Risk Factors Comparison 2024-03-20 to 2023-03-22 Form: 10-K

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

Investing in our Class A common stock involves a high degree of risk. You should carefully consider the risks described below, including our consolidated financial statements and related notes, as well as the other information in this report, and in our other public filings, before investing in our Class A common stock. While we believe that the risks and uncertainties described below are the material risks currently facing us, additional risks that we do not yet know of or that we currently think are immaterial may also arise and materially affect our business. If any of the following risks materialize, our business, financial condition and results of operations could be adversely affected. In that case, the trading price of our Class A common stock could decline. You should consider all of the risk factors described when evaluating our business. Risks Related to Operating History, Financial Position and Capital Requirements **There is substantial doubt regarding our ability to continue as a going concern. We will need to raise additional funding, which may not be available on acceptable terms. If we are unable to raise additional capital when needed, we may be forced to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. Our operations have consumed substantial amounts of cash since our inception. We are in early clinical development with certain product candidates and have conducted or are in preclinical development with other product candidates. We intend to advance our product candidates into initial and later stages of clinical development, which requires significant capital. In addition, we are developing the RaniPill HC. If the FDA or any comparable foreign regulatory authorities, such as the EMA, require that we perform studies or trials in addition to those that we currently anticipate with respect to the development of our product candidates or any of our future product candidates, or repeat studies or trials, our expenses would further increase beyond what we currently expect, and any delay resulting from such further or repeat studies or trials could also result in the need for additional financing. As of December 31, 2023, our cash, cash equivalents and marketable securities totaled $ 48. 5 million. Based on our available cash resources and current operating plan, there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that our financial statements for the year ended December 31, 2023 are issued. Our existing capital resources, including the net proceeds from our IPO and term loans we received under a loan and security agreement and related supplement (the " Loan Agreement ") with Avenue Venture Opportunities Fund, L. P (the " Lender "), will not be sufficient to enable us to initiate any pivotal clinical trials. We will need to raise substantial additional funds in the future in order to complete the development of the RaniPill platform, to complete the clinical development of our product candidates and seek regulatory approval thereof, to expand our manufacturing capabilities, to further develop the RaniPill HC device and to commercialize any of our product candidates. If we are unable to continue as a going concern, we may have to cease operations and liquidate our assets. We may receive less than the value at which those assets are carried on our audited financial statements, and investors may lose all or a part of their investment. We may not be able to obtain additional funding on acceptable terms, or at all. As a result of geopolitical events, including the conflicts in Ukraine and Gaza, inflation, rising interest rates and other conditions, the global credit and financial markets have experienced volatility and disruptions. In addition, the report from our independent registered public accounting firm issued in connection with this Annual Report on Form 10- K contains statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide funding to us on commercially reasonable terms, if at all. If we are unable to obtain funding on a timely basis, or to generate sufficient revenues, if at all, from collaboration arrangements, we may be required to: • significantly curtail, delay or discontinue one or more of our research or development programs, the development of our oral delivery technology, including the RaniPill HC, the commercialization of any product candidates or cease operations altogether; • seek collaborators for one or more of our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; • relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or • forego expansion of our operations or refrain from pursuing business opportunities. For example, in November 2023, we underwent a reduction in our workforce and paused or discontinued certain programs to reduce our expenses and focus our financial resources on key priorities. As a result of any of the foregoing types of actions, our business, financial condition and results of operations could be materially affected. Our efforts to raise additional funding may divert our management from their day- to- day activities, which may adversely affect our ability to develop the RaniPill platform, including the RaniPill HC, to progress development of our product candidates or to automate our manufacturing processes. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our Class A common stock to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants and other operating restrictions that could adversely impact our ability to conduct our business. The Lender already has a security interest in substantially all of our assets, including our intellectual property, which may prevent or limit our ability to incur additional indebtedness. Our funding requirements and the timing of our need for additional capital are subject to change based on a number of factors, including: • the progress, costs, trial**

design, results and timing of our preclinical studies and clinical trials; • the progress, costs, and results of our research pipeline; • the progress and costs of development of the RaniPill HC device and other improvements or advancements to our delivery technologies; • the willingness of the FDA or other regulatory authorities to accept data from our clinical trials, as well as data from our completed and planned preclinical studies and clinical trials and other work, as the basis for review and approval of our product candidates; • the outcome, costs, and timing of seeking and obtaining FDA, and any other regulatory approvals; • the number and characteristics of product candidates that we pursue; • our ability to manufacture sufficient quantities of the RaniPill capsule; • our need to expand our research and development activities; • the costs associated with manufacturing, and obtaining drug supply for, our product candidates, including for clinical and commercial supplies; • the costs associated with securing and establishing commercial infrastructure, including establishing sales, marketing, and distribution capabilities; • the costs of acquiring, licensing, or investing in businesses, product candidates, and technologies; • our ability to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense, and enforcement of any patents or other intellectual property rights; • our need and ability to retain key management and hire scientific, technical, business, and engineering personnel; • the effect of competing drugs and product candidates and other market developments; • the timing, receipt, and amount of sales from our potential products, if approved; • our ability to establish strategic collaborations; • our need to implement additional internal systems and infrastructure, including financial and reporting systems; • security breaches, data losses or other disruptions affecting our information systems; • our ability to realize savings from any restructuring plans and cost- containment measures we propose to implement; • the economic and other terms, timing of and success of any collaboration, licensing, or other arrangements which we may enter in the future; and • the effects of disruptions to and volatility in the credit and financial markets in the United States and worldwide from geopolitical conflicts or other such disruptions. We may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. We have incurred operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue from commercial products or become profitable or, if we achieve profitability, we may not be able to sustain it. Biologics delivery is a highly speculative undertaking and involves a substantial degree of risk. We are an early clinical stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We were formed in 2012, and to date, we have devoted the majority of our resources to research and development, manufacturing automation and scaleup, and establishing our intellectual property portfolio. We are in early clinical development with a limited number of product candidates, and are in preclinical development with other product candidates. We have not yet demonstrated an ability to successfully complete pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing oral therapeutic products. We have incurred significant operating losses since our formation. Our net loss for the year ended December 31, ~~2022~~ **2023** was approximately $ ~~63~~ **67** . ~~3~~ **9** million. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders, deficit and working capital. The majority of our losses have resulted from expenses incurred in connection with research and development, manufacturing automation and scaleup, and establishing our intellectual property portfolio. All of our product candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue incurring significant research, development, manufacturing and other expenses related to our ongoing business operations and product development, and as a result, we expect to continue incurring losses for the foreseeable future. We also expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and our product candidates are in preclinical and early- stage clinical trials. If any of our product candidates fail in preclinical studies or clinical trials or do not gain regulatory approval, or even if approved, fail to achieve market acceptance, we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable may adversely affect the market price of our Class A common stock and our ability to raise capital and continue operations. If one or more of our product candidates is approved for commercial sale and we retain commercial rights, we anticipate incurring significant costs associated with manufacturing and commercializing such approved product. Therefore, even if we are able to generate revenue from the sale of any approved product, we may never become profitable. We are an early clinical stage biopharmaceutical company with no approved products and no historical commercial product revenue, which makes it difficult to assess our future prospects and financial results. We are an early clinical stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. Biologics development, especially as it relates to biologic- device combination products, is a highly speculative undertaking and involves a substantial degree of uncertainty. Our operations to date have been limited to developing our technology and undertaking preclinical studies and early clinical trials of our product candidates, which consist of investigational biologics delivered via the RaniPill capsule. We are in early clinical development with a limited number of product candidates, and are in preclinical development with other product candidates. As an early clinical stage company, we have not yet demonstrated an ability to generate revenue or successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields such as biologics development and delivery. Consequently, the ability to accurately assess our future operating results or business prospects is significantly more limited than if we had a longer operating history or approved products on the market. We expect that our financial condition and operating results will fluctuate significantly from period to period due to a variety of factors, many of

which are beyond our control, including, but not limited to: • the clinical outcomes from the continued development of our product candidates; • occurrence of adverse events or serious adverse events in preclinical studies or clinical trials of our product candidates; • potential side effects of our product candidates, whether caused by the biologic formulation or the RaniPill capsule, that could delay or prevent approval or cause an approved product to be taken off the market; • our ability to obtain, as well as the timeliness of obtaining, additional funding to develop, and potentially manufacture and commercialize our product candidates **and develop the RaniPill HC** ; • our ability to manufacture our product candidates to our specifications and in a timely manner to support our preclinical studies and clinical trials, and, if approved, commercialization; • our ability to scale, optimize and expand automation of our manufacturing processes for our product candidates for the conduct of preclinical studies and clinical trials and, if approved, for successful commercialization; • competition from existing products directed against the same biologic target or therapeutic indications of our product candidates as well as new products that may receive marketing approval; • the timing of regulatory review and approval of our product candidates; • market acceptance of our product candidates that receive regulatory approval, if any, including perception of the safety and efficacy of the oral delivery of biologics; • our ability to **enter into collaboration agreements with third parties who may desire to license our oral delivery technology for use with their own product candidates; • our ability to** expand our commercial reach by selectively entering into strategic partnerships on favorable terms or at all; • our ability to establish an effective sales and marketing infrastructure directly or through collaborations with third parties; • the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for our products; • our ability to manufacture our product candidates in accordance with current Good Manufacturing Practices, for the conduct of preclinical studies and clinical trials and, if approved, for successful commercialization; • our ability as well as the ability of any third- party collaborators, to obtain, maintain and protect intellectual property rights covering our product candidates and technologies, and our ability to develop, manufacture and commercialize our product candidates without infringing on the intellectual property rights of others; • our ability to add infrastructure and adequately manage our future growth; and • our ability to attract and retain key personnel with appropriate expertise and experience to manage our business effectively. Accordingly, the likelihood of our success must be evaluated in light of many potential challenges and variables associated with a clinical stage biopharmaceutical company, many of which are outside of our control, and past results, including operating or financial results, should not be relied on as an indication of future results. ~~If we are unable to raise additional capital when needed on acceptable terms, we may be forced to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. Our operations have consumed substantial amounts of cash since our inception. We are in early clinical development with certain product candidates and have conducted or are in the process of conducting preclinical studies with other product candidates. We intend to advance our product candidates into initial and later stages of clinical development, which requires significant capital. In addition, we are developing the RaniPill HC and intend to evaluate the safety of the RaniPill capsule, independent of any biologic. Developing biologic product candidates, including conducting preclinical studies and clinical trials, and developing the RaniPill platform, is expensive. We will require substantial additional future capital in order to complete the development of the RaniPill platform, expand our manufacturing capabilities, and seek regulatory approval for our product candidates, and to complete the clinical development of our product candidates and, if we are successful, to commercialize any of our current product candidates. If the U. S. Food and Drug Administration (FDA) or any comparable foreign regulatory authorities, such as the European Medicines Agency (EMA), require that we perform studies or trials in addition to those that we currently anticipate with respect to the development of our product candidates or any of our future product candidates, or repeat studies or trials, our expenses would further increase beyond what we currently expect, and any delay resulting from such further or repeat studies or trials could also result in the need for additional financing. Based on our current operating plan, we estimate that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 12 months. This period could be shortened if there are any significant increases beyond our expectations in spending on development programs or more rapid progress of development programs than anticipated. Our existing capital resources, including the net proceeds from our IPO and Loans, will not be sufficient to enable us to initiate any pivotal clinical trials. Accordingly, we expect that we will need to raise substantial additional funds in the future in order to complete the development of the RaniPill platform, to complete the clinical development of our product candidates and seek regulatory approval thereof, to expand our manufacturing capabilities, to further develop the RaniPill HC device and to commercialize any of our product candidates. Our funding requirements and the timing of our need for additional capital are subject to change based on a number of factors, including: • the progress, costs, trial design, results and timing of our preclinical studies and clinical trials; • the progress, costs, and results of our research pipeline; • the progress and costs of development of the RaniPill HC device and other improvements or advancements to our delivery technologies; • the willingness of the FDA or other regulatory authorities to accept data from our clinical trials, as well as data from our completed and planned preclinical studies and clinical trials and other work, as the basis for review and approval of our product candidates; • the outcome, costs, and timing of seeking and obtaining FDA, and any other regulatory approvals; • the number and characteristics of product candidates that we pursue; • our ability to manufacture sufficient quantities of the RaniPill capsule; • our need to expand our research and development activities; • the costs associated with manufacturing, and obtaining drug supply for, our product candidates, including for clinical and commercial supplies; • the costs associated with securing and establishing commercial infrastructure, including establishing sales, marketing, and distribution capabilities; • the costs of acquiring, licensing, or investing in businesses, product candidates, and technologies; • our ability to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense, and enforcement of any patents or other intellectual property rights; • our need and ability to retain key management and hire scientific, technical, business, and engineering personnel; • the effect of competing drugs and product candidates and other market developments; • the timing, receipt, and amount of sales from our potential products, if approved; • our ability to~~

