, including punitive damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, imprisonment, additional oversight and reporting obligations, or the curtailment or restructuring of our operations, and injunctions, any of which could adversely affect our ability to operate our business and financial results. We may in- license and acquire product candidates and may engage in other strategic transactions, which could impact our liquidity, increase our expenses and present significant distractions to our management. Part of our strategy is to in- license and acquire product candidates and we may engage in other strategic transactions. Additional potential transactions that we may consider include a

variety of different business arrangements, including spin- offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non- recurring or other charges, may increase our near- and long- term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. Accordingly, there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, and any transaction that we complete could harm our business, financial condition, operating results and prospects. Our failure to successfully in- license, acquire, develop and market additional product candidates or approved products would impair our ability to grow our business. We may in- license, acquire, develop and market additional products and product candidates. Because our internal research and development capabilities are limited, we may be dependent on pharmaceutical and biotechnology companies, academic or government scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly on our ability to identify and select promising pharmaceutical and biologic product candidates and products, negotiate licensing or acquisition agreements with their current owners, and finance these arrangements. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in- licensing of third- party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable or at all. Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including preclinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any approved products that we acquire will be manufactured or sold profitably or achieve market acceptance. We expect to rely on agreements with third parties for the successful development and commercialization of our product candidates. We expect to rely upon the efforts of third parties for the successful development and commercialization of our current and future product candidates. The clinical and commercial success of our product candidates may depend upon maintaining successful relationships with third- party partners which are subject to a number of significant risks, including the following: ● our partners' ability to execute their responsibilities in a timely, cost- efficient and compliant manner; ● reduced control over delivery and manufacturing schedules; ● price increases and product reliability; ● manufacturing deviations from internal or regulatory specifications; ● quality incidents; ● the failure of partners to perform their obligations for technical, market or other reasons; ● misappropriation of our current or future product candidates; and ● other risks in potentially meeting our current and future anticipated commercialization schedule for product candidates or satisfying the requirements of our end- users. We cannot assure you that we will be able to establish or maintain third- party relationships in order to successfully develop and commercialize our product candidates. We rely completely on third- party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates, which may include sole- source suppliers and manufacturers; we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates receive regulatory approval; and we expect to rely on third parties for supply, manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates. We do not currently have, nor do we plan to acquire, the infrastructure or capability to supply, store, manufacture or distribute preclinical, clinical or commercial quantities of drug substances or products. Additionally, we have not entered into a long- term commercial supply agreement to provide us with such drug substances or products. As a result, our ability to develop our product candidates is dependent, and our ability to supply our products commercially will depend, in part, on our ability to obtain active pharmaceutical ingredient, or API, and other substances and materials used in our product candidates successfully from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing and commercialization. If we fail to develop and maintain supply and other technical relationships with these third parties, we may be unable to continue to develop or commercialize our products and product candidates. We do not have direct control over whether our contract suppliers and manufacturers will maintain current pricing terms, be willing to continue supplying us with API and finished products or maintain adequate capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. We are dependent on our contract suppliers and manufacturers for day- to- day compliance with applicable laws and cGMP for production of both API and finished products. If the safety or quality of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to commercialize or obtain regulatory approval for the affected product or product candidate successfully, and we may be held liable for injuries sustained as a result. In order to conduct larger or late- stage clinical trials for our product candidates and supply sufficient commercial quantities of any of our products, if approved, our contract manufacturers and suppliers will need to produce our API and other substances and materials used in our product candidates in larger quantities, more cost- effectively and, in certain cases, at higher yields than they currently achieve. If our third- party contractors are unable to scale up the manufacture of any of our product candidates successfully in sufficient quality and quantity and at commercially reasonable prices, or are shut down or put on clinical hold by government regulators, and we are unable to find one or more replacement suppliers or manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to transfer the processes successfully on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, operating results and prospects. We expect to continue to depend on third- party contract suppliers and manufacturers for the foreseeable future. Our supply and

~~manufacturing agreements, if any, do not guarantee that a contract supplier or manufacturer will provide services adequate for our needs. Additionally, any damage to or destruction of our third- party manufacturers' or suppliers' facilities or equipment, even by force majeure, may significantly impair our ability to have our products and product candidates manufactured on a timely basis. Our reliance on contract manufacturers and suppliers further exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate our trade secrets or other proprietary information. In addition, the manufacturing facilities of certain of our suppliers may be located outside of the United States. This may give rise to difficulties in importing our products or product candidates or their components into the United States or other countries. The manufacture of biologics is complex and our third- party manufacturers may encounter difficulties in production. If our CDMO encounters such difficulties, the ability to provide supply of TARA- 002 for clinical trials, our ability to obtain marketing approval, or our ability to obtain commercial supply of TARA- 002, if approved, could be delayed or stopped. We have no experience in biologic manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. We are completely dependent on CDMOs to fulfill our clinical and commercial supply of TARA- 002. The process of manufacturing biologics is complex, highly regulated and subject to multiple risks. Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions and higher costs. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of drug product and adversely harm our business. Moreover, if the FDA determines that our manufacturer is not in compliance with FDA laws and regulations, including those governing cGMP, the FDA may deny BLA approval until the deficiencies are corrected or we replace the manufacturer in our BLA with a manufacturer that is in compliance.~~ In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale- up, process reproducibility, stability issues, compliance with cGMP, lot consistency and timely availability of raw materials. Even if we obtain regulatory approval for TARA- 002 or any future product candidates, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. Scaling up a biologic manufacturing process is a difficult and uncertain task, and any CDMO we contract may not have the necessary capabilities to complete the implementation and development process of further scaling up production, transferring production to other sites, or managing its production capacity to timely meet product demand. **Our CDMOs and suppliers use biological materials and may use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time- consuming or costly. Our CDMOs and suppliers may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. The operations of our third- party manufacturers and suppliers also produce hazardous waste products. Federal, state, and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay. As product candidates proceed through preclinical studies to late- stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.** If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan. Our ability to compete in the highly competitive biopharmaceuticals industry depends on our ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in- licensing or acquisition of new assets and could impact negatively our ability to implement successfully our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We might not be able to attract or retain qualified management and other key personnel in the future due to

the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. From time to time, the United States has experienced a decrease in unemployment rates and an increasingly competitive labor market, which has at times resulted in difficulties in hiring or retaining sufficient qualified personnel to maintain and grow our business. We are uncertain as to the employment environment in the future, or how that environment will impact our workforce, including our ability to attract and retain qualified management and other key personnel. We **or the third parties upon which we depend** may be adversely affected by natural disasters and other catastrophic events and by man- made problems such as terrorism and war that could disrupt our business operations, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Our office is located in New York, New York. If a disaster, power outage, computer hacking, or other event occurred that prevented us from using all or a significant portion of an office, that damaged critical infrastructure, such as enterprise financial systems, IT systems, manufacturing resource planning or enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. For example, we have expanded our clinical development of TARA- 002 in NMBIC to clinical trial sites outside the United States, including in Ukraine **, Canada, Argentina** ~~and potentially in other countries in Europe~~ and may expand to other geographies. If political or civil conditions require it, our sites may need to delay or suspend clinical trial activities. In addition, enrollment and retention of patients at such sites could be disrupted by geopolitical events, including civil or political unrest, such as the current ongoing conflict between Russia and Ukraine. All of the aforementioned risks may be further increased if we do not implement a disaster recovery plan or our partners' or manufacturers' disaster recovery plans prove to be inadequate. To the extent that any of the above should result in delays in the research, development, regulatory approval, manufacture, distribution or commercialization of TARA- 002 or IV Choline Chloride, our business, financial condition, operating results and prospects would suffer. The effects of epidemics and pandemics and their corresponding macroeconomic impacts could materially and adversely impact our business, including our clinical development plans and non-clinical research. As a result of the COVID- 19 pandemic and the associated health and safety measures that were imposed, we had and, in the event of a resurgence of the pandemic or the onset of another public health crisis, may again experience, disruptions that could severely impact our business, including but not limited to delays or difficulties in clinical trial site operations and in the enrollment, scheduling and retention of patients in our clinical trials; interruption of key manufacturing, research and clinical development and other activities; and delays or difficulties conducting and completing non- clinical studies. In addition, macroeconomic factors, including supply chain disruptions, rising inflation and resulting increases in interest rates, which were, in part, tied to the impacts of the COVID- 19 pandemic, had an impact on our operations **,** and any future pandemic or public health crisis may have the same effects. Similarly, if banks and financial institutions enter receivership or become insolvent in the future due to financial conditions affecting the banking system and financial markets, there could be an adverse effect on our ability to access our cash ~~,~~ **and** cash equivalents and investments, including transferring funds, making payments or receiving funds, any of which could have a material adverse effect on our business and financial condition. If we are not able to respond to and manage the impact of such events effectively, our business will be harmed. Risks Related to Our Common Stock We expect our stock price to be highly volatile. The market price of our shares could be subject to significant fluctuations. Market prices for securities of biotechnology and other life sciences companies historically have been particularly volatile, even subject to large daily price swings. For example, the closing price of our common stock from the period January 1, ~~2023~~ **2024** to December 31, ~~2023~~ **2024** has ranged from a low of $ 1. ~~13~~ **62** to a high of $ ~~3~~ **6** . ~~91~~ **67** . Some of the factors that may cause the market price of our shares to fluctuate include, but are not limited to: ● the results of current and any future clinical trials of TARA- 002 or IV Choline Chloride and any clinical trial failure, including any failure resulting from difficulties or delays in identifying patients, enrolling patients, retaining patients, meeting specific **clinical** trial endpoints or completing and timely reporting the results of any **clinical** trial; ● our ability to obtain regulatory approvals for TARA- 002, IV Choline Chloride or future product candidates, and delays of, or failures to obtain such approvals; ● the failure of TARA- 002 or IV Choline Chloride or future product candidates, if approved, to achieve commercial success; ● potential side effects associated with TARA- 002 or IV Choline Chloride or future product candidates; ● issues in manufacturing, or the inability to obtain adequate supply of, TARA- 002, IV Choline Chloride or future product candidates; ● the entry into, or termination of, or breach by partners of key agreements, including key commercial partner agreements; ● the initiation of, material developments in, or conclusion of, any litigation or other actions to enforce or defend any intellectual property rights or defend against the intellectual property rights of others; ● announcements of any dilutive equity financings; ● inability to obtain additional funding; ● announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments; ● failure to elicit meaningful stock analyst coverage and downgrades of our stock by analysts; ● the loss of key employees; ● changes in laws or regulations application to TARA- 002 or IV Choline Chloride or future product candidates; and ● sales of our common stock by us, our insiders or our other stockholders. Moreover, the stock markets in general have experienced substantial volatility in our industry that has often been unrelated to the operating performance of individual companies or a certain industry segment. These broad market fluctuations may also adversely affect the trading price of our shares. In the past, following periods of volatility in the market price of a company' s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation. In addition, such securities litigation often has ensued after a reverse merger or other merger and acquisition activity. Such litigation if brought could impact negatively our business. We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies. As a public company, we have incurred, and will continue to incur, significant legal, accounting and other expenses, including costs associated with public company reporting and other SEC requirements. We have also incurred, and will continue to incur, costs associated with corporate governance requirements, including requirements under the Exchange Act, the Sarbanes- Oxley Act