~~establish strategic collaborations; • our need to implement additional internal systems and infrastructure, including financial and reporting systems; • security breaches, data losses or other disruptions affecting our information systems; • the economic and other terms, timing of and success of any collaboration, licensing, or other arrangements which we may enter in the future; and • the effects of disruptions to and volatility in the credit and financial markets in the United States and worldwide from the COVID- 19 pandemic, the conflict between Ukraine and Russia or other such disruptions. Additional funding may not be available to us on acceptable terms, or at all. As a result of the COVID- 19 pandemic and actions taken to slow its spread as well as the conflict between Ukraine and Russia, inflation, rising interest rates and other conditions, the global credit and financial markets have experienced volatility and disruptions. If we are unable to obtain additional funding from equity offerings or debt financings, including on a timely basis, we may be required to: • seek collaborators for one or more of our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; • relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or • significantly curtail one or more of our research or development programs or cease operations altogether. Conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.~~ Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates or technologies. We may seek additional funding through a combination of equity offerings, debt financings, collaborations and / or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, current stockholders' interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. The incurrence of indebtedness and / or the issuance of certain equity securities could result in fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur debt and / or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our Class A common stock to decline. In the event that we enter into collaborations and / or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to the RaniPill capsule, the RaniPill HC or our product candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms. Our existing indebtedness contains restrictions that limit our flexibility in operating our business. In addition, we may be required to make a prepayment or repay our outstanding indebtedness earlier than we expect. In August 2022, we entered into ~~a loan and security agreement and related supplement (~~ the ~~"~~ Loan Agreement ~~")~~ with ~~Avenue Venture Opportunities Fund, L. P (~~ the ~~"~~ Lender ~~"). The Loan Agreement provides~~ for term loans (the " Loans ") in an aggregate principal amount up to $ 45. 0 million. A Loan of $ 30. 0 million was committed at closing, with $ 15. 0 million funded immediately and $ 15. 0 million available to be drawn between October 1, 2022 and December 31, 2022, which was drawn in December 2022. The remaining $ 15. 0 million of Loans is uncommitted and is subject to certain conditions and approval by the Lender. The Loan Agreement contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things: • incur or assume certain debt; • merge or consolidate or acquire all or substantially all of the capital stock or property of another entity; • enter into any transaction or series of related transactions that would be deemed to result in a change in control of us under the terms of the agreement; • change the nature of our business; • change our organizational structure or type; • license, transfer, or dispose of certain assets; • grant certain types of liens on our assets; • make certain investments; • pay cash dividends; and • enter into material transactions with affiliates. The restrictive covenants in the Loan Agreement could prevent us from pursuing business opportunities that we or our stockholders may consider beneficial. A breach of any of these covenants could result in an event of default under the Loan Agreement. An event of default will also occur if, among other things, a material adverse effect in our business, operations, or condition occurs, which could potentially include a material impairment of the prospect of our repayment of any portion of the amounts we owe under the Loan Agreement. In the case of a continuing event of default under the Loan Agreement, the Lender could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted the Lender a security interest under the Loan Agreement, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the Loan Agreement are secured by substantially all of our existing and future assets, including intellectual property. The Loan Agreement also gives us the ability to access an additional $ 15. 0 million, which may be drawn in an additional tranche with the approval of the Lender and subject to the other terms and conditions set forth in the Loan Agreement. If we are unable to satisfy these or other required conditions, or if the Lender does not consent, as applicable, we would not be able to draw down the remaining tranche of financing and may not be able to obtain alternative financing on commercially reasonable terms or at all, which could adversely impact our business. We may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financings to repay or refinance our indebtedness at the time any such repayment is required. In such an event, we may be required to delay, limit, reduce, or terminate our product development or commercialization efforts. Our business, financial condition, and results of operations could be materially adversely affected as a result. **Any restructuring actions that we undertake may not deliver the expected results and these actions may adversely affect our business operations. We may**

undertake various restructuring activities in an effort to better align our resources, organizational structure and costs with our strategic priorities, including streamlining of business operations and development program priorities and reduction in force. For example, in November 2023, we committed to a restructuring plan involving the reduction of our workforce by approximately 25 %. As a result of the restructuring activities, we estimate we will incur approximately $ 0. 3 million in costs of which nearly all are cash expenditures related to severance and half of which was incurred in the fourth quarter of 2023. The restructuring is expected to be substantially completed by the end of the second quarter of 2024. The estimates of costs that we expect to incur in connection with the restructuring and the timing thereof are subject to a number of assumptions and actual results may differ materially from estimates. We may also incur other charges or cash expenditures not currently contemplated in connection with the restructuring due to unanticipated events that may occur, including in connection with the implementation of the restructuring. In connection with such activities, and any other future restructuring activities, we may experience a disruption in our ability to perform functions critical to our strategy or business objectives. While we strive to reduce the negative impact of such restructuring actions, such actions could result in significant disruptions to our operations, including adversely affecting our clinical program development, technology platform development, the successful implementation and completion of our strategic objectives and the results of our operations. We expect to continue to actively manage our costs. However, if we do not fully realize or maintain the anticipated benefits of our restructuring plans and cost reduction initiatives, our business could be adversely affected. Restructuring activities may also yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond our intended reduction- in- force, a reduction in morale among our remaining employees, and the risk that we may not achieve the anticipated benefits, all of which may have an adverse effect on our results of operations or financial condition. Risks Related to the Development and Regulatory Approval of Our Product Candidates We are early in our development efforts and have only a limited number of product candidates in clinical development, and our other product candidates are still in preclinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed. We are in the early stages of our development efforts and have only a limited number of product candidates in early clinical development. Other product candidates are still in the formulation and preclinical stages. We will need to progress our product candidates through Investigational New Drug (IND)- enabling studies and submit INDs to the FDA or equivalent regulatory filings to foreign regulatory authorities prior to initiating their clinical development. None of our product candidates have advanced into a pivotal study. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following: • successful enrollment in clinical trials and completion of preclinical studies and clinical trials with favorable results; • acceptance of INDs by the FDA or similar regulatory filings by comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials; • demonstrating safety and efficacy to the satisfaction of applicable regulatory authorities; • receipt of marketing approvals from applicable regulatory authorities, including BLAs or NDAs, from the FDA, and maintaining such approvals; • establishing clinical and commercial manufacturing capabilities, and securing adequate supply of drugs for our product candidates; • expanding automation of our manufacturing machinery and procedures; • establishing and maintaining multiple suppliers for our critical manufacturing materials; • establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others; • establishing and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates; • maintaining an acceptable safety profile and shelf life of our products following approval; • the class of drugs that are included in our product candidates continuing to represent the standard- of- care for the respective disease target and continuing to have a long- term favorable safety profile; and • maintaining and growing an organization of people who can develop our products and technology. The success of our business, including our ability to finance our company and generate any revenue in the future, will depend on the successful development, regulatory approval and commercialization of our product candidates, which may never occur. We may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter. We may not be able to successfully deliver the biologic payload to the intestinal wall with great enough certainty to achieve adequate efficacy or safety for any of our product candidates or to the satisfaction of the FDA or other regulatory bodies **or potential collaborators** . Given our early stage of development, it may be several years, if at all, before we have demonstrated the safety and efficacy of a treatment sufficient to warrant approval for commercialization. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. Our business and future profitability is substantially dependent on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize our product candidates. Our approach presents a novel method of delivering biologics directly into the intestinal wall, and we are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or any comparable foreign regulatory authorities. The pathway for obtaining regulatory approval for our approach has not been definitively established, and we may never receive such regulatory approval for any of our product candidates. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. Approval policies, regulations and the types and amount of clinical and manufacturing data necessary to gain approval may change during the course of clinical development and may vary among jurisdictions. We have not obtained

regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we have in development or may seek to develop in the future will ever obtain regulatory approval. Our product candidates could fail to receive regulatory approval for many reasons, including the following: • the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; • we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication; • the results of clinical trials may fail to achieve the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; • we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; • the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data submitted in support of regulatory approval; • the data collected from preclinical studies and clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other regulatory submissions necessary to obtain regulatory approval in the United States or elsewhere; • we may not meet the cGMP and other applicable requirements for manufacturing processes, procedures, documentation and facilities necessary for approval by the FDA or comparable foreign regulatory authorities; and • changes to the approval policies or regulations of the FDA or comparable foreign regulatory authorities with respect to our product candidates may result in our clinical data becoming insufficient for approval. The lengthy regulatory approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market the RaniPill capsule with our core programs and any other biologics, which would harm our business, results of operations and prospects significantly. In addition, even if we were to obtain regulatory approval, regulatory authorities may approve our product candidates for fewer or more limited indications than what we requested approval for, may include safety warnings or other restrictions that may negatively impact the commercial viability of our product candidates, including the potential for a favorable price or reimbursement at a level that we would otherwise intend to charge for our products. Likewise, regulatory authorities may grant approval contingent on the performance of costly post- marketing clinical trials, which could significantly reduce the potential for commercial success or viability of our product candidates. Any of the foregoing possibilities could materially harm the prospects for our product candidates and business and operations. We have not previously submitted a BLA, or a marketing authorization application, (" MAA "), or any corresponding drug approval filing to the FDA or any comparable foreign regulatory authorities for any product candidate. Further, our product candidates may not receive regulatory approval even if we complete such filing. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Clinical failure can occur at any stage of clinical development. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. The results of preclinical studies and early clinical trials of our product candidates and studies and trials of other products may not be predictive of the results of later- stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. For example, the results generated to date in preclinical studies and the Phase 1 clinical trials ~~of~~ **ofRT- 102 and** RT- **111** ~~101 and RT- 102~~ do not ensure that future Phase 2 or later clinical trials of these product candidates will have similar results or be successful. In the Phase 1 clinical trials of RT- ~~101~~ **102** and RT- ~~102~~ **111** , we tested the RaniPill capsule in a limited number of healthy volunteers. While we have not observed any serious adverse events as a result of these clinical trials, we have not widely tested the RaniPill capsule in humans and cannot be certain how the RaniPill capsule will perform when more widely tested in humans in any additional or later clinical trials. In addition to our ongoing and planned preclinical studies and clinical trials, we expect to have to complete at least two large scale, or adequate, well- controlled trials to demonstrate substantial evidence of efficacy and safety for each product candidate we intend to commercialize. Further, given the patient populations for which we are developing biologics, we expect to have to evaluate long- term exposure to establish the safety of our biologics in a chronic dose setting. Clinical trial failures may result from a multitude of factors including, but not limited to, flaws in trial design, dose and formulation selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety and / or efficacy traits of the product candidate. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials. We may experience delays in ongoing clinical trials, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to: • obtaining regulatory approvals to commence a clinical trial; • fraud or negligence on the part of consultants or contractors; • obtaining institutional review board or ethics committee approval at each site; • recruiting suitable patients to participate in a clinical trial; • having patients complete a clinical trial or return for post- treatment follow- up; • clinical sites deviating from the clinical trial' s protocol or dropping out of a clinical trial; • the impacts of the ~~COVID- 19 pandemic or the~~ conflict between Russia and Ukraine on our ongoing and planned preclinical studies and clinical trials; • adding new clinical trial sites; or • manufacturing sufficient quantities of product candidate for use in our preclinical studies and clinical trials, including product candidates manufactured in accordance with our specifications. In addition, ~~disruptions caused by the COVID- 19 pandemic may increase the likelihood that~~ we ~~encounter such difficulties or delays in initiating, enrolling, conducting, or completing our ongoing and planned clinical trials. We~~ could encounter delays if a clinical trial is modified, suspended or terminated by us, by the IRBs or ethics committees of the institutions in which such clinical trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose a modification, suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or clinical trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold,

unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed and our ability to generate product revenue from any of these product candidates will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. **Moreover** ~~In addition~~ , data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Further, if patients drop out of our clinical trials, miss scheduled doses or follow- up visits, or otherwise fail to follow clinical trial protocols ~~, whether as a result of the COVID- 19 pandemic, actions taken to slow the spread of COVID- 19 or otherwise,~~ the integrity of data from our clinical trials may be compromised or not accepted by the FDA or comparable foreign regulatory authorities, which would represent a significant setback for the applicable program. For the foregoing reasons, our ongoing and planned preclinical studies and clinical trials may not be successful. Any safety concerns observed in any one of our clinical trials in our targeted or contemplated indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have an adverse effect on our business, financial condition and results of operations. Any inability to develop, or difficulties or delays in developing, formulations of drugs for our product candidates could prevent or delay our ability to advance our existing product candidates or develop new product candidates, which could adversely affect our commercial prospects and ability to generate revenues. We ~~are required to~~ develop microtablets of drugs for use in **the RaniPill GO and may need to develop** ~~our~~ **or** ~~existing~~ **modify formulations of drugs for use in the RaniPill HC or future versions of the** RaniPill capsule ~~. Accordingly, we develop or modify formulations of drugs to be suitable for the creation of such microtablets~~ . Drug formulation work is difficult and the outcomes are uncertain. If we are not able to develop a drug formulation suitable for use with our RaniPill capsule, it could prevent, limit or delay our ability to pursue or advance product candidates. Even if we are successful in developing drug formulations of product candidates that are suitable for the RaniPill capsule, such formulations may cause the drug to perform differently than another formulation of the drug and could result in our product candidates having a safety or efficacy profile different or worse than other formulations of the drug. If we are unable to develop, or have difficulties or delays in developing, suitable formulations of drugs for the RaniPill capsule, our ability to develop and commercialize product candidates, to expand use of the RaniPill oral delivery technology and to generate revenues could be adversely affected. Any difficulties or delays in the commencement or completion, or termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. We are in the early stages of our development efforts and have a limited number of product candidates in early clinical development. Other product candidates are still in the formulation or preclinical stages. While we intend to advance our product candidates into initial and later stages of clinical development, we have not, to date, submitted an IND for any of our product candidates. We will be required to submit applicable equivalent regulatory filings to foreign regulatory authorities to the extent we initiate clinical trials outside of the United States. We do not know whether our planned clinical trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to: • the FDA or comparable foreign regulatory authorities disagreeing with the design or implementation of our clinical trials **or the risks and benefits of the product candidate** ; • obtaining regulatory authorizations to commence a trial, or reaching a consensus with regulatory authorities on trial design; • any failure or delay in reaching an agreement with contract research organizations (" CROs ") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • obtaining approval from one or more IRBs; • IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional volunteers or withdrawing their approval of the trial; • changes to clinical trial protocol; • clinical sites deviating from trial protocol or dropping out of a trial; • manufacturing sufficient quantities of a product candidate or obtaining sufficient quantities of other therapies or active pharmaceutical ingredients for use in clinical trials; • volunteers failing to enroll or remain in our trial at the rate we expect, or failing to return for post- treatment follow- up; • volunteers choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials; • lack of adequate funding to continue the clinical trial; • volunteers experiencing severe or unexpected drug- related or device- related adverse effects; • occurrence of serious adverse events in clinical trials of the same class of agents conducted by other companies; • selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data; • a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP regulations or other applicable requirements, or infections or cross- contaminations of product candidates in the manufacturing process; • any changes to our manufacturing process or product formulation that may be necessary or desired; • shortages in, or delays in obtaining, raw materials for manufacturing our product candidates or adequately scaling our manufacturing processes and procedures to deliver sufficient quantities for use in our clinical trials; • third- party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical protocol or relevant regulatory requirements; • third- party contractors not performing data collection or analysis in a timely or accurate manner; or • third- party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or comparable foreign regulatory authorities for violations of regulatory requirements, in which case we may

need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications. **Regulatory authorities may require that filings related to the commencement, continuation or termination of a clinical trial be submitted through specific electronic systems or in a specific manner (e. g. format), which may differ from one jurisdiction to another. We may seek to conduct a clinical trial in multiple jurisdictions in an effort to enroll sufficient numbers of patients or to do so in a timely manner or for other reasons. Meeting the requirements of various regulatory agencies could be costly and any delay in meeting, or inability to meet, the regulatory requirements of different jurisdictions regarding submissions could delay or negatively impact our ability to initiate or complete our clinical trials as planned. Any failure or inability by us to submit required regulatory documents for our planned or future clinical trials or any failure or inability to do so in the required manner could delay or prevent us from initiating or completing our planned or future clinical trials when we are otherwise ready or at all.** We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled participants in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes and data protection regulations, as well as political and economic risks relevant to such foreign countries. Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates. In addition, we work with third parties to manufacture, develop, and supply the drug payloads for inclusion in the RaniPill capsule, a development process that is lengthy and expensive. Some of the active ingredients we are utilizing in our development are used by other sponsors to make biosimilars in the United States, and others are not. We and our third - party manufacturers may discover, even late in the process, that a particular drug payload does not demonstrate the necessary characteristics or is unacceptable to the FDA or other regulatory authorities, and we may be forced to abandon such manufacturing and development efforts for such compound and pursue alternative sourcing, or conduct additional, more involved development work to be able to use such compound, which could have an adverse effect on our operations. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. We may make formulation or manufacturing changes to our product candidates, in which case we may need to conduct additional preclinical studies or clinical trials to bridge our modified product candidates to earlier versions. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly. Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control. We may encounter delays in enrolling, or be unable to enroll or maintain, a sufficient number of patients to complete any of our clinical trials. Patient enrollment and retention in clinical trials is a significant factor in the timing of clinical trials and depends on many factors, including the size and nature of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical trial sites and the eligibility criteria for the clinical trial. For most of our product candidates, we are working to deliver known biologic products via the RaniPill platform, and accordingly, patients who are currently prescribed or eligible to be prescribed the approved injectable versions of these biologics may be unable or unwilling to participate in our clinical trials to test an unapproved delivery system of these medications. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Furthermore, any negative results we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same candidate. Also, negative results in clinical trials by other companies regarding the biologics we are using or