and other applicable legislation, as well as rules implemented by the SEC and Nasdaq. We expect the rules and regulations applicable to public companies will continue to substantially increase our legal and financial compliance costs and to make some activities more time- consuming and costly. Our executive officers and other personnel will need to continue to devote substantial time to managing operations as a public company and compliance with applicable laws and regulations. These rules and regulations may also make it expensive for us to operate our business. If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired **, investors may lose confidence in our financial reporting and the trading price of our common stock may decline** . We are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process ~~evaluation~~ **evaluations** and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10- K filing for that year, as required by Section 404 of the Sarbanes- Oxley Act. ~~This~~ **While we remain a smaller reporting company and non- accelerated filer, we** will **not be** ~~require~~ **required** ~~that~~ **to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. When** we **cease to be a smaller reporting company and no longer qualify as a non- accelerated filer, we would** incur substantial professional fees and internal costs to expand our accounting and finance functions ~~and that we expend significant management efforts~~ . We may experience difficulty in meeting these reporting requirements in a timely manner. We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system' s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities or by Nasdaq. We are able to take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies, which could result in our common stock being less attractive to investors. We qualify as a smaller reporting company under the rules of the SEC. As a smaller reporting company, we are able to take advantage of reduced disclosure requirements, such as certain simplified executive compensation disclosures and reduced financial statement disclosure requirements in our SEC filings. Comparatively reduced disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for our investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive due to our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of the reporting exemptions applicable to a smaller reporting company until we are no longer a smaller reporting company, which status would end once we have a public float greater than $ 250 million. In that event, we could still be a smaller reporting company if our annual revenues were below $ 100 million and we have a public float of less than $ 700 million. We do not anticipate paying any dividends in the foreseeable future. The current expectation is that we will retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of your shares of our stock will be your sole source of gain, if any, for the foreseeable future. If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline. **We will not receive a significant amount, or potentially any, additional funds upon the exercise of our Pre- Funded Warrants; however, any exercise would increase the number of shares eligible for future resale in the public market and result in substantial dilution to our stockholders. In April 2024 and December 2024, we issued Pre- Funded Warrants to purchase a total of 1, 700, 000 and 2, 325, 372 shares of our common stock, respectively, all of which are outstanding as of the date of this report. Each Pre- Funded Warrant is exercisable for $ 0. 001 per share of common stock underlying such Pre- Funded Warrant. Accordingly, we will not receive a significant amount of additional funds upon the exercise of the Pre- Funded Warrants. To the extent such Pre-Funded Warrants are exercised, additional shares of common stock will be issued for nominal consideration, which will result in dilution to the then existing holders of our common stock and will increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could adversely affect the market price of the common stock, causing our stock price to decline. The number of shares of common stock underlying our outstanding warrants is significant in relation to our currently outstanding common stock, which could have a negative effect on the market price of our common stock and make it more difficult for us to raise funds through future equity offerings. In addition, in connection with any merger, consolidation or sale of all or substantially all of our assets, holders of our outstanding warrants would be entitled to receive consideration in excess of their reported beneficial ownership of our common stock and this could adversely impact the consideration our other stockholders**

would receive. In April 2024 and December 2024, we issued the Pre- Funded Warrants and the Common Warrants. Each Common Warrant is exercisable solely by means of a cash exercise, except that the Common Warrant is exercisable via cashless exercise if at the time of exercise, a registration statement registering the issuance of the shares of common stock underlying the common stock warrants under the Securities Act of 1933, as amended, is not then effective. The Common Warrants include certain rights upon " fundamental transactions " as described in the Common Warrants. Additionally, each holder of warrants will not be entitled to exercise any portion of any Pre- Funded Warrant or Common Warrant, which, upon giving effect to such exercise, would cause (A) for the holders of the April 2024 Pre-Funded Warrants and Common Warrants, (i) the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 9. 99 %, or for certain holders, 4. 99 %, of the number of shares of our common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of our securities beneficially owned by the holder (together with its affiliates) to exceed 9. 99 % of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise and (B) for the holders of the December 2024 Pre- Funded Warrants, the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 4. 99 % of the number of shares of our common stock outstanding immediately after giving effect to the exercise. However, for the April 2024 Pre- Funded Warrants, December 2024 Pre-Funded Warrants and Common Warrants, any holder may increase or decrease such percentage to any other percentage (not in excess of 19. 99 %) upon prior notice from the holder to us. Although these warrants are subject to beneficial ownership limitations, upon exercise in full of the warrants, the shares issuable upon exercise would represent a significant portion of our outstanding common stock. As a result, the holders of these warrants may be able to exert substantial influence over our business. The concentration of voting power resulting from the exercise of the warrants could delay, defer or prevent a change of control, entrench our management and our board of directors or delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire. In addition, conflicts of interest could arise in the future between us and the holders of these warrants concerning potential competitive business activities, business opportunities, the issuance of additional securities and other matters. In addition, sales of these shares could cause the market price of our common stock to decline significantly. We have registered the issuance and / or resale of shares issuable upon exercise of these warrants under an effective registration statement. As a result, the shares issuable upon exercise of these warrants can be freely sold in the public market upon issuance. Sales of these shares could cause the market price of our common stock to decline