biosimilars or analogs thereof can additionally make it difficult or impossible to recruit and retain patients in our clinical trials. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible ~~. Our preclinical studies and clinical trials have been affected and may in the future be affected by the COVID- 19 pandemic, such as by a reduction in staffing at a CRO, a pause in clinical trial patient enrollment to focus on, and direct resources to, COVID- 19, or patients choosing not to enroll or continue participating in a clinical trial as a result of the pandemic. Further, some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services~~ . Our product candidates or similar investigational or approved drugs may cause undesirable side effects or have other properties impacting safety that could delay or prevent the regulatory approval of, limit the commercial profile of an approved label for, or result in limiting the commercial opportunity for our product candidates if approved. Undesirable side effects that may be caused by our product candidates or caused by similar investigational or approved drugs within the same class by other companies, could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or adverse events related to our product candidates. In such an event, our clinical trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of our product candidates for any or all targeted biologic indications. For example, in our Phase 1 clinical trial of RT- ~~101~~ **102** , the RaniPill capsule was well tolerated by all subjects, and no subjects had difficulty swallowing the pill. Capsule remnants were passed by all trial subjects and no serious adverse events were observed. However, we have generated limited clinical data with the RaniPill capsule to date, and further analysis may reveal adverse events inconsistent with the safety profile observed to date. Drug- related side effects could negatively affect patient recruitment or the ability of enrolled patients to complete the trial and even if our clinical trials are completed and our product candidate is approved, drug- related side effects could restrict the label or result in potential product liability claims. Any of these occurrences could significantly harm our business, financial condition and prospects. Moreover, since our product candidates are being developed for indications for which subcutaneous and IV injectable pharmaceuticals have been approved, we expect that our clinical trials would need to show a risk / benefit profile that is competitive with those existing products and product candidates in order to obtain regulatory approval or, if approved, a product label that is favorable for commercialization. In addition, similar investigational or approved drugs within the same class as our product candidates may encounter serious adverse events. In the event these products encounter serious adverse events, the FDA may remove the class of drugs from the market, impose a class wide REMS, or require other class wide regulatory requirements. We may face increased regulatory scrutiny and ultimately may have to abandon our product candidate of the same class, which would have an adverse effect on our business, financial condition and operations. Additionally, if one or more of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw approvals of such product; • regulatory authorities may require additional warnings on the label; • we may be required to create a medication guide outlining the risks of such side effects for distribution to patients; • we could be sued and held liable for harm caused to patients; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate which could significantly harm our business and prospects. Also, any undesirable side effects caused by or safety concerns related to our delivery device apart from a drug or biologic could delay, limit or prevent us from developing and commercializing any product candidates. As an organization, we have conducted limited early clinical development, have not submitted an IND to the FDA and we have never conducted later- stage clinical trials or submitted a BLA or NDA, and may be unable to do so for any of our product candidates. We are early in our development efforts for our product candidates, and we will need to successfully complete later- stage and pivotal clinical trials in order to obtain FDA or comparable foreign regulatory approval to market our current or any future product candidates. Carrying out later- stage clinical trials and the submission of a successful BLA or NDA is a complicated process. As an organization, we have conducted ~~two~~ Phase 1 clinical trials ~~, both of which were conducted~~ in Australia ~~, and have not yet conducted any clinical trials for our other product candidates~~ . We have not previously conducted any later stage or pivotal clinical trials, have limited experience as a company in preparing, submitting and prosecuting regulatory filings and have not previously submitted a BLA, NDA or other comparable foreign regulatory submission for any product candidate. We also plan to conduct a number of clinical trials for multiple product candidates in parallel over the next several years. This may be a difficult process to manage with our limited resources and may divert the attention of management. In addition, we have had limited interactions with the FDA, and we have never filed an IND. We cannot be certain how many clinical trials of our product candidates will be required or how such trials will have to be designed. For example, we anticipate relying on data developed on the RaniPill platform to enable shortened or more efficient development for our subsequent product candidates, but this may not be the case and the FDA or other regulatory authorities may require us to perform a full suite of studies for each of our product candidates. Consequently, we may be unable to successfully and efficiently commence, execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of any of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in submitting BLAs or NDAs for and commercializing our product candidates. Our product candidates are subject to extensive regulation and compliance, which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates. The clinical development, manufacturing, labeling, storage, record- keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we

are not permitted to market our product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels and the ability to hire and retain key personnel and accept the payment of user fees. In addition, approval policies or regulations may change, and the FDA has substantial discretion in the approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we must demonstrate with substantial evidence from adequate and well- controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post- approval, or may object to elements of our clinical development program. The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including: • such authorities may disagree with the design or implementation of our clinical trials; • negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; • serious and unexpected drug- related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates; • the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval; • such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States; • such authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials; • such authorities may disagree regarding the formulation, labeling and / or the specifications of our product candidates; • approval may be granted only for indications that are significantly more limited than what we apply for and / or with other significant restrictions on distribution and use; • such authorities may find deficiencies in the manufacturing processes or facilities of our third- party manufacturers with which we contract for clinical and commercial supplies; • regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval; or • such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission. With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed biologics may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new biologics based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates. Because we have multiple product candidates in our clinical pipeline and are considering a variety of target indications, we may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we focus on specific product candidates, indications and development programs. We also plan to conduct several clinical trials for our product candidates in parallel over the next several years, which may make our decision as to which product candidates to focus on more difficult. As a result, we may forgo or delay pursuit of opportunities with other product candidates or other indications that could have had greater commercial potential or likelihood of success. In addition, we are focused on developing the RaniPill capsule in addition to the drug formulations for use in the RaniPill capsule. While we intend to focus on well- characterized molecules with attractive commercial characteristics, focusing both on drug delivery and formulation will require substantial resource and attention. In addition, we are developing a new device with a payload capacity up to 20 mg, RaniPill HC, and in the future we may seek to develop other variations of the RaniPill capsule. In such cases, we need to redesign and conduct additional preclinical and clinical studies of any new design of the RaniPill capsule. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Additionally, we may pursue additional in- licenses or acquisitions of development- stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management' s time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment. A breakthrough therapy designation or Fast Track designation by the FDA for a drug may not lead to a faster development or regulatory review or approval process, and it would

not increase the likelihood that the drug will receive marketing approval. In the future, we may seek a breakthrough therapy designation for one or more of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the biologics license application. Designation as a breakthrough therapy is at the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a drug may not result in a faster development process, review, or approval compared to drugs considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meets the conditions for qualification, or it may decide that the time period for FDA review or approval will not be shortened. We may seek Fast Track designation for some of our product candidates. If a therapy is intended for the treatment of a serious or life- threatening condition and the therapy demonstrates the potential to address significant unmet medical needs for this condition, the drug sponsor may apply for Fast Track designation. The FDA has broad discretion whether or not to grant this designation, and even if we believe a particular product candidate is eligible for this designation, the FDA may not decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review, or approval compared to conventional FDA procedures. If our clinical development program does not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended, or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation and priority review do not change the standards for approval. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA' s priority review procedures. Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose interim, topline or preliminary data from our 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 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 topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, others, including regulatory authorities, 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 is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. Product candidates comprising a biologic or drug within the RaniPill capsule employ novel technologies that have not yet been approved by the FDA or comparable foreign regulatory authorities, and we anticipate that our applications will have to be submitted as original, standalone BLAs or NDAs. These regulatory authorities have limited experience in evaluating our technologies and product candidates. Our novel technologies also make it difficult to predict the time and cost of product candidate development. We are developing product candidates based on novel technologies, and we, directly or with potential collaboration partners, intend to understand and deliver the requisite demonstration of safety and efficacy that the FDA and comparable foreign regulatory authorities may seek for the approval of our product candidates, which comprise a biologic or drug within the RaniPill capsule. It is possible that the regulatory approval process may take significant time and resources and require deliverables from independent third parties not under our control. For some of our product candidates, the regulatory approval path and requirements may not be clear or may change, which could add significant delay and expense. For example, although we have engaged in pre- submission meetings with the FDA, we have limited feedback from the FDA on the clinical trials that will be necessary to support BLA or NDA submissions for any of our product candidates. **The FDA or regulatory authorities outside the U. S. may require more or different data or documentation regarding the RaniPill technology or our product candidates than we generate or anticipate, which could cause delays to planned clinical activities.** Delays or

failure to obtain regulatory approval of any of the products that we or potential collaboration partners develop using our novel technologies would adversely affect our business. In addition, we are still developing our platform and any development problems we experience in the future may cause significant delays or unanticipated costs, and such development problems may not be able to be overcome. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all. In addition, our expectations with regard to our scalability and costs of manufacturing may vary significantly as we develop our product candidates and understand these critical factors. We have limited clinical data on our product candidates to indicate whether they are safe or effective for long- term use in humans. We have limited clinical data on our product candidates and we have not conducted any studies to evaluate whether they are safe or effective for long- term use in humans, including to evaluate the safety of any degradation products that may result after the drug is injected into the intestinal wall. In our Phase 1 clinical ~~trial~~ **trials** ~~of RT- 101 and Phase 1 clinical trial of RT- 102~~ , we tested the RaniPill capsule in a limited number of healthy volunteers. While we have not observed any serious adverse events as a result of these preclinical studies or our clinical trials, we have not widely tested the RaniPill capsule in humans and cannot be certain how the RaniPill capsule will perform when more widely tested in humans in any later clinical trials. If treatment with any of our product candidates in our ongoing or future clinical trials results in concerns about their safety or efficacy, we and / or any collaboration partners may be unable to successfully develop or commercialize any or all of our product candidates or enter into collaborations with respect to our product candidates. We have conducted and may in the future conduct clinical trials for current or future product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials. We have conducted and may in the future choose to conduct one or more clinical trials outside the United States. For example, we **have** conducted ~~a~~ **our** Phase 1 clinical ~~trial~~ **trials** ~~of RT- 101 in Australia and a Phase 1 clinical trial of RT- 102~~ in Australia. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U. S. population and U. S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practice regulations; and (iii) the data may be considered valid without the need for an on- site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well- designed and well- conducted in accordance with GCP and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time- consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction. Risks Related to Commercialization of Our Product Candidates Even if we receive regulatory approval for any product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved. If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, conduct of post- marketing studies, and submission of safety, efficacy, and other post- market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers, if any, will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA or MAA. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. Any regulatory approvals that we receive for our product candidates will be subject to limitations on the approved indicated uses for which the product may be marketed and promoted or to the conditions of approval (including the requirement to implement a risk evaluation and mitigation strategy) or contain requirements for potentially costly post- marketing testing. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post- approval marketing and promotion of products to ensure that they are manufactured, marketed, and distributed only for the approved indications and in accordance with the provisions of the approved labeling. We will have to comply with requirements concerning advertising and promotion for our products. The holder of an approved BLA or MAA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post- marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post- marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post- marketing study or failure to complete such a study could result

in the withdrawal of marketing approval. If a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory authorities may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory authority or enforcement authority may, among other things: • issue warning letters that would result in adverse publicity; • impose civil or criminal penalties; • suspend or withdraw regulatory approvals; • suspend any of our ongoing clinical trials; • refuse to approve pending applications or supplements to approved applications submitted by us; • impose restrictions on our operations, including closing our contract manufacturers' facilities; • seize or detain products; or • require a product recall. Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. Even if our product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, government payors (including Medicare and Medicaid programs), private insurers, and other third- party payors, or others in the medical community necessary for commercial success. If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, government payors, other third- party payors and other healthcare providers. If any of our approved products fail to achieve an adequate level of acceptance, we may not generate significant revenue to become profitable. The degree of market acceptance, if approved for commercial sale, will depend on a number of factors, including but not limited to: • the potential or perceived advantages or disadvantages of the oral delivery of biologics as compared to subcutaneous or IV injections of biologics; • the efficacy of our product candidates compared to alternative treatments; • the shelf- life of our product candidates; • the effectiveness of sales and marketing efforts; • the cost of treatment in relation to alternative treatments; • our ability to offer our product candidates for sale at competitive prices; • the willingness of the target patient population to try the RaniPill capsule; • the willingness of physicians to prescribe use of the RaniPill capsule and to prescribe biologics that utilize the RaniPill capsule; • the willingness of the medical community to offer patients our product candidates in addition to or in the place of current subcutaneous and IV injectable therapies; • the strength of marketing and distribution support; • the availability of government and third- party coverage and adequate reimbursement; • our ability to manufacture sufficient supply to meet patients' demand; • the prevalence and severity of any side effects; and • any restrictions on the use of our product candidates together with other medications or treatments. Because we expect sales of our product candidates, if approved, to generate revenue for us to achieve profitability, the failure of our product candidates to achieve market acceptance would harm our business and could require us to seek collaborations or undertake additional financings sooner than we would otherwise plan. The FDA and comparable foreign regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off- label uses. If we are found or alleged to have improperly promoted off- label uses, we may become subject to significant liability. The FDA and comparable foreign regulatory authorities strictly regulate the promotional claims that may be made about prescription products, as our product candidates would be, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or comparable foreign regulatory authorities as reflected in the product' s approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with a product' s FDA approved labeling. If we receive marketing approval for any one of our product candidates, physicians could prescribe such product to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off- label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off- label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management' s attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would adversely affect our business and financial condition. The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates could limit our ability to generate revenue. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford medications and therapies. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain adequate pricing that will allow us to realize a sufficient return on our investment. Factors payors consider in determining reimbursement are based on whether the product is: • a covered benefit under its health plan; • safe, effective and medically necessary; • appropriate for the specific patient; • cost- effective; and • neither experimental nor investigational. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new products are typically made by the Centers for Medicare and Medicaid Services, an agency within the United States Department of Health and Human Services. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel products

such as ours since there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries may cause us to price our product candidates on less favorable terms that we currently anticipate. In many countries, particularly the countries of the European Union, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidates to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Certain other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits. Moreover, increasing efforts by governmental and third- party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market. We face significant competition from other biotherapeutics and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. The biotherapeutics and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors worldwide, including major multinational pharmaceutical companies, biotherapeutics companies, specialty pharmaceutical and generic pharmaceutical companies as well as universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, and experienced marketing and manufacturing organizations. Mergers and acquisitions in our industry may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of newer technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, pharmaceutical products that are easier to develop, more effective or less costly than any product candidates that we are currently developing or that we may develop. Unforeseen technological advances to those of our technologies may be developed by these competitors. If approved, our product candidates are expected to face competition from commercially available drugs as well as drugs and devices that are in the development pipelines of our competitors. Pharmaceutical companies may invest heavily to accelerate discovery and development of novel technologies or to in- license novel technologies that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate advantages in efficacy, convenience, tolerability or safety in order to overcome price competition and to be commercially successful. If our competitors succeed in obtaining FDA or comparable foreign regulatory approval before we do or develop blocking intellectual property to which we do not have a license, there would be a material adverse impact on the future prospects for our product candidates and business. We face competition primarily from current and future (generic and biosimilars) manufacturers of subcutaneous and IV injectable versions of our product candidates, such as AbbVie Inc., Eli Lilly and Company, ~~Novartis AG,~~ Janssen Biotech, Inc. and the SOMA and LUMI from the Novo Nordisk- MIT collaboration. Additionally, we face competition from companies that are pursuing the development and manufacture of oral biologics, including Oramed Pharmaceuticals, Inc., Entera Bio Ltd., ~~Applied Molecular Transport Inc.,~~ Protagonist Therapeutics, Inc., ~~Amryt Pharma Plc~~ **Chiesi Farmaceutici SpA** , i2O Therapeutics, Biora Therapeutics, Inc., Intract Pharma, and Novo Nordisk A / S ~~. For example, Amryt Pharma Plc (which announced it is being acquired by Chiesi Farmaceutici SpA) received FDA approval for an oral octreotide product, MYCAPSSA, in June 2020~~ . We also face competition from gene and cell therapy companies. Further, our product candidates aim to treat chronic diseases. As a result, we also compete with curative therapies on the basis that they cure the chronic disease we are intending to treat. We believe that our ability to successfully compete will depend on, among other things: • the efficacy and safety of our product candidates, in particular compared to marketed products and products in late- stage development; • the time it takes for our product candidates to complete clinical development and receive regulatory approval, if at all; • the ability to commercialize and market any of our product candidates that receive regulatory approval; • the price of our products, including in comparison to branded or generic competitors; • whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare; • the ability to protect our intellectual property rights related to our product candidates; • the ability to avoid infringing on the intellectual property rights of others; • the ability to manufacture and sell commercial quantities of any of our product candidates that receive regulatory approval; and • acceptance of any of our product candidates, if approved, by payors, patients, and physicians and other healthcare providers, including perception of the safety and efficacy of the oral delivery of biologics. Because our research approach depends on our proprietary RaniPill platform, it may be difficult for us to continue to successfully compete in the face of rapid changes in technology. If we fail to continue to advance the RaniPill platform, technological change may impair our ability to compete effectively and technological advances or products developed by our competitors may render our technologies or product

candidates obsolete, less competitive or not economical. We currently have no marketing and sales organization. To the extent any of our product candidates for which we maintain commercial rights is approved for marketing, if we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell any of our product candidates, or generate product revenue. We currently do not have a marketing or sales organization for the marketing, sales and distribution of biologics products. In order to commercialize any product candidates that receive marketing approval, we would have to build 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. In the event of successful development of any of our product candidates, we may elect to build a targeted specialty sales force which will be expensive and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. With respect to our product candidates, we may choose to partner with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into collaborations with third parties for the commercialization of approved products, if any, on acceptable terms or at all, or if any such partner does not devote sufficient resources to the commercialization of our products or otherwise fails in commercialization efforts, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future revenue will be materially and adversely impacted. If the market opportunities for any product that we develop are smaller than we believe they are, our commercial revenue may be adversely affected and our business may suffer. Our projections of both the number of people who have the diseases we may be targeting, as well as the subset of people with these health issues who have the potential to benefit from treatment with our current and any of our future product candidates are based on our beliefs and estimates. For example, we are developing RT- ~~101 for the treatment of acromegaly, for which we estimate the patient population is approximately 25, 000 people in the United States as of November 2016, and RT-~~ 102, an oral administration of PTH for the treatment of osteoporosis, for which we estimate the patient population is approximately ten million in the United States as of 2018 **, and RT- 111 for the treatment of inflammatory conditions, for which we estimate the patient population to be seven million for psoriasis and three million for Crohn' s disease or ulcerative colitis in the United States as of 2021** . These estimates, and estimates for our other product candidates, have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new information may change the estimated incidence or prevalence of these diseases. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria for indications included in the final label for each of our product candidates approved for sale for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of our product candidates relative to such alternative treatments, acceptance by the medical community and patients, and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Even if we obtain significant market share for our products, if approved, if the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications. Additional time may be required to obtain regulatory approval for our product candidates because they are combination products. We believe our product candidates are biologic- device combination products that require coordination within the FDA and comparable foreign regulatory authorities for review of their device and biologic components. Although the FDA and comparable foreign regulatory authorities have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process. Even if we obtain and maintain approval for any of our product candidates from the FDA, we may never obtain approval for our product candidates outside of the United States, which would limit our market opportunities and adversely affect our business. Sales of our product candidates outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval and, to the extent that we retain commercial rights following clinical development, we would plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union and additional foreign countries. Even if the FDA grants marketing approval for a product candidate, comparable foreign regulatory authorities must also approve the manufacturing and marketing of that product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our products is also subject to approval. We may decide to submit an MAA to the EMA for approval in the European Economic Area (" EEA "). As with the FDA, obtaining approval of an MAA from the EMA is a similarly lengthy and expensive process and the EMA has its own procedures for approval of product candidates. Even if a product is approved, the FDA or the EMA, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time- consuming clinical trials or reporting as conditions of approval. Foreign regulatory authorities in countries outside of the United States and the EEA also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by comparable foreign regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in

obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, regulatory approval for any of our product candidates may be withdrawn. If we fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. Risks Related to Our Reliance on Third Parties We may not be successful in maintaining or obtaining formulation and manufacturing collaborations, and any potential partner may not devote sufficient resources to the formulation and manufacturing of our product candidates or may otherwise fail in formulation and manufacturing efforts, which could adversely affect our ability to develop certain of our product candidates and adversely affect our financial condition and operating results. In the past, we have entered into evaluation agreements with Takeda and certain other pharmaceutical companies concerning the formulation and manufacture of oral versions of Factor VIII and other molecules. In January 2023, we entered into a License and Supply Agreement with Celltrion, under which we receive supply of ustekinumab biosimilar from Celltrion for RT- 111 and Celltrion has a right of first negotiation to obtain development and commercialization rights for RT- 111 ~~(a " Collaboration ")~~ after completion of a Phase 1 clinical trial that meets its primary endpoint (s). ~~If~~ **In May 2023,** we **entered into another License and Supply Agreement with Celltrion, under which we receive supply of adalimumab biosimilar from Celltrion for RT- 105 and Celltrion has a right of first negotiation to obtain development and commercialization rights for RT- 105 after** ~~complete~~ **completion** ~~such~~ **of a Phase 1** clinical trial **that meets its primary endpoint (s). We believe the Phase 1 clinical trial that we completed with RT- 111** , **the topline data of which we announced in February 2024, satisfies the requirements for triggering** Celltrion ~~exercises its~~ **' s** right of first negotiation ~~, and~~ **with respect to that program. If** the parties enter into ~~a Collaboration~~ **an agreement granting Celltrion development and commercialization rights for RT- 111 or RT- 105** , we may be reliant on Celltrion to develop and commercialize ~~RT- 111~~ **the applicable product (s)** in certain countries or worldwide. Future evaluation agreements, supply agreements or collaborations entered into, may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and growth prospects. While we plan to expand our reach by selectively entering into strategic partnerships, we may not be able to enter into such partnerships, and if we do, we may not be able to maintain significant rights or control of future development and commercialization of our product candidates. Accordingly, if we collaborate with a third party for development and commercialization of a product candidate, we may relinquish some or all of the control over the future success of that product candidate to the third party, and that partner may not devote sufficient resources to the formulation and manufacture of our product candidate or may otherwise fail in these efforts, in which event the formulation and manufacture of the product candidate in the collaboration could be delayed or terminated and our business could be substantially harmed. We believe our product candidates are biologic- device combination products that we anticipate will be regulated under the biologic regulations of the FDA based on ~~its~~ **their** primary mode of action as a biologic. Third- party manufacturers may not be able to comply with the regulatory requirements, known as cGMP, applicable to biologic- device combination products, including applicable provisions of the FDA' s drug and biologics cGMP regulations, device cGMP requirements embodied in the medical device Quality System Regulations (" QSRs"), or similar regulatory requirements outside the United States. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit any BLA or NDA to the FDA. In addition, the terms of any potential collaboration or other arrangement that we may establish may not be favorable to us or may not be perceived as favorable, which may negatively impact the price of our Class A common stock. In some cases, we may be responsible for continuing formulation and manufacture of a product candidate under a collaboration, and the payments we receive from our partner may be insufficient to cover the cost of this work or may result in a dispute between the parties. Moreover, collaborations and sales and marketing arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain, which may be detrimental to the development of our other product candidates. We are subject to a number of additional risks associated with our dependence on collaborations with third parties, the occurrence of which could cause our collaboration arrangements to fail. Conflicts may arise between us and partners, such as conflicts concerning the implementation of development plans, efforts and resources dedicated to the product candidate, interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any such conflicts arise, a collaborator could act in its own self- interest, which may be adverse to our interests. Any such disagreement between us and a partner could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating sufficient revenue to achieve or maintain profitability: • reductions in the payment of royalties or other payments we believe are due pursuant to the applicable collaboration arrangement; • actions taken by a partner inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration; or • unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities. In addition, the termination of a collaboration may limit our ability to obtain rights to the product or intellectual property developed by our collaborator under terms that would be sufficiently favorable for us to consider further development or investment in the terminated collaboration product candidate, even if it were returned to us. We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or do not meet regulatory requirements or expected deadlines, we may not be able to obtain timely regulatory approval for or commercialize our product candidates and our business could be substantially harmed. We have relied upon and plan to continue to rely upon third- party CROs to monitor and manage clinical trials and collect data during our

preclinical studies and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that their conduct meets regulatory requirements and that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities. Thus, we and our CROs are required to comply with GCPs, which are regulations and guidelines promulgated by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may not accept the data or may require us to perform additional clinical trials before considering our filing for regulatory approval or approving our marketing application. We cannot assure you that upon inspection by a regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCPs. While we have agreements governing activities of our CROs, we may have limited influence over their actual performance and the qualifications of their personnel conducting work on our behalf. Failure to comply with applicable regulations in the conduct of the clinical studies for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process. Some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the volunteers participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third- party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. We depend on third- party suppliers for key materials used in our manufacturing processes as well as for the manufacturing of APIs and drug substances. We do not have long- term supply arrangements in place for APIs and drug substances. The loss of third-party suppliers or their inability to supply us with adequate materials and APIs or drug substances could prevent or delay the conduct of our clinical trials and the commercialization of our products, if approved, and could harm our business. We rely on third- party suppliers for the supply of the raw materials and APIs or drug substances required for the production of our product candidates, and we may to some extent rely on third- party manufacturers for the commercial supply of any of our product candidates for which we seek to obtain marketing approval. In addition, we work with third parties to manufacture and develop biologics for inclusion in the RaniPill capsule and for use in our clinical trials. Our dependence on these third parties and the challenges we may face in obtaining adequate supplies of raw materials, APIs and drug substances involve several risks, including limited control over pricing, availability, quality, delivery schedules and non- exclusivity. As a small company, our negotiation leverage is limited, and we are likely to get lower priority than our competitors who are larger than we are. We do not have long- term supply agreements, and we purchase our required supplies on a development manufacturing services agreement or purchase order basis or the like. These third parties may not continue to provide us with the quantities of these materials that we require to satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials, APIs or drug substances could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could prevent us from conducting, or cause delays to, our current or planned clinical trials, commercialization of our products, if approved, and have an adverse effect on our business, financial condition and results of operations. We may seek to enter into collaborations, licenses and other similar arrangements and may not be successful in doing so, and even if we are, we may not realize the benefits of such relationships. We may seek to enter into, and have entered into, collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of our product candidates, due to capital costs required to develop or commercialize the product candidate or manufacturing constraints. **In addition, we may seek to enter into collaborations, joint ventures, licenses and other similar arrangements with third party biopharmaceutical companies for use of the RaniPill technology in developing and commercializing their own molecules.** We may not be successful in our efforts to establish or maintain such collaborations ~~for~~ **because our research and development pipeline may be insufficient,** our product candidates ~~because our~~ **or technology** ~~research and development pipeline may be insufficient, our product candidates~~ may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates **or technology** as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time consuming and complex. Further, any future collaboration agreements may restrict us from entering into additional agreements with potential collaborators. Following a strategic transaction or license, we may not achieve an economic benefit that justifies such transaction. In January 2023, we entered into a License and Supply Agreement with

Celltrion, under which Celltrion has a right of first negotiation to obtain development and commercialization rights for RT- 111 after completion of a Phase 1 clinical trial that meets its primary endpoint (s). ~~Even if~~ **In June 2023,** we **entered into another License and Supply Agreement with Celltrion, under which we receive supply of adalimumab biosimilar from Celltrion for RT- 105 and Celltrion has a right of first negotiation to obtain development and commercialization rights for RT- 105 after** ~~complete~~ **completion** ~~such~~ **of a Phase 1** clinical trial **that meets its primary endpoint (s). We believe the Phase 1 clinical trial that we completed with RT- 111 , the topline data of which we announced in February 2024, satisfies the requirements for triggering** Celltrion ~~may~~ **' s right of first negotiation. However, even if we complete the requisite clinical trial for RT- 111 or RT- 105, Celltrion has** ~~not~~ **no obligation to** exercise its right of first negotiation, ~~or~~ **and** if it does exercise such right we may not be able to agree on terms favorable to us or acceptable to us or Celltrion. Accordingly, there can be no assurance that ~~we will complete the required development of RT- 111, that Celltrion will exercise its right of first negotiation if we do, or that~~ the parties will enter into ~~a Collaboration~~ **an agreement granting Celltrion development and commercialization rights for the applicable product** following **completion of a Phase 1 trial that meets its primary endpoint (s) or** any ~~such~~ exercise of the right of first negotiation. **In November 2023, we announced that we have paused the RT- 105 program until we have appropriate resources to continue the development. While the License and Supply Agreement with Celltrion regarding adalimumab biosimilar for RT- 105 remains in place, if we do not initiate a Phase 1 trial with RT- 105 within a certain time period specified in the agreement or fail to deliver Phase 1 data to Celltrion within a later timepoint specified in the agreement, Celltrion will have a right to terminate that License and Supply Agreement. In addition, as a result of a pausing of the RT- 105 program, Celltrion' s interest in exercising its right of first negotiation with respect to that program or negotiating a collaboration for that program could diminish.** Even if we are successful in our efforts to establish a ~~Collaboration~~ **collaboration** with Celltrion or collaborations with other third parties, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed, the safety of a product candidate is questioned or sales of an approved product candidate are unsatisfactory. In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and **, if approved,** commercialization of our product candidates ~~, if approved~~ , and may not conduct those activities in the same manner as we do. Any termination of collaborations that we may enter into in the future, or any delay in entering into collaborations related to our product candidates, could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations. Risks Related to Our Business and Industry Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide. Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to: • the timing, degree of success and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our product candidates, which may change from time to time; • coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products; • the cost of manufacturing our product candidates, which may vary depending on the quantity of production; • expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies; • the level of demand for any approved products, which may vary significantly; • future accounting pronouncements or changes in our accounting policies; and • the timing and success or failure of preclinical studies or clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners. The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide. We are heavily dependent on the success of our product candidates in our core programs, and if any of these product candidates fail to enter clinical trials, receive regulatory approval or are not successfully commercialized, our business would be adversely affected. We currently have no product candidates that are in late- stage clinical trials or are approved for commercial sale, and we may never be able to develop a marketable product. We have a limited number of product candidates in early clinical development. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to the development of the RaniPill platform that is designed to enable the oral administration of a broad range of biologics and drugs used to treat multiple diseases and disorders. The RaniPill capsule may not receive regulatory approval in connection with any biologic or drug or, if approved, it may not be successfully commercialized. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of our product candidates for the indications we are seeking will remain subject to extensive regulation by the FDA and comparable foreign regulatory authorities in the United States and other countries, each of which has differing regulations. In addition, even if approved, pricing and reimbursement will be subject to further review and discussions with payors. We are not permitted to market any product candidate in the United States until after approval of a BLA or NDA from the FDA, or a similar marketing authorization from comparable authorities in any foreign countries until after approval of a marketing application by corresponding foreign regulatory authorities. We have conducted early clinical development of some of our product candidates.