significantly. Furthermore, if our stock price rises, the holders of these warrants may be more likely to exercise their warrants and sell a large number of shares, which could negatively impact the market price of our common stock and reduce or eliminate any appreciation in our stock price that might otherwise occur. Given the amount and terms of these warrants, we may find it more difficult to raise additional equity capital on favorable terms or at all while these warrants are outstanding. Risk Related to Our Ownership Structure and Governance Certain stockholders have the ability to control or significantly influence certain matters submitted to our stockholders for approval. Certain stockholders have consent rights over certain significant matters of our business. These include decisions to effect a merger or other similar transaction, changes to our principal business, and the sale or other transfer of TARA- 002 or other assets with an aggregate value of more than $ 2, 500, 000. As a result, these stockholders have significant influence over certain matters that require approval by our stockholders. Anti- takeover provisions in our charter documents and under Delaware law could make an acquisition of our business more difficult and may prevent attempts by our stockholders to replace or remove management. Provisions in our certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which prohibits stockholders owning in excess of 15 % of the outstanding voting stock from merging or combining with us. These provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management. Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees. Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to any provisions of the DGCL, our certificate of incorporation or our bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for certain disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in the certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions. Risks Related to Intellectual Property Rights We may not be able to obtain, maintain or enforce global patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us. Our success with respect to our product candidates will depend, in part, on our ability to obtain and maintain patent protection in both the United States and other countries, to preserve our trade secrets and to prevent third parties from infringing on our proprietary rights. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents around the world. The patent application process, also known as patent prosecution, is expensive and time- consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all

necessary or desirable patent applications at a reasonable cost or in a timely manner in all the countries that are desirable. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, our competitors independently may develop equivalent knowledge, methods and know- how or discover workarounds to our patents that would not constitute infringement. Any of these outcomes could impair our ability to enforce the exclusivity of our patents effectively, which may have an adverse impact on our business, financial condition and operating results. Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions especially across countries. Accordingly, rights under any existing patents or any patents we might obtain or license may not cover our product candidates or may not provide us with sufficient protection for our product candidates to afford a sustainable commercial advantage against competitive products or processes, including those from branded, generic and over- the- counter pharmaceutical companies. In addition, we cannot guarantee that any patents or other intellectual property rights will issue from any pending or future patent or other similar applications owned by or licensed to us. Even if patents or other intellectual property rights have issued or will issue, we cannot guarantee that the claims of these patents and other rights are or will be held valid or enforceable by the courts, through injunction or otherwise, or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us in every country of commercial significance that we may target. Competitors in the field of immunology and oncology therapeutics have created a substantial amount of prior art, including scientific publications, posters, presentations, patents and patent applications and other public disclosures including on the Internet. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. We do not have outstanding issued patents covering all of the recent developments in our technology and are unsure of the patent protection that we will be successful in obtaining, if any. Even if the patents do successfully issue, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates is challenged, it could dissuade companies from collaborating with us to develop or threaten our ability to commercialize or finance our product candidates. The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent or duration as in the United States, and many companies have encountered significant difficulties in acquiring, maintaining, protecting, defending and especially enforcing such rights in foreign jurisdictions. If we encounter such difficulties in protecting, or are otherwise precluded from effectively protecting, our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed, especially internationally. Proprietary trade secrets and unpatented know- how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know- how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with officers, directors, employees, and certain consultants and advisors, there can be no assurance that binding agreements will not be breached or will be enforced by courts, that we would have adequate remedies for any breach, including injunctive and other equitable relief, or that our trade secrets and unpatented know-how will not otherwise become known, inadvertently disclosed by us or our agents and representatives, or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use and if we and our agents or representatives inadvertently disclose trade secrets and / or unpatented know- how, we may not be allowed to retrieve this and maintain the exclusivity we previously enjoyed. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on our product candidates does not guarantee exclusivity. The requirements for patentability differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States, especially when it comes to granting use and other kinds of patents and what kind of enforcement rights will be allowed, especially injunctive relief in a civil infringement proceeding. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States and even in launching an identical version of our product notwithstanding we have a valid patent in that country. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, or produce copy products, and, further, may export otherwise infringing products to territories where we have patent protection but enforcement on infringing activities is inadequate or where we have no patents. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our global patents at risk of being invalidated or interpreted narrowly and our global 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 or infringement actions brought against us, and the damages or other remedies awarded, if any, may not be commercially meaningful when we are the plaintiff. When we are the defendant we may be required to post large bonds to stay in the market while we defend ourselves from an infringement action. In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties, especially if the patent owner does not enforce or use its patents over a protracted period of time. In some cases, the courts will force compulsory licenses on the patent holder even