We will need to conduct larger, more extensive clinical trials in the target patient populations for these product candidates and their indications to support a potential application for regulatory approval by the FDA or corresponding foreign regulatory authorities. We have not previously submitted a BLA or NDA to the FDA, or similar product approval filings to comparable foreign authorities, for any product candidate, and our product candidates may not be successful in clinical trials or receive regulatory approval. Filing an application and obtaining regulatory approval for a biologic product candidate or drug product candidate is an extensive, lengthy, expensive and inherently uncertain process, and the regulatory authorities may delay, limit or deny approval of our product candidates for many reasons, including: • we may not be able to demonstrate that any of our product candidates is safe and effective to the satisfaction of the FDA or comparable foreign regulatory authorities; • the FDA or comparable foreign regulatory authorities may require additional preclinical studies or clinical trials prior to granting approval, which would increase our costs and extend the pre- approval development process; • the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for approval; • the FDA or comparable foreign regulatory authorities may disagree with the number, design, size, conduct or statistical analysis of one or more of our clinical trials; • the FDA or comparable foreign regulatory authorities may disagree with, or not accept, our interpretation of data from our preclinical studies and clinical trials; • the FDA or comparable foreign regulatory authorities may identify deficiencies in our manufacturing processes or facilities which would be required to be corrected prior to regulatory approval; • the success or further approval of competitor products approved in indications in which we undertake development of our product candidates may change the standard of care or change the standard for approval of our product candidate in our proposed indications; and • the FDA or comparable foreign regulatory authorities may change their approval policies or adopt new regulations. Our product candidates will require additional research, clinical development, manufacturing activities, regulatory approval in multiple jurisdictions (if regulatory approval can be obtained at all), securing sources of commercial manufacturing supply and building of or partnering with a commercial organization. Our planned clinical trials for our product candidates may not be initiated or completed in a timely manner or successfully, or at all. Further we may not advance any other product candidates into clinical trials. Moreover, any delay or setback in the development of any product candidate would be expected to adversely affect our business and cause our stock price to fall. We may not be successful in our efforts to use and expand our proprietary RaniPill platform to build a pipeline of product candidates **and partnered programs** . A key element of our strategy is to leverage the RaniPill platform to expand our pipeline of product candidates and **to enter into collaborations, licenses or similar arrangements with third party biopharmaceutical companies to use the RaniPill technology** in **developing and commercializing the third party' s molecules. In** order to do so, we must continue to invest in the RaniPill platform and development capabilities. Although our research and development efforts to date have resulted in a pipeline of our core product candidates, these product candidates may not be safe and effective and may not obtain regulatory approval. In addition, although we plan to develop the RaniPill platform to deliver a diverse pipeline of product candidates across multiple diseases and disorders **(alone or with partners)** , we may not prove to be successful at doing so. **Potential partners** ~~Furthermore, we~~ may **not see** ~~also find that~~ the ~~uses of~~ **opportunities created by** the RaniPill platform ~~are limited because alternative uses of~~ **the same way we do,** ~~our~~ - **or** ~~biologics prove~~ **at all, and even if they do we may** not ~~to~~ be ~~safe~~ **able to negotiate and enter into licensing** or ~~effective~~ **other transactions with potential partners on favorable terms, or at all** . Even if we are successful in continuing to build our pipeline **or establishing licensing arrangements with third parties regarding use of our platform for their molecules** , the potential product candidates that we **or they** identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval or achieve market acceptance. Even after approval, if we **or potential partners** cannot successfully develop or commercialize ~~our~~ products **using the RaniPill technology** , or if serious adverse events are discovered after commercialization, we will not be able to generate any product revenue, which would adversely affect business. Changes in regulatory requirements and guidance may also occur and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs or ethics committees for re- examination, which may impact the costs, timing or successful completion of a clinical trial. The policies of the FDA and comparable foreign regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our current or any of our future product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability, which would harm our business, prospects, financial condition and results of operations. If we are required to conduct additional clinical trials or other preclinical studies with respect to our current or future product candidates, or if we are unable to successfully complete our preclinical studies or planned clinical trials, we may be delayed in obtaining regulatory approval of our current or any of our future product candidates, we may not be able to obtain regulatory approval at all or we may obtain approval for indications that do not provide a broad commercial opportunity. Our product development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process for our current or any of our future product candidates. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products if and when approved. If any of this occurs, our business would be harmed. Most of our product candidates are in research or preclinical development and have not entered into clinical trials. If we are unable to develop, test and commercialize our product candidates, our business will be adversely affected. As part of our strategy, we seek to discover, develop and commercialize a portfolio of product candidates that deliver different biologics through the RaniPill capsule. Research programs to identify appropriate biological targets and product candidates require substantial scientific, technical, financial and human resources, whether or not any product

candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including: • our financial and internal resources are insufficient; • our research methodology used may not be successful in identifying potential product candidates; • competitors may develop alternatives that render our product candidates uncompetitive; • our product candidates may be shown to have harmful side effects or other characteristics that indicate such product candidate is unlikely to be effective or otherwise unlikely to achieve applicable regulatory approval; • our product candidates may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or • our product candidates may not be accepted by patients, the medical community, healthcare providers or third- party payors. Our proprietary RaniPill platform may not result in any products of commercial value. We have developed a proprietary platform designed to enable the administration of biologics previously only administrable by subcutaneous or IV injection, and this approach forms the basis of our overall development strategy for all of our product candidates. For multiple reasons, the RaniPill platform may not ultimately be commercially valuable, including: • the RaniPill platform may not work in conjunction with our targeted biologic indications or future indications to yield product candidates that can enter clinical development; • we may not be successful in our efforts to expand the applicability of the RaniPill platform beyond our current product pipeline; • we may not be able to enter into licensing or partnership agreements on suitable terms to obtain and develop oral versions of biologics; and • the medical community may not accept the RaniPill platform and physicians may not prescribe our products to patients, if approved. In addition, we have designed our platform to be drug- agnostic, which we believe could enable us to expand into additional markets beyond our current pipeline. While our research and development efforts support the use of the peptides and antibodies we have evaluated to date for inclusion in the RaniPill capsule, there could be molecules that are unable to be inserted in the RaniPill capsule, whether as a result of payload capacity, mechanism of action, or otherwise, the result of which would significantly harm our product candidates' commercial potential. Furthermore, **certain of** the product candidates contemplated by our current product pipeline ~~were designed~~ **may require use of the RaniPill HC, which is in preclinical testing and has not been tested clinically. There is no guarantee that we will be able to complete development of the RaniPill HC or that it will be compatible for use** with ~~needles~~ **product candidates or** that ~~have the ability~~ **it will achieve test results sufficient** to **advance it** ~~deliver 3 mg of a biologic, which we refer to as payload capacity. While we are developing an oral delivery capsule intended to deliver up to 20 mg which could enable us to expand our~~ **or** ~~platform~~ **our product candidates** to **later stages of development and /** ~~include additional molecules, we may still be precluded from using certain high load biologics for~~ **or commercialization** ~~inclusion in the RaniPill capsule~~ , **, any of** which could adversely affect the commercial potential of the RaniPill platform. Additionally, to the extent we are able to develop RaniPill HC or another device with a larger payload capacity, we may be required to conduct additional preclinical or clinical studies to establish performance characteristics of the updated design, and for regulatory authorities to permit evaluation of the updated design in human subjects. As a result of a failure in any one of these factors, our business, financial condition and results of operations could be adversely affected. Our high- capacity oral delivery device, RaniPill HC, is in early stages of development, and it is subject to the inherent risks and uncertainties of developing a novel, innovative technology. Our efforts to develop RaniPill HC may not be successful. RaniPill HC is in early stages of development, and it is subject to the inherent risks and uncertainties of developing a novel, innovative potential technology. Development of a new delivery device is time- consuming and costly, and could distract the attention of our management or other employee resources from our existing and future business. Our efforts to develop RaniPill HC may not be successful or RaniPill HC may require modifications that could limit its utility or viability as an oral delivery device. We may not be able to complete development of RaniPill HC in a timely manner, or at all, or such development may require an amount of time and resource that we are not able to devote to it or ~~believes~~ **believe** is not warranted based on the estimated benefits. The potential value of RaniPill HC may never be realized for a variety of reasons, including that we are not able to successfully develop RaniPill HC, third parties develop competitive technologies or products similar to or more effective or attractive than RaniPill HC, we are not able to develop manufacturing processes to produce RaniPill HC consistently and reliably or within a cost range that makes RaniPill HC products commercially viable. Any such factor could reduce or eliminate the potential value of RaniPill HC or product candidates that could be developed using RaniPill HC. In addition, while we currently expect that RaniPill HC will be able to leverage many of the same components and manufacturing processes as are used for our existing delivery device, it may turn out that such components or manufacturing processes are not suited for RaniPill HC or RaniPill HC may require modifications that negatively affect our ability to use common components or processes between the RaniPill GO and RaniPill HC. Any of the foregoing factors or circumstances may adversely affect our business prospects, our attractiveness as a business partner or collaborator, our ability to raise additional capital, and our financial results. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any of our product candidates, if approved. We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to stop development or, if approved, limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • delay or termination of clinical studies; • injury to our reputation; • withdrawal of clinical trial participants; • initiation of investigations by regulators; • costs to defend the related litigation; • a diversion of management' s time and our resources; • substantial monetary awards to trial participants or patients; • decreased demand for our product candidates; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • loss of revenue from product sales; and • the

inability to commercialize any of our product candidates, if approved. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the development or commercialization of our product candidates. Although we maintain clinical trial liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. The manufacture and packaging of biologics is subject to FDA requirements and those of comparable foreign regulatory authorities. If we or our third- party manufacturers fail to satisfy these requirements, our product development and commercialization efforts may be harmed. The manufacture and packaging of biologics is regulated by the FDA and comparable foreign regulatory authorities and must be conducted in accordance with the FDA' s cGMP and comparable requirements of foreign regulatory authorities. There are a limited number of manufacturers that operate under these cGMP regulations who are both capable of manufacturing biologics and willing to do so. Failure by us or our third- party manufacturers to comply with applicable regulations or requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product, operating restrictions and criminal prosecutions, any of which could harm our business. Our product candidates require aseptic manufacturing techniques that may present additional manufacturing challenges compared to other oral route of administration products. The same requirements and risks are applicable to the suppliers of the key raw material used to manufacture the active pharmaceutical ingredients or drug substances for the biologics of our product candidates. Manufacturers of combination products need to comply with both pharmaceutical cGMPs and medical device QSRs enforced by the FDA through its facilities inspection programs. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. We or third- party manufacturers of our product candidates may be unable to comply with these cGMP and QSR requirements and with other FDA and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any of our product candidates is compromised due to failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize such product candidate, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in the commercialization of our product candidates, entail higher costs or even prevent us from effectively commercializing our product candidates. Changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third- party manufacturer, may require prior FDA review and approval of the manufacturing process and procedures in accordance with the FDA' s cGMPs and QSRs. Any new facility is subject to a pre- approval inspection by the FDA and would again require us to demonstrate product comparability to the FDA. We would also need to verify, such as through a manufacturing comparability study, that any new manufacturing process would produce our product candidate according to the specifications previously submitted to the FDA, and there are comparable foreign requirements. The delays associated with the verification of a new third- party manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. This review may be costly and time consuming and could delay or prevent the launch of a product. Furthermore, in order to obtain approval of our product candidates by the FDA and comparable foreign regulatory authorities, we will be required to consistently produce our formulation of the API or drug substance, and the finished product in commercial quantities and of specified quality on a repeated basis and document our ability to do so. This requirement is referred to as process validation. Each of our potential API and drug substance suppliers will likely use a different method to manufacture API or drug substance, which has the potential to increase the risk to us that our manufacturers will fail to meet applicable regulatory requirements. We also need to complete process validation on the finished product in the packaging we propose for commercial sales. This includes testing of stability, measurement of impurities and testing of other product specifications by validated test methods. If the FDA does not consider the result of the process validation or required testing to be satisfactory, we may not obtain approval to launch the product or approval, launch or commercial supply after launch may be delayed. The FDA and comparable foreign regulatory authorities may also implement new requirements, or change their interpretation and enforcement of existing requirements, for manufacture, packaging or testing of products at any time. If we are unable to comply, we may be subject to regulatory actions, civil actions or penalties which could harm **our business. As a vertically- integrated manufacturer of a novel oral delivery technology, we may require significant time to develop manufacturing operations and processes capable of producing safe and reliable product at sufficient scale to meet business needs, if we are able to do so at all. Since our RaniPill capsule employs novel technologies, we manufacture many of the components and have customized equipment needed for manufacturing the RaniPill capsule and we are required to develop novel manufacturing processes. This requires the development of new methods and know- how, as well as specifications and testing appropriate for manufacture of the RaniPill capsule. It may take significant time to develop manufacturing operations and processes capable of producing safe and reliable product at sufficient scale to meet business needs, if we are able to do so at all. We may find that certain materials used for the RaniPill capsule are not suitable for use with some or any product candidates, that certain processes as designed do not perform as intended and must be re- designed, or that certain operations as currently performed cannot be scaled up or automated as planned or at all. Even if we are able to develop manufacturing operations and processes that perform as we intend, the FDA, EMA or other regulatory authorities or potential collaboration partners may not deem such operations or processes to be acceptable, in which event we may need to change such operations, processes, specifications or testing or develop new operations, processes, specifications or testing, which may result in delays in or**

adversely affect the development or potential approval of product candidates or the negotiation or completion of third party collaboration arrangements, or require us to divert resources and attention from our product candidates or other business opportunities. Any such event could have a material adverse impact on our business. We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws health information privacy and security laws, and other healthcare laws and regulations. Violations of such laws and regulations could subject us to significant penalties. We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws data privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Healthcare providers and third- party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our arrangements with third- party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which we would market, sell and distribute our products. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third- party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. The laws that may affect our ability to operate include, but are not limited to: • the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation; • the federal false claims and civil monetary penalties laws, including the False Claims Act, which can be enforced through civil whistleblower or qui tam actions, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent; knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti- Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to " cause " the submission of false or fraudulent claims; • HIPAA, which created new federal criminal statutes that prohibit a person or entity from, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • HIPAA, as amended by HITECH, and their implementing regulations, which also imposes obligations, including mandatory contractual terms, on " covered entities, " including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective " business associates " that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions; • the federal civil monetary penalties statute, which prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary' s selection of a particular supplier of items or services reimbursable by a Federal or state governmental program; • the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to the government information related to certain payments and other " transfers of value " made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and requires applicable manufacturers to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members; and • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by any third- party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the data privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Further, in March 2010, the ACA, among other things, amended the intent requirements of the federal Anti- Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the ACA

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 False Claims Act. Moreover, while we do not submit claims and our customers make the ultimate decision on how to submit claims, from time to time, we may provide reimbursement guidance to our customers. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have continued their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and significant settlements in the healthcare industry. Responding to investigations can be time- and resource- consuming and can divert management' s attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we, or our directors, officers, employees, independent contractors, and / or agents, may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain. In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. For example, in the United States in March 2010, the ACA was enacted to increase access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and the health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry' s regulatory burdens and operating costs. **The** ~~Among the provisions of the~~ ACA **, among other things, increased the minimum level** of ~~importance to our potential product candidates~~ **Medicaid rebates payable by manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed** ~~are~~ **care organizations; required manufacturers to participate in a coverage gap discount program, under which** ~~the~~ **they** ~~following: • an annual~~ **must agree to offer point- of-sale discounts (increased to 70 percent** , **effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D; imposed a** non- ~~tax~~ deductible **annual** fee **on pharmaceutical** ~~payable by any entity that manufactures~~ **manufacturers** or ~~imports~~ **importers** ~~specified~~ **who sell certain "** branded prescription drugs **"** ~~and biologic agents payable~~ to ~~the~~ **specified** federal government ~~based on each company' s market share of prior year total sales of branded products to certain federal healthcare~~ programs **, implemented** ~~; • an increase in the statutory minimum rebates~~ a **new** ~~manufacturer must pay under the Medicaid Drug Rebate Program; • a~~ methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted **,** or injected **expanded the types of entities eligible for the 340B drug discount program** ; **expanded** ~~• extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations; • expansion of~~ eligibility criteria for Medicaid programs ~~in certain states~~ ; ~~• a Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 50 % (increased~~ -- **created** ~~to 70 % pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point- of- sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries under their coverage gap period, as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D; • expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; • a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and •~~ a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research **; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending** . There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021 the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. Moreover, prior to the U. S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period coverage through the Affordable Care Act marketplace, and instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost through a newly established manufacturer discount program. It is possible that the ACA will be subject to additional challenges in the future. It is unclear how such challenges and

the healthcare reform measures of the Biden administration will impact the ACA, or the impact any changes to the ACA may have on our ability to commercialize products or the prices we are able to obtain. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2 % per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, will remain in effect through 2031 unless additional action is taken by Congress ~~. Under current legislation the actual reduction in Medicare payments will vary from 1 % in 2022 to up to 4 % in the final fiscal year of this sequester~~ . Further, Congress is considering additional health reform measures. In addition, recently there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their commercial products. At the federal level, the former Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. 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, on September 9, 2021, the U. S. Department of Health and Human Services 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 as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain single- source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023 **. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations** , although ~~they~~ **the** ~~may be~~ **Medicare drug price negotiation program is currently** subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. ~~Further,~~ **In response to** the Biden administration ~~released an additional~~ **' s October 2022** executive order **,** on ~~October~~ **February** 14, ~~2022~~ **2023** , ~~directing~~ HHS **released** ~~to submit~~ a report **outlining** ~~on how the~~ **three** ~~Center for Medicare and Medicaid Innovation can be further leveraged to test~~ new models for **testing by the CMS Innovation Center which will be evaluated on their ability to** ~~lowering~~ **lower** ~~drug~~ **the** ~~costs~~ **cost** ~~for Medicare~~ **of drugs, promote accessibility,** and ~~Medicaid beneficiaries~~ **improve quality of care** . It is unclear whether **the models** ~~this executive order or similar policy initiatives~~ will be ~~implemented~~ **utilized in any health reform measures** in the future **. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework** . Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control drug pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures **. For example, on January 5, 2024, the FDA approved Florida' s Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs** . The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates, if approved. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare therapies, which could result in reduced demand for our product candidates or additional pricing pressures. Legislative and regulatory proposals have also been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U. S. Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any. In some countries, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution or arbitrage between low- priced and high- priced countries, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidate to other available therapies, which is time- consuming and costly. If coverage and reimbursement of our product candidates are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially. Our future success depends on our ability to retain our executive officers and to attract, retain and motivate highly qualified personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Our industry has experienced a high rate of turnover of management personnel in recent years. Our ability to compete in the highly competitive biotherapeutics and pharmaceuticals industries depends upon our

ability to attract and retain highly qualified managerial, scientific, medical, engineering and regulatory personnel. We are highly dependent on our ~~founder and Chairman, Mir Imran, and our~~ existing senior management team. We are not aware of any present intention of any of these individuals to leave us. All of our employees may terminate their employment with us at any time, with or without notice. In addition, we manufacture the RaniPill capsule internally. As a result, we rely and will continue to rely on highly qualified manufacturing personnel to manufacture the RaniPill capsule. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements would harm our manufacturing efforts as well as our business, financial condition and prospects. Our success depends on our ability to continue to attract, retain and motivate highly skilled and experienced personnel with scientific, medical, regulatory, manufacturing and management training and skills. We may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among biotherapeutics, biotechnology, pharmaceutical and other businesses. Many of the other biopharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation or more diverse opportunities and better opportunities for career advancement. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize product candidates and to grow our business and operations as currently contemplated. We will need to expand the size of our organization, and we may experience difficulties in managing this growth. As our development and commercialization plans and strategies develop and we operate as a public company, we expect to need additional managerial, operational, scientific, sales, marketing, development, regulatory, manufacturing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including: • designing and managing our clinical trials effectively; • identifying, recruiting, maintaining, motivating and integrating additional employees; • managing our manufacturing and development efforts effectively; • improving our managerial, development, operational and financial systems and controls; and • expanding our facilities. ~~As~~ **Although in November 2023 we underwent a reduction in our workforce and paused or discontinued certain programs, we are continuing development of other programs and expanding our manufacturing footprint to support scale- up and automation. At such time as** our operations expand, we expect that we will need to manage relationships with our partners, suppliers, vendors and other third parties. Our future financial performance and our ability to develop and commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. We may not be successful in accomplishing these tasks in growing our company, and our failure to accomplish any of them could adversely affect our business and operations. If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed, and our business will be harmed. We estimate for planning purposes the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies, clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval, or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including: • our available capital resources or capital constraints we experience; • the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators, and our ability to identify and enroll patients who meet clinical trial eligibility criteria; • our receipt of approvals by the FDA and comparable foreign regulatory authorities and the timing thereof; • other actions, decisions or rules issued by regulators; • our ability to access sufficient, reliable and affordable supplies of compounds used in the manufacture of our product candidates; • the ability of our suppliers to reliably provide the quantity of materials needed to manufacture and commercialize our products; • the non- occurrence of adverse events or serious adverse events in preclinical studies or clinical trials of our product candidates; • the efforts of our collaborators and the success of our own efforts with respect to the commercialization of our products; and • the securing of, costs related to, and timing issues associated with, product manufacturing, including scale and automation processes, as well as sales and marketing activities. If we fail to achieve announced milestones in the timeframes we announce and expect, **our stock price may decrease,** the commercialization of our product candidates may be delayed and our business and results of operations may be harmed. We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management. From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out- licensing or in- licensing of intellectual property, products or technologies. Any future transactions could increase our near and long- term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in- process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Accordingly, although we may not undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects. Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured

liabilities. We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include products and completed operations liability, business personal property and directors' and officers' insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work- related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Our employees, independent contractors, principal investigators, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business. We are exposed to the risk that our employees, independent contractors, principal investigators, consultants and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information to the FDA, (ii) manufacturing standards, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations established and enforced by comparable foreign regulatory authorities, or (iv) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions. Our headquarters and certain of our data storage facilities are located near known earthquake fault zones. The occurrence of an earthquake, fire or any other catastrophic event could disrupt our operations or the operations of third parties who provide vital support functions to us, which could have a material adverse effect on our business and financial condition. We and some of the third- party service providers on which we depend for various support functions, such as data storage, are vulnerable to damage from catastrophic events, such as power loss, natural disasters, terrorism and similar unforeseen events beyond our control. Our corporate headquarters is located in San Jose, **California,** which in the past has experienced severe earthquakes and fires. We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as our data storage facilities or financial 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. We do not have a disaster recovery and business continuity plan in place. We may incur substantial expenses as a result of the absence or limited nature of our internal or third- party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our development plans and business. ~~Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U. S. government has shut down several times and certain regulatory authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our~~

~~regulatory submissions, which could have a material adverse effect on our business. Since March 2020 when foreign and domestic inspections were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre- approval inspections to prioritized basis and may experience delays in their regulatory activities. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections and resumed inspections in China and India in 2021. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Should FDA determine that an inspection is necessary for approval and inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interaction evaluation to be appropriate, the agency has stated that it generally intends to issue a complete response letter. Further, if there is an inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID- 19 pandemic. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or comparable foreign regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or comparable foreign regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.~~ A public health crisis ~~such as the COVID- 19 pandemic~~ could adversely impact our business including our ongoing and planned preclinical studies and clinical trials. **A public** ~~Since COVID- 19 surfaced in Fall 2019, the virus has spread to numerous countries, including the United States, resulting in the World Health~~ **health crisis may cause** ~~Organization characterizing COVID- 19 as a pandemic. As a result of the COVID- 19 pandemic, we experienced~~ delays in our preclinical and planned clinical development activities ~~. The COVID- 19 pandemic has~~ and may ~~continue to~~ impact our third- party manufacturers and suppliers, which could disrupt its supply chain or the availability or cost of materials. ~~Other public health crises could do the same.~~ If governmental authorities reinstate or issue new public health directives as a result of a public health crisis, these may negatively impact productivity, disrupt our business, and delay clinical programs and timelines and future clinical trials, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact business, results of operations and financial condition, including our ability to obtain financing. Such disruptions could severely impact our business, current and planned clinical trials and preclinical studies, including as a result of: • inability of our management to travel in connection with establishing partnerships and collaborations; • delays in receiving the supplies, materials and services needed to conduct preclinical studies and clinical trials; • disruption of our access to capital in the global financial markets; • delays or difficulties in enrolling patients in future planned clinical trials of our product candidates; • delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff; • diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of clinical trials; • interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints; • limitations in resources, including our employees, that would otherwise be focused on the conduct of our business or our current or planned preclinical studies or clinical trials, including because of sickness, the desire to avoid contact with large groups of people or restrictions on movement or access to our facility as a result of government- imposed " shelter in place " or similar working restrictions; • interruptions or delays in the operations of the FDA or comparable foreign regulatory authorities, which may impact review and approval timelines; • changes in regulations as part of a response to **a public health crisis** ~~the COVID- 19 pandemic~~ or other such disruptions which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs or require us to discontinue clinical trials altogether; • interruptions or delays to our pipeline and research programs; and • delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or furlough of government or contractor personnel. Further, as a result of a public health crisis, ~~such as the COVID- 19 pandemic,~~ we may be required to develop and implement additional clinical trial policies and procedures designed to help protect trial participants, which may include using telemedicine visits, remote monitoring of patients and clinical sites, and measures to ensure that data from clinical trials that may be disrupted as a result of the crisis are collected pursuant to the trial protocol and consistent with GCPs, with any material protocol deviation reviewed and approved by the site IRB. In addition, potential patients in our planned clinical trials may choose to not enroll, not participate in follow- up clinical visits, or drop out of the trial as a precaution during any such crisis. Additionally, governmental and medical resources and attention may be focused on the applicable crisis, which may make it more difficult to obtain required reviews or approvals, necessary materials, or clinical or preclinical sites or slots, or manufacturing slots for the products needed for our planned clinical trials, which could lead to delays in these trials. A continued and prolonged public health crisis ~~such as the COVID- 19 pandemic~~ could have a material negative impact on our business, financial condition, and operating results. It could also have the effect of heightening many of the other risks described in this " Risk Factors " section. We are subject to stringent and ~~changing~~ **evolving U. S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other** 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 **(including class claims) and mass arbitration demands** ; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences. In the ordinary course of business, we process personal data and other sensitive ~~information~~ **data** , including proprietary and confidential business data, trade secrets, intellectual property, **and** data we collect about trial participants in connection with clinical trials **(collectively** , ~~and~~ sensitive ~~third- party~~ data **)** . Our data

processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, ~~and~~ consumer protection laws **(e. g., Section 5 of the Federal Trade Commission Act), and other similar laws (e. g., wiretapping laws)** . For example, HIPAA, as amended by HITECH, imposes specific requirements relating to ~~the~~ privacy, security, and transmission of individually identifiable health information. **In** ~~As another example,~~ the ~~CCPA~~ **past few years, numerous U. S. states — including California, Virginia, Colorado, Connecticut, and Utah — have enacted comprehensive privacy laws that** ~~imposes~~ **impose certain** obligations on covered businesses **,** ~~. These obligations include~~ **including** ~~, but are not limited to,~~ providing specific disclosures in privacy notices and affording ~~California~~ residents **with** certain rights **concerning** ~~related to~~ their personal data. **As applicable, such rights include the right to access, correct, or delete certain personal data, and to opt- out of certain data processing activities, such as targeted advertising, profiling, and automated decision- making.** The ~~CCPA~~ **exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws** ~~allows~~ **allow** for statutory fines for noncompliance **. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020** (**collectively, " CCPA "), applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of** up to $ 7, 500 per **intentional** violation ~~)~~ **and allows private litigants affected by certain data breaches to recover significant statutory damages** . Although the CCPA exempts some data processed in the context of clinical trials, the CCPA ~~may increase~~ **increases** compliance costs and potential liability with respect to other personal data we ~~may~~ maintain about California residents. **Similar laws are being considered** ~~In addition, it is anticipated that the CPRA will be effective~~ in **several** ~~2023 and will expand the CCPA. The CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of enforcement.~~ ~~Other~~ **other** states ~~have enacted data privacy laws. For example~~ , **as well as** ~~Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which become effective in 2023. In addition, data privacy and security laws have been proposed~~ at the federal ~~, state,~~ and local levels ~~in recent years~~ , ~~which could~~ **and we expect more states to pass similar laws in the future. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments may** further complicate compliance efforts **, and increase legal risk and compliance costs for us and the third parties on which we rely** . Outside the United States, an increasing number of laws, regulations, and industry standards ~~apply to~~ **may govern** data privacy and security. For example, the EU GDPR, the UK GDPR and China' s Personal Information Protection Law (" PIPL "), impose strict requirements for processing personal data. For example, under the ~~EU~~ GDPR, **companies** ~~government regulators~~ may ~~impose~~ **face** temporary or definitive bans on data processing ~~, as well as~~ **and other corrective actions;** fines of up to 20 million ~~euros~~ **Euros under the EU GDPR, 17. 5 million pounds sterling under the UK GDPR** or **, in each case** 4 % of annual global revenue, whichever is greater **; or private** ~~. Further, individuals may initiate~~ litigation related to processing of ~~their~~ personal data **brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests** . We conduct clinical trials in Australia, may conduct clinical studies in the EU and other countries and may be subject to EU GDPR, UK GDPR or other data privacy regulations, and we work with companies and vendors in Asia and may be subject to new and emerging data privacy regimes in Asia, including China' s PIPL, Japan' s Act on the Protection of Personal Information, and Singapore' s Personal Data Protection Act. **In addition** ~~Certain jurisdictions have enacted data localization laws and cross- border personal data transfer laws~~ , **we** ~~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 **unable** ~~invalidated. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the EEA that the European Commission does not consider provide an adequate level of data privacy and security, such as the United States. The European Commission released a set of " Standard Contractual Clauses " (" SCCs ") that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. Currently, these Standard Contractual Clauses are a valid mechanism~~ to transfer personal data **from Europe and** ~~outside of the EEA, but there~~ **other** ~~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 United Kingdom similarly restrict personal data transfers outside of those~~ jurisdictions to ~~countries such as~~ the United States **or other countries due to** ~~that do not provide an adequate level of personal~~ data **localization requirements** ~~protection, and certain countries outside Europe (e. g., Russia, China, 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~~ **or limitations on** cross- border data **flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the** ~~transfers~~ **transfer of** ~~, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring~~ personal data **to** ~~from Europe or~~ other **countries** ~~foreign jurisdictions~~ . ~~The inability to import~~ **In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of** personal data to the United States ~~could significantly~~ and **other countries whose privacy laws it generally believes** ~~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 that~~ are ~~subject to such~~ **inadequate. Other jurisdictions may adopt similarly stringent**

interpretations of their data localization and cross- border data transfer ~~or localization~~ laws ~~; or requiring us~~ **. Although there are currently various mechanisms that may be used** to **transfer** ~~increase our~~ personal data **from the EEA and UK to the United States in compliance with law, such as the EEA' s standard contractual clauses, the UK' s International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U. S.- based organizations who self- certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data** processing **activities to other** ~~capabilities and infrastructure in foreign~~ jurisdictions **(such as Europe)** at significant expense ~~. In addition~~ , ~~privacy advocates~~ **increased exposure to regulatory actions, substantial fines** and ~~industry~~ **penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activitist** groups **. Some European regulators** have ~~proposed, and may propose, standards with which we~~ **ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR' s cross- border data transfer limitations. We** are **also** ~~legally or contractually~~ bound **by contractual** ~~to comply. Our~~ obligations related to data privacy and security **, and our efforts to comply with such obligations may not be successful. We publish a privacy policy on our website. If this policy or other privacy or security- related statements or materials we may publish is found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences. Obligations related to data privacy and security (and consumers' data privacy expectations)** are quickly changing ~~in an~~ **, becoming** increasingly stringent ~~fashion~~ , **and** creating ~~some~~ uncertainty ~~as to the effective future legal framework~~ . Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires **us to devote** significant resources and may necessitate changes to our **services,** information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. **We** ~~Although we endeavor to comply with all applicable data privacy and security obligations, we~~ may at times fail (or be perceived to have failed) **in our efforts** to ~~do so~~ **comply with our data privacy and security obligations** . Moreover, despite our efforts, our personnel or third parties ~~upon whom~~ **on which** we rely may fail to comply with such obligations, which could negatively impact our business operations ~~and compliance posture~~ . **If we** ~~For~~ **or the** ~~example, any failure by a~~ third ~~- party processor~~ **parties on which we rely fail, or are perceived** to **have failed, to address or** comply with applicable ~~law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others. If we fail, or are perceived to have failed, to address or comply with~~ data privacy and security obligations, we could face significant consequences **,** ~~. These consequences may include~~ **including** ~~,~~ but ~~are~~ not limited to ~~, :~~ government enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class- ~~related~~ **action** claims) **; and mass arbitration demands** ; additional reporting requirements and / or oversight; bans on processing personal data; and orders to destroy or not use personal data **; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations** . Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including, as relevant, clinical trials) **; loss of customers** ; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or ~~revision~~ **substantial changes to** ~~or~~ **our** ~~restructuring of~~ **business model** ~~our~~ **or** operations. If our ~~internal~~ **information** technology systems or ~~sensitive information, or~~ those **of** ~~used by our~~ third ~~- party collaborators~~ **parties on which we rely** , **or** ~~vendors, contractors or~~ **our data** ~~consultants,~~ 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; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences. In the ordinary course of our business, we ~~may~~ **and the third parties upon which we rely** process sensitive **data, and as a result, we face a variety of evolving threats that could cause security incidents. Cyberattacks, malicious internet- based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and** information **technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer " hackers, " threat actors, " hacktivists, " organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation- state- supported actors. Some actors now engage and are expected to continue to engage in cyber- attacks, including without limitation nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber- attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, develop, test and distribute our capsules, product candidates, and other goods and services** . We ~~may~~ **and the third parties upon which we** rely ~~upon~~ **are subject to a variety of evolving threats, including**

but not limited to social- engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. We regularly have employees that work remotely. Remote work has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. In addition, our reliance on third- party **collaborators, consultants, contractors, suppliers, and** service providers **could introduce new cybersecurity risks and vulnerabilities, including supply- chain attacks, and other threats to our business operations. We rely on third parties** and technologies to operate critical business systems to process sensitive ~~information~~ **data** in a variety of contexts, including, without limitation, **contract research organizations** ~~third- party providers of cloud- based infrastructure, encryption and authentication technology~~, employee email, ~~content delivery to customers, clinical trials~~ and other functions **. We also rely on third parties to provide other products, services, parts, or otherwise to operate our business** . 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. **If** ~~We may share or~~ **our** ~~receive sensitive information with or from~~ third parties **experience** ~~. Cyberattacks, malicious internet- based activity, and online and offline fraud are prevalent and continue to increase. These threats come from~~ a **security incident** ~~variety of sources, including traditional computer " hackers, " threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation- state- supported actors. Some actors now engage and are expected to continue to engage in cyber- attacks, including without limitation nation- state actors for~~ - **or** ~~geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and~~ other **interruption** ~~major conflicts~~, we ~~and~~ **could experience adverse consequences. While we may be entitled to damages if** the third parties ~~upon~~ **on** which we rely **fail** ~~may be vulnerable~~ to **satisfy their privacy or security** ~~a heightened risk of these attacks, including cyber~~ - ~~attacks~~ **related obligations to us** , ~~that could materially disrupt~~ **any award may be insufficient to cover our damages,** ~~our~~ - **or** ~~systems and operations, supply chain, and ability to produce, develop, test and distribute our capsules, product candidates, and other goods and services. We and the third parties upon which~~ we ~~rely~~ may be ~~subject~~ **unable** to **recover** ~~a variety of evolving threats, including but not limited to social- engineering attacks (including through phishing attacks), malicious code (~~such **award** ~~as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats~~ . **In addition** ~~Ransomware attacks, including by organized criminal threat actors, nation- states, and nation- state- supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting 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 or our third- party partners' supply chains have not been compromised ~~or~~ **. While we have implemented security measures designed to protect against security incidents, there can be no assurance** that ~~they do~~ **these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and / or software, including that of third parties upon which we rely). We may** not ~~contain~~ **, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be** ~~exploitable~~ --- **exploited** ~~defects~~ **and result in a security incident. Any of the previously identified** or ~~bugs~~ **similar threats could cause a security incident or other interruption** that could result in ~~a breach~~ **unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure** of **, or access to** ~~or~~ **our** ~~disruption to~~ **sensitive data or** our information technology systems **,** or **those of** the third **parties on** ~~- party information technology systems that support us and our services. Travel and our remote workforce poses increased risks to our information technology systems and data, as employees utilize network connections outside our premises. Future or past business transactions (such as acquisitions or integrations) could also expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Despite the implementation of security and back- up measures, our internal computer, server, and other information technology systems as well as those of our third- party collaborators, consultants, contractors, suppliers, and service providers, have and may continue to be vulnerable to the previously identified or similar threats, any of~~ which **we rely** ~~could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized~~

~~access to, use or disclosure of, corruption of, or loss of sensitive, and / or proprietary information, including personal data and health- related information, and could subject us to significant liabilities and regulatory and enforcement actions, and reputational damage~~ . A security incident or other interruption could disrupt our ability (and that of third parties ~~upon whom~~ **on which** we rely) to provide our products. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in any regulatory approval or clearance efforts and significantly increase our costs to recover or reproduce the data, and subsequently commercialize the product. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, **or** industry- standard or reasonable security measures to protect our information technology systems and sensitive ~~information~~ **data** . ~~While we have implemented~~ **Applicable data privacy and** security ~~measures designed~~ **obligations may require us** to ~~protect against~~ **notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of** security incidents ~~, there can be no assurance that these measures will be effective. 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 address vulnerabilities, if any, in our information technology systems (including our products), 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 our third- party collaborators, consultants, contractors, suppliers, or service providers were to suffer a security incident, for example, that resulted in the unauthorized access to or use or disclosure of personal data or health information, we may have to notify consumers, partners, collaborators, government authorities, and the media~~ . Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. **If** ~~Additionally, if~~ we ~~or (our~~ **or a** third party **on which we rely)** ~~collaborators, consultants, contractors, suppliers, or service providers~~ experience a security incident or are perceived to have experienced a security incident, we may **experience adverse consequences** ~~be subject to investigations~~ , **such as government** ~~civil penalties, administrative and~~ enforcement actions **(for example** , **investigations, fines, penalties, audits,** and **inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive data (including personal data);** litigation **(including class claims); indemnification obligations; negative publicity;** ~~, any of which could harm our business and reputation. Likewise, we rely on our third- party research institution collaborators and other third parties to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security incident were to result in a loss of, or damage to, our data or systems, or inappropriate or unauthorized access to or disclosure or use of confidential, proprietary, or other sensitive, personal, or health information, we could incur liability and suffer~~ reputational harm ~~,~~ **; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss;** and ~~the~~ **other** ~~development~~ **similar harms. Security incidents** and **attendant consequences may prevent** ~~commercialization of the RaniPill capsule and our~~ **or** ~~product candidates could be delayed~~ **cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business** . Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our ~~data~~ privacy and security practices, **such coverage** ~~or that it~~ will **continue to** be available on commercially reasonable terms or at all, or that such coverage will pay future claims **. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position** . Risks Related to Our Intellectual Property Our commercial success may depend in part on our ability to build and maintain our intellectual property portfolio. Our commercial success may depend in part, and perhaps in large part, on having a strong portfolio of intellectual property rights globally to prevent others from copying our products. We rely on a combination of contractual provisions, patent rights, trademark rights, and trade secrets to protect our core technology and products. However, these legal measures may only afford limited protection. For example, we may not be able to obtain or maintain intellectual property rights that we believe are important to our business, or in a form that provides us with a competitive advantage. Moreover, obtaining and maintaining intellectual property protection is expensive, and reduces the budget available for research, development, and other expenditures. We must balance the need for intellectual property protection against the need for furthering our development and commercialization activities, which may mean that aspects of our technology and methodology may not be protected by our intellectual property portfolio. Where our intellectual property rights are insufficient to prevent or limit commercialization of competitive products in a jurisdiction, potential competitors might be able to enter or expand in a market more easily, which could have a material adverse effect on our business. The following ways in which our intellectual property portfolio may be limited represent risks to our capability to reduce competition and thus risks to our business. We may not be able to obtain sufficient patent coverage. The process of applying for and obtaining a patent is considerably time consuming and expensive, and we may not have the resources to prepare, file, prosecute, or maintain all desirable patent applications and patents in all jurisdictions where protection may be commercially advantageous. It is also possible that we may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them, or before others file patent applications covering our product candidates. Moreover, we might not have been the first to make the inventions for which we apply for patents and therefore not be entitled to a patent on such inventions. Additionally, the scope of our patent coverage may not provide desired coverage for all aspects of our product candidates in all jurisdictions, and scope may differ between jurisdictions. For example, examination