when finding the patent holder' s patents are valid if the court believes it is in the best interests of the country to have widespread access to an essential product covered by the patent. In these situations, the royalty the court requires to be paid by the license holder receiving the compulsory license is not calculated at fair market value and can be inconsequential, thereby adversely affecting the patent holder' s business. In these countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third- party, which could also materially diminish the value of those patents. This would limit our potential revenue opportunities. 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 own or license, especially in comparison to what we enjoy from enforcing our intellectual property rights in the Unites States. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in both U. S. and foreign intellectual property laws, or changes to the policies in various government agencies in these countries, including but not limited to the patent office issuing patents and the health agency issuing pharmaceutical product approvals. For example, in Brazil, pharmaceutical patents require initial approval of the Brazilian health agency (ANVISA). Finally, many countries have large backlogs in patent prosecution, and in some countries in Latin America it can take years, even decades, just to get a pharmaceutical patent application reviewed notwithstanding the merits of the application. Obtaining and maintaining 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. Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction just for failure to know about and / or timely pay a prosecution fee. 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 in prescribed time periods, and failure to properly legalize and submit formal documents in the format and style the country requires. If we or our licensors fail to maintain the patents and patent applications covering our product candidates for any reason, our competitors might be able to enter the market, which could materially adversely affect our business, financial condition, operating results and prospects. If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business. Additionally, these agreements may be subject to disagreement over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors. We have entered into in- license arrangements with respect to certain of our product candidates. These license agreements impose various diligence, milestone, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the respective licensors may have the right to terminate the license, in which event we may not be able to develop or market the affected product candidate. The loss of such rights could materially adversely affect our business, financial condition, operating results and prospects. If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates. Our commercial success depends on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We cannot assure that marketing and selling such candidates and using such technologies will not infringe existing or future patents. Numerous U. S.- and foreign- issued patents and pending patent applications owned by third parties exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our product candidates, technologies or methods of delivery or use infringe their patent rights. Moreover, it is not always clear to industry participants, including us, which patents and other intellectual property rights cover various drugs, biologics, drug delivery systems or their methods of use, and which of these patents may be valid and enforceable. Thus, because of the large number of patents issued and patent applications filed in our fields across many countries, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods. In addition, there may be issued patents of third parties that are infringed or are alleged to be infringed by our product candidates or proprietary technologies notwithstanding patents we may possess. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our own and in- licensed issued patents or our pending applications. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to our technology. Any such patent application may have priority over our own and in- licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies, which may mean paying significant licensing fees or the like. If another party has filed a U. S. patent application on inventions similar to those owned or in- licensed to us, or, in the case of in- licensed technology, the licensor may have to participate, in the United States, in an interference proceeding to determine priority of invention. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates or proprietary technologies infringe such third parties' intellectual property rights, including litigation resulting from filing under Paragraph IV of the Hatch- Waxman Act or other countries' laws similar to the Hatch- Waxman Act. These lawsuits could claim that there are existing patent rights for such drug, and this type of litigation can be costly and could adversely affect our operating results and divert the attention of managerial and technical personnel, even if we do not infringe such patents or the patents asserted against us are ultimately established as invalid. There is a risk that a court would decide that

we are infringing the third- party' s patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court would order us to pay the other party significant damages for having violated the other party' s patents. Because we rely on certain third- party licensors and partners and will continue to do so in the future, if one of our licensors or partners is sued for infringing a third- party' s intellectual property rights, our business, financial condition, operating results and prospects could suffer in the same manner as if we were sued directly. In addition to facing litigation risks, we have agreed to indemnify certain third- party licensors and partners against claims of infringement caused by our proprietary technologies, and we have entered or may enter into cost- sharing agreements with some our licensors and partners that could require us to pay some of the costs of patent litigation brought against those third parties whether or not the alleged infringement is caused by our proprietary technologies. In certain instances, these cost- sharing agreements could also require us to assume greater responsibility for infringement damages than would be assumed just on the basis of our technology. The occurrence of any of the foregoing could adversely affect our business, financial condition or operating results. We may be subject to claims that our officers, directors, employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their former employers or their former or current customers. As is common in the biotechnology and pharmaceutical industries, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our products and product candidates, many of whom were previously employed at, or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees and consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. Even if we are successful in defending against any such claims, any such litigation could be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties, and may potentially result in an unfavorable outcome. General Risk Factors **We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; a disruption of our business operations, including our clinical trials; harm to our reputation; and other adverse effects on our business or prospects. In the ordinary course of business, we collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share, or collectively, Process (or Processing of), personal data and other sensitive and confidential information, including information we collect about patients in connection with clinical trials, sensitive third- party data or, as necessary to operate our business, for legal and marketing purposes, and for other business- related purposes. Accordingly, we are, or may become, subject to numerous federal, state, local and international data privacy and security laws, regulations, guidance and industry standards as well as external and internal privacy and security policies, contracts and other obligations that apply to the Processing of personal data by us and on our behalf, collectively, Data Protection Requirements. The number and scope of Data Protection Requirements are changing, subject to differing applications and interpretations, and may be inconsistent between jurisdictions or in conflict with each other. If we fail, or are perceived to have failed, to address or comply with Data Protection Requirements, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions against us that could include investigations, fines, penalties, audits and inspections, additional reporting requirements and / or oversight, temporary or permanent bans on all or some Processing of personal data, orders to destroy or not use personal data. Further, individuals or other relevant stakeholders could bring a variety of claims against us for our actual or perceived failure to comply with the Data Protection Requirements. Any of these events could have a material adverse effect on our reputation, business, or financial condition, and could lead to a loss of actual or prospective customers, collaborators or partners; interrupt or stop clinical trials; result in an inability to Process personal data or to operate in certain jurisdictions; limit our ability to develop or commercialize our products; or require us to revise or restructure our operations, or each, a material adverse impact. We are, or may become, subject to U. S. privacy laws. For example, in the United States, there are a broad variety of data protection laws and regulations that may apply to our activities such as state data breach notification laws, state personal data privacy laws (for example, the California Consumer Privacy Act of 2018, or CCPA), state health information privacy laws, and federal and state consumer protection laws. A number of U. S. states have enacted data privacy laws. In particular, the CCPA, together with the California Privacy Rights Act, or CPRA, requires covered businesses that process personal data of California residents to disclose their data collection, use and sharing practices. Further, the CCPA provides California residents with new data privacy rights (including the ability to opt out of the sale of personal data), imposes new operational requirements for covered businesses, provides for civil penalties for violations (up to $ 7, 500 per violation), as well as a private right of action for certain data breaches (that is expected to increase data breach class action litigation and result in significant exposure to costly legal judgements and settlements). The CPRA, among other things, gives California residents the ability to limit use of certain sensitive personal data, establishes restrictions on the retention of personal data, expands the types of data breaches subject to the CCPA' s private right of action, and establishes a new California Privacy Protection Agency to implement and enforce the new law. Although there are limited exemptions for clinical trial data under the CCPA and the CPRA, the CCPA and the CPRA may increase compliance costs and potential liability with respect to other personal data we maintain about California residents. The federal government is also considering comprehensive privacy legislation. Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union' s General Data Protection Regulation, or EU GDPR, the United Kingdom' s GDPR, or UK GDPR, Japan' s Act on the Protection of Personal Information, or**

APPI, China' s Personal Information Protection Law, or PIPL, and Brazil' s General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13, 709 / 2018) impose strict requirements for processing personal data. Under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4 % of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to processing of their personal data. European data protection laws (including the EU GDPR and UK GDRP) are wide- ranging in scope and impose numerous, significant and complex compliance burdens in relation to the Processing of personal data, such as: limiting permitted Processing of personal data to only that which is necessary for specified, explicit and legitimate purposes; requiring the establishment of a legal basis for Processing personal data; broadening the definition of personal data; creating obligations for controllers and processors to appoint data protection officers in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; establishing limitations on the collection and retention of personal data through " data minimization " and " storage limitation " principles; honoring data subject rights; formalizing a heightened standard to obtain data subject consent; establishing obligations to implement certain technical and organizational safeguards to protect the security and confidentiality of personal data; introducing the obligation to provide notice of certain significant personal data breaches to the relevant supervisory authority (ies) and affected individuals; and mandating the appointment of representatives in the UK and / or EU in certain circumstances. In particular, the Processing of " special categor [ies] [of] personal data " (such as personal data related to health and genetic information), which could be relevant to our operations in the context of our clinical trials, imposes heightened compliance burdens under European data protection laws and is a topic of active interest among relevant regulators. Certain jurisdictions have enacted data localization laws and cross- border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Existing mechanisms that facilitate cross- border personal data transfers may change or be invalidated. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the European Economic Area, or EEA, that the European Commission does not consider to provide an adequate level of data privacy and security, such as the United States. The European Commission released a set of " Standard Contractual Clauses, " or SCCs, that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. Currently, these SCCs are a valid mechanism to transfer personal data outside of the EEA, but there exists a possibility that the validity of SCCs will be challenged in European courts. Additionally, the SCCs impose additional compliance burdens, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at- issue personal data. In addition, Switzerland and the UK similarly restrict personal data transfers outside of those jurisdictions to countries that they do not consider to provide an adequate level of personal data protection, such as the United States, and certain countries outside Europe (e. g., Brazil) have also passed or are considering laws requiring local data residency or otherwise impeding the transfer of personal data across borders, any of which could increase the cost and complexity of doing business. While we use SCCs for transfers of personal data from the EEA, UK and Switzerland to recipients in non- adequate countries, in the event we are unable to implement a valid compliance mechanism for cross- border data transfers (e. g., SCCs are invalidated), we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. Inability to import personal data to the United States may significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties subject to European and other data protection laws or requiring us to increase our personal data processing capabilities in Europe and / or elsewhere at significant expense. These laws exemplify the vulnerability of our business to the evolving regulatory environment related to personal data and may require us to modify our Processing practices at substantial costs and expenses in an effort to comply. Given the breadth and evolving nature of Data Protection Requirements, preparing for and complying with these requirements is rigorous, time- intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third- party collaborators, service providers, contractors or consultants that Process personal data on our behalf. We may publish privacy policies and other documentation regarding our Processing of personal data and / or other confidential, proprietary or sensitive information. Although we endeavor to comply with our published policies and other documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees, third- party collaborators, service providers, contractors or consultants fail to comply with our policies and documentation. Such failures can subject us to potential regulatory action if they are found to be deceptive, unfair, or misrepresentative of our actual practices. Moreover, subjects about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights or failed to comply with data protection laws or applicable privacy notices even if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business or have other material adverse impacts. If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; loss of revenue or profits; interruptions to our operations such as our clinical trials; harm to our reputation; loss of customers or sales; and other adverse consequences. In the ordinary course of our business, we may collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share, or collectively, Process, proprietary,

confidential and sensitive information, including personal data (including, key- coded data, health information and other special categories of personal data), intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other parties, or collectively, Sensitive Information. We may use third- party service providers and subprocessors to help us operate critical business systems to Process Sensitive Information on our behalf in a variety of contexts, including without limitation, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive Sensitive Information with or from third parties. If we, our service providers, partners or other relevant third parties have experienced, or in the future experience, any security incident (s) that result in, any data loss; deletion or destruction; unauthorized access to; loss, unauthorized acquisition, disclosure, or exposure of, Sensitive Information, or compromise related to the security, confidentiality, integrity or availability of our (or their) information technology, software, services, communications or data, or collectively, a Security Incident, it may materially adversely affect our business, financial condition, operating results and prospects, including the diversion of funds to address the breach, and interruptions, delays, or outages in our operations and development programs. In the first quarter of 2020, our email server was compromised in a cyber- attack. We quickly isolated the incident and have, since, implemented additional risk prevention measures. Cyberattacks, malicious internet- based activity and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect especially as more advanced artificial intelligence and machine learning become available and increasingly used. These threats come from a variety of sources, including traditional computer " hackers ", threat actors, employee error, theft or misuse, sophisticated nation- states, and nation- state supported actors. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social- engineering attacks (including through phishing attacks); software bugs; malicious code (such as viruses and worms); denial- of- service attacks (such as credential stuffing); malware (including as a result of advanced persistent threat intrusions); supply- chain attacks, server malfunctions, software and hardware failures; loss of data or other information technology assets; adware; natural disasters; terrorism; war; telecommunication and electrical failures; ransomware attacks; and other similar threats. Ransomware attacks, including those from organized criminal threat actors, nation- states and nation- state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data, loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the financial, operational and reputational impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments). Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our systems and networks or the systems and networks of third parties that support us and our services. We may also be the subject of server malfunction, software or hardware failures, loss of data or other computer assets, and other similar issues. A significant portion of our workforce and third- party partners work remotely from time to time, and reliance on remote working technologies and the prevalent use of mobile devices that access confidential and personal data information increase the risk of Security Incidents, which could lead to the loss confidential information, personal data, trade secrets or other intellectual property. We may be required to expend additional, significant resources, fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against Security Incidents and to mitigate, detect, and remediate actual and potential vulnerabilities. Certain data privacy and security obligations may require us to implement specific security measures or use industry- standard or reasonable measures to protect our information technology systems and Sensitive Information. Even if we were to take and have taken security measures designed to protect against Security Incidents, there can be no assurance that such security measures or those of our service providers, partners and other third parties will be effective in protecting against all Security Incidents and material adverse impacts that may arise from such Security Incidents. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a Security Incident has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. If we (or a third- party upon whom we rely) experience a Security Incident or are perceived to have experienced a Security Incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. In addition, our actual or prospective customers, collaborators, partners and / or clinical trial participants may stop using our product candidates or working with us. This discontinuance, or failure to meet the expectations of such third parties, could result in material harm to our operations, financial performance or reputation and affect our ability to grow and operate our business. Failures or significant downtime of our information technology or telecommunication systems or those used by our third- party service providers could cause significant interruptions in our operations and adversely impact the confidentiality, integrity and availability of Sensitive Information, including preventing us from conducting clinical trials, tests or research and development activities and prevent us from managing the administrative aspects of our business. Applicable Data Protection Requirements (as defined below) may require us to notify relevant stakeholders of Security Incidents, including affected individuals, partners, collaborators, customers, regulators, law enforcement agencies, credit reporting agencies and others. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could materially adversely affect our business, financial condition, operating results and

prospects. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that any limitations or exclusions of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with Data Protection Requirements related to information security or Security Incidents. We cannot be sure that our insurance coverage will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or material adverse impacts arising out of our Processing operations, privacy and security practices, or Security Incidents we may experience. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large excess or deductible or co- insurance requirements), could materially adversely affect our business, financial condition, operating results and prospects. ~~We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; a disruption of our business operations, including our clinical trials; harm to our reputation; and other adverse effects on our business or prospects. In the ordinary course of business, we collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share, or collectively, Process or Processing of, personal data and other sensitive and confidential information, including information we collect about patients in connection with clinical trials, sensitive third- party data or, as necessary to operate our business, for legal and marketing purposes, and for other business-related purposes. Accordingly, we are, or may become, subject to numerous federal, state, local and international data privacy and security laws, regulations, guidance and industry standards as well as external and internal privacy and security policies, contracts and other obligations that apply to the Processing of personal data by us and on our behalf, collectively, Data Protection Requirements. The number and scope of Data Protection Requirements are changing, subject to differing applications and interpretations, and may be inconsistent between jurisdictions or in conflict with each other. If we fail, or are perceived to have failed, to address or comply with Data Protection Requirements, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions against us that could include investigations, fines, penalties, audits and inspections, additional reporting requirements and / or oversight, temporary or permanent bans on all or some Processing of personal data, orders to destroy or not use personal data, and imprisonment of company officials. Further, individuals or other relevant stakeholders could bring a variety of claims against us for our actual or perceived failure to comply with the Data Protection Requirements. Any of these events could have a material adverse effect on our reputation, business, or financial condition, and could lead to a loss of actual or prospective customers, collaborators or partners; interrupt or stop clinical trials; result in an inability to Process personal data or to operate in certain jurisdictions; limit our ability to develop or commercialize our products; or require us to revise or restructure our operations, or each, a material adverse impact. We are, or may become, subject to U. S. privacy laws. For example, in the United States, there are a broad variety of data protection laws and regulations that may apply to our activities such as state data breach notification laws, state personal data privacy laws (for example, the California Consumer Privacy Act of 2018, or CCPA), state health information privacy laws, and federal and state consumer protection laws. The CCPA requires covered businesses that process personal data of California residents to disclose their data collection, use and sharing practices. Further, the CCPA provides California residents with new data privacy rights (including the ability to opt out of the sale of personal data), imposes new operational requirements for covered businesses, provides for civil penalties for violations (up to $ 7, 500 per violation), as well as a private right of action for certain data breaches (that is expected to increase data breach class action litigation and result in significant exposure to costly legal judgements and settlements). Aspects of the CCPA and its interpretation and enforcement remain uncertain. Further, the new California Privacy Rights Act, or CPRA, substantially expanded the CCPA' s requirements effective January 1, 2023. The CPRA, among other things, gives California residents the ability to limit use of certain sensitive personal data, establish restrictions on the retention of personal data, expand the types of data breaches subject to the CCPA' s private right of action, and establish a new California Privacy Protection Agency to implement and enforce the new law. Although there are limited exemptions for clinical trial data under the CCPA and the CPRA, the CCPA and the CPRA may increase compliance costs and potential liability with respect to other personal data we maintain about California residents. Other states have enacted data privacy laws as well. For example, Virginia passed its Consumer Data Protection Act, which went into effect on January 1, 2023, and Colorado passed the Colorado Privacy Act, which went into effect on July 1, 2023, both of which differ from the CPRA. The federal government is also considering comprehensive privacy legislation. Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union' s General Data Protection Regulation, or EU GDPR, the United Kingdom' s GDPR, or UK GDPR, and Brazil' s General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13, 709 / 2018) impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4 % of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to processing of their personal data. European data protection laws (including the EU GDPR and UK GDRP) are wide- ranging in scope and impose numerous, significant and complex compliance burdens in relation to the Processing of personal data, such as: limiting permitted Processing of personal data to only that which is necessary for specified, explicit and legitimate purposes; requiring the establishment of a legal basis for Processing personal data; broadening the definition of personal data; creating obligations for controllers and processors to appoint data protection officers in certain circumstances; increasing transparency obligations to data subjects; introducing the obligation to carry out data protection impact assessments in certain circumstances; establishing limitations on the collection and retention of personal data through " data minimization " and " storage limitation " principles; introducing obligations to honor increased rights for data subjects; formalizing a heightened standard to obtain data subject consent; establishing obligations to implement certain technical and organizational safeguards to protect the security and confidentiality of personal data; introducing the obligation to~~

provide notice of certain significant personal data breaches to the relevant supervisory authority (ies) and affected individuals; and mandating the appointment of representatives in the UK and / or EU in certain circumstances. In particular, the Processing of " special categor [ies] [of] personal data " (such as personal data related to health and genetic information), which could be relevant to our operations in the context of our clinical trials, imposes heightened compliance burdens under European data protection laws and is a topic of active interest among relevant regulators. Certain jurisdictions have enacted data localization laws and cross- border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Existing mechanisms that facilitate cross- border personal data transfers may change or be invalidated. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the European Economic Area, or EEA, that the European Commission does not consider to provide an adequate level of data privacy and security, such as the United States. The European Commission released a set of " Standard Contractual Clauses, " or SCCs, that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. Currently, these SCCs are a valid mechanism to transfer personal data outside of the EEA, but there exists some uncertainty regarding whether the SCCs will remain a valid mechanism. Additionally, the SCCs impose additional compliance burdens, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at- issue personal data. In addition, Switzerland and the UK similarly restrict personal data transfers outside of those jurisdictions to countries that they do not consider to provide an adequate level of personal data protection, such as the United States, and certain countries outside Europe (e. g., Brazil) have also passed or are considering laws requiring local data residency or otherwise impeding the transfer of personal data across borders, any of which could increase the cost and complexity of doing business. If we cannot implement a valid compliance mechanism for cross- border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. Inability to import personal data to the United States may significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties subject to European and other data protection laws or requiring us to increase our personal data processing capabilities in Europe and / or elsewhere at significant expense. These laws exemplify the vulnerability of our business to the evolving regulatory environment related to personal data and may require us to modify our Processing practices at substantial costs and expenses in an effort to comply. Given the breadth and evolving nature of Data Protection Requirements, preparing for and complying with these requirements is rigorous, time- intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third- party collaborators, service providers, contractors or consultants that Process personal data on our behalf. We may publish privacy policies and other documentation regarding our Processing of personal data and / or other confidential, proprietary or sensitive information. Although we endeavor to comply with our published policies and other documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees, third- party collaborators, service providers, contractors or consultants fail to comply with our policies and documentation. Such failures can subject us to potential regulatory action if they are found to be deceptive, unfair, or misrepresentative of our actual practices. Moreover, subjects about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights or failed to comply with data protection laws or applicable privacy notices even if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business or have other material adverse impacts. Item 1B. Unresolved Staff Comments.