of each national or regional patent application is an independent proceeding; as a result, patent applications in the same family may issue with claims of different scope in various jurisdictions, or may even be refused in some or all jurisdictions. If we fail to achieve the desired coverage for all aspects of our product candidates, competitors may be able to copy our technology or design around our patents, and our business may be harmed. Because the patent position of companies in our industry involves complex legal and factual questions, we cannot predict the validity and enforceability of our patents or provide any assurances that any of our patent applications will be found to be patentable, with certainty. Our issued patents may not provide us with any competitive advantages, may be held invalid or unenforceable as a result of legal challenges by third parties or could be circumvented. Our competitors may also independently develop processes, technologies or products similar to ours or design around or otherwise circumvent any patents issued to, or licensed by, us. Thus, any patents that we own or license from others may not provide adequate protection against competitors. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in patents being issued. If these patents are issued, they may not provide us with proprietary protection or competitive advantages. After the completion of development and registration of our patents, third parties may still manufacture or market our products despite our patent protected rights. If the protection of our proprietary rights is inadequate to prevent use or appropriation by third parties, the value of our brand and other intangible assets may be diminished and competitors may be able to more effectively mimic our technology. If competitors were to mimic our technology, it may result in loss of sales and material litigation expenses. Such infringement of our patent protected rights is likely to cause us damage and lead to a reduction in the prices of our products, thereby reducing our anticipated profits. We may also inadvertently lose patent assets by failing to follow agency procedures. The **U. S. Patent and Trademark Office (“** USPTO **”)** and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent issues. Non- compliance with provisions of the various patent agencies can result in the expiration or abandonment of a patent or patent application, resulting in partial or complete loss of associated patent rights in the relevant jurisdiction. For example, periodic maintenance fees, renewal fees, and annuity fees must often be paid to the USPTO and various foreign governmental patent agencies over the lifetime of a patent and / or patent application. These maintenance and annuity fees for our patents and patent applications are handled by a third- party annuity provider. Any errors by the annuity provider, including but not limited to, incomplete patent information, missed payment instructions, or errors in fund transfers may cause granted patents to expire and pending patent applications to be deemed abandoned. If we are unable to timely pay the annuity provider for their services, they may cease to pay the maintenance and annuity fees, and our patents and applications may lapse and no longer be in force. Additional 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 and failure to properly legalize and submit formal documents within prescribed time limits. While an unintentional lapse of a patent or patent application can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. This may create opportunities for competitors to enter the market, which could hurt our competitive position and could impair our ability to successfully commercialize our product candidates in any indication for which they are approved. For these and other reasons, we cannot guarantee that our patents will provide a basis for an exclusive market for our commercially viable products, or will even provide us with any competitive advantage. It is possible that defects of form in the preparation, filing or prosecution of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope or requests for patent term adjustments. If we fail to establish, maintain or protect such patent rights, they may be reduced or eliminated. If there are material defects in the form, preparation, prosecution or enforcement of our patents or patent applications, such patents may be invalid and / or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. We may not be able to obtain sufficient brand protection. We may rely on a combination of trademarks, service marks, brand names, trade names, and trade dress, and in some cases pending applications for the same, to protect our brands, in an effort to distinguish our products from the products of our competitors. Some of these mechanisms are protectable under state, federal, and foreign trademark laws and regulations. Although limited protection is available without registration, it is preferable to register trademarks in jurisdictions where we may commercialize. We have registered or applied to register several trademarks in the United States and many other jurisdictions globally. We cannot ensure that our pending trademark applications will be approved. During trademark registration proceedings, our applications may be rejected by the USPTO or foreign agencies, or may be opposed by third parties. Although we are given an opportunity to respond, we may be unable to overcome such rejections or oppositions. In addition, third parties may seek to cancel registered trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are finally rejected or successfully challenged, we could be forced to rebrand, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing with new branding. Our existing trademarks, whether registered or unregistered, face additional hurdles which may have a material adverse effect on our business. For example: one or more of our current or future trademarks may become used by the public in a manner that the use of the trademark becomes generic and loses its trademark protection in one or more jurisdictions; competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion; and, if we are unable to establish name recognition based on our branding, then we may not be able to compete effectively. Any of the foregoing could have a material adverse effect on our competitiveness. In addition, our competitors may infringe or otherwise violate our trademarks and we may not have adequate resources to enforce our trademarks. Domain names are also important to our brand identity and commercialization efforts and we have many registered domain names. However, there are several dozens of top- level domains and more coming, and there are several trademarks or other names that we may wish to incorporate into domain names. The

combination of domains and names that may be of interest to our business could number in the hundreds or the thousands. Further, many domain names of interest are already registered by a third party. Therefore, we will not be able to obtain each and every domain name that may be of interest to our business. There is a risk that a competitor or other third party could register a domain name that inhibits our ability to advertise, confuses our customers, or redirects our potential business to other companies. Trademarks and domain names are intended, and in some cases required, to be used by their owners. In the absence of meaningful use, we may be forced to forfeit various ones of our trademarks and domain names. Intellectual property law and regulation could affect the value of our intellectual property portfolio. Interpretation of existing laws and regulations is uncertain and may depend on specific facts of a case. Therefore, we cannot be certain of the effectiveness of our intellectual property against third parties. Further, laws and regulations in general may not provide sufficient protection to prevent, or provide adequate remedy for, the infringement, use, violation or misappropriation of our patents, trademarks, data, technology and other intellectual property and services. Moreover, changes in laws, or changes in interpretations of laws, may unpredictably weaken our ability to obtain, defend, or enforce our intellectual property rights. A weakened ability to obtain, defend, or enforce rights covering our proprietary technologies could materially and adversely affect our business prospects and financial condition. For example, the United States Supreme Court and the United States Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations, and there are other open questions under patent law that courts have yet to decisively address. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we own or that we might obtain or license in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. Changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them, or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. We cannot predict interpretations of existing laws and regulations, future changes to laws or regulations, or changes in the interpretation of laws or regulations. Such changes could increase uncertainty with respect to the value of patents and trademarks once obtained. Intellectual property rights do not provide complete protection for our business activities. The combination of contractual provisions, confidentiality procedures, and intellectual property rights that we rely on to protect the proprietary aspects of our products, brands, technologies and data afford limited protection. The degree of protection is uncertain, and our intellectual property rights may not adequately protect our business or permit us to maintain our competitive advantage. We may not be able to successfully commercialize our products prior to patent expiration. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or soon after such candidates are commercialized. The exclusivity period provided by a patent is limited; in the United States, if all maintenance fees are timely paid, the expiration of a patent is generally 20 years from its earliest claimed United States non-provisional filing date. Even if patents covering our future products are obtained, once the patent life has expired, we may be open to competition from competitive products entering the market and we may suffer a subsequent decline in market share and profits. Although there may be a possibility to extend the term of one or more of our patents through various laws and regulations, most of our patents will not be eligible for such term extension. An example of legislation providing patent term extension is the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments, and similar legislation in some foreign jurisdictions, which provides a patent term extension of up to five years for patent term lost during product development and the FDA regulatory review process. Our intellectual property rights may not be effective against certain competitive products. While we seek to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our intellectual property position in various jurisdictions may be inadequate in posing an effective challenge to competitive products, and also may not be conducive to successfully commercializing our product candidates in such jurisdictions. Further, it is quite possible that a competitor may duplicate portions of our technology, or may develop a similar or alternative technology, without infringing our intellectual property rights; or a competitor may offer similar, duplicative, or competitive products for sale in major commercial markets not covered by our intellectual property rights. Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In addition, the U. S. federal government retains certain rights in inventions produced with its financial assistance under the Bayh- Dole Act which could allow the government, in specified circumstances, to require a company to grant a license to a third party. We do not currently have intellectual property falling under these provisions. We cannot be sure that if we acquire intellectual property in the future it will be free from government rights or regulations pursuant to the Bayh- Dole Act. If, in the future, we own, co- own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh- Dole Act, our ability to enforce or

otherwise exploit patents covering such technology may be adversely affected. Third parties may hold intellectual property rights that cover our product candidates. Our intellectual property rights, including our patent rights, do not give us the right to practice our patented inventions. Third parties may have blocking patents that could prevent us from marketing our own products and practicing our own technology. In some cases, it may be advantageous to license or acquire such patents. However, we may be unable to do so on commercially reasonable terms, such as on terms that would allow us to make an appropriate return on our investment. In addition, companies that perceive us to be a competitor may be unwilling to transfer or license rights to us. Moreover, the licensing or acquisition of third- party intellectual property rights is a competitive area, and other companies may pursue strategies to license or acquire third- party intellectual property rights that we may consider important to our business. Some such companies may have a competitive advantage over us due to their size, capital resources, clinical development stage, or commercialization capabilities. If we are unable to successfully obtain or maintain rights to third- party intellectual property rights which we deem important to an aspect of our business, we may deem it to be in our best interests to forego further development of the relevant program or product candidate, which could have a material adverse effect on our business. We are presently reliant upon an in- license with InCube Labs, LLC (“ ICL ”) to certain of ICL’ s patent rights. Additional in- licenses with other third parties may be negotiated in the future. License agreements may impose fee, royalty, insurance, milestone, and other obligations on us. If we fail to comply with our obligations to a licensor, that licensor may have the right to terminate our license, in which event we might not be able to develop, manufacture or market any product that is covered by the intellectual property we in- license. Such an occurrence would materially adversely affect our business prospects. Further, we are presently party to a Service Agreement with ICL effective January 1, 2021, as amended in March 2022 **and March 2024** (as amended, the" Rani LLC- ICL Service Agreement"), pursuant to which Rani LLC and ICL agreed to provide personnel services to the other upon requests, and Rani LLC occupies certain facilities leased by ICL. Pursuant to the Rani LLC- ICL Service Agreement, we may engage ICL to perform development work on behalf of our company. We will wholly own intellectual property resulting from such development work only if it relates to the oral delivery of a biotherapeutic agent or sensor (the “ Rani Field ”), and was developed on our time and with our resources. All other resulting intellectual property will be wholly owned by ICL. ICL has agreed to exclusively license certain intellectual property to us for use solely within the Rani Field, but we may not obtain a license on favorable terms. In addition, intellectual property rights that we in- license in the future may be sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our sublicense agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, or if we fail to comply with our development obligations under our license agreements when applicable, our ability to develop and commercialize our product candidates may be materially harmed. If we do not control the prosecution, maintenance and enforcement of our in- licensed intellectual property, we will not be certain that the prosecution, maintenance and enforcement of the licensed intellectual property rights will be in a manner consistent with the best interests of our business. Competitors could purchase our products and attempt to replicate or reverse engineer some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, or design around our patents, any of which could materially affect our business, and we may not be able to prevent or stop such actions from occurring. Legal or administrative proceedings related to intellectual property could materially adversely affect our ability to commercialize our products and could result in significant expenditures of resources. There are several types of legal or administrative proceedings in which we may become involved, such as the ones outlined below. Any proceeding, even those asserted against us without merit and even those where we prevail, may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of management from our core business, divert our employees from development activities, delay commercialization activities, and harm our reputation. Others may challenge our intellectual property in administrative proceedings. Administrative proceedings available for challenging issued patents include re- examination, post grant review, inter partes review, and similar proceedings in foreign jurisdictions as applicable. Such a proceeding could result in a patent being deemed invalid, or the scope of the patent coverage being reduced. Similarly, a registered trademark may be challenged, which could result in loss of the trademark, or reduction in the scope of the trademark. Patents and trademarks that we in- license may also be deemed invalid, or the scope reduced. Any of the foregoing outcomes could affect our ability to commercialize our products. Our European patents are presently being challenged in Europe, and if one or more of such challenges is successful it could encourage such party or other parties to challenge additional patents of ours in Europe or other jurisdictions. Our patent portfolio includes numerous issued European patents and pending European patent applications directed to various technical aspects of our business. The European Patent Office (**“** EPO **”**) provides for an opposition proceeding that could result in revocation of or amendment to a European patent. We are presently involved in opposition proceedings involving four of our European patents at the EPO, all of which opposition proceedings were asserted against us by Novo Nordisk ~~AS~~ **A / S** . The first opposition proceeding involves European Patent No. 2515992, which is generally directed to an ingestible device. In July 2021, the EPO **Opposition Division** issued a decision resulting in an amendment to the claims of the patent. ~~We~~ **Both parties** subsequently filed a notice of appeal with the EPO Appeal Board and we are awaiting a final decision. The second opposition proceeding involves European Patent No. 2544668, which is generally directed to a therapeutic agent preparation. In December 2021, the EPO **Opposition Division** issued a decision resulting in revocation of the patent. ~~We~~ **Both parties** subsequently filed a notice of appeal with the EPO Appeal Board and we are awaiting a final decision. The third opposition proceeding involves European Patent No. 3461478, which is in the same family as European Patent No. 2515992 noted above. In April 2022, the EPO **Opposition Division** issued a decision resulting in an amendment to the claims of the patent. ~~We~~ **Both parties** subsequently filed a notice of appeal with the EPO Appeal Board and **we** are awaiting a final decision. The fourth opposition proceeding involves European Patent No. 3653223, which is generally

directed to a swallowable device. ~~We~~ **In October 2023, the EPO Opposition Division issued a decision resulting in an amendment to the claims of the patent. Both parties subsequently** filed ~~an initial response to~~ **a notice of appeal with** the EPO **Appeal Board and we are awaiting a final decision** . While we own numerous issued European patents and pending European patent applications, including several in the same patent families as the four patents noted above and which are not currently the subject of opposition proceedings, there is a risk that one or more of our issued European patents will be revoked, or have its claims amended, through an opposition process. If this were to happen to one of our European patents, the corresponding national patent in each European country in which the European patent was validated would similarly be revoked or have its claims amended. We believe that our current patent portfolio provides us with meaningful protection of the RaniPill technology in Europe even apart from the four European patents which are the subject of the current opposition proceedings. However, if any of the current oppositions results in a revocation or reduction in our patent protection, it could encourage Novo Nordisk ~~As~~ **A / S** or other parties to seek to invalidate or reduce additional patents in Europe or other jurisdictions. If current or future opposition proceedings result in the revocation or amendment of one or more of our patents that cover important aspects of our technology, it could have a material adverse impact on our ability to commercialize and / or our ability to defend against potential competitors in Europe or the applicable jurisdiction (s). There is a risk that we may face additional oppositions in Europe as additional European patents are granted. We may assert challenges against others of infringement of our intellectual property. We may determine that our competitors are infringing our patents or trademarks. In such case we could initiate infringement proceedings against them. Such proceedings are generally quite expensive in terms of money and employee time, and may be prohibitively expensive so that we may decide it not to be cost effective. Indeed, there can be no assurance that we will have sufficient financial or other resources to file and pursue all such proceedings. The monetary costs of such proceedings, the fact that they could last for years before they are concluded, and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. We may also be hindered or prevented from enforcing our rights with respect to a government entity or instrumentality because of the doctrine of sovereign immunity. Additionally, a legal proceeding might harm our business relationships, and thus we may determine that it is in our best interests not to pursue such course. Moreover, any claims we assert against perceived infringers or other third parties could provoke those parties to assert counterclaims against us alleging, for example, that we infringe their patents or other proprietary rights, that our patents or other proprietary rights are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of any patent is upheld, the court will construe the patent' s claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making or selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are unenforceable, that the alleged infringing mark does not infringe our trademark rights or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this last instance, we could ultimately be forced to cease use of such trademarks. Any of these outcomes could adversely affect our competitive business position, financial condition and results of operations. Even if our patents or other intellectual property are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and / or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer' s competition in the market and, thus, may not be commercially meaningful. However, we may not prevail in any legal challenge that we do initiate. Additionally, if a defendant were to prevail on invalidity of our asserted patents, we may lose some, and perhaps all, of the intellectual property protection on our product candidates, which could have a material adverse impact on our business. Furthermore, because of the substantial amount of discovery that may be required in connection with intellectual property litigation, there is a risk that some of our proprietary information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments; if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our stock. We may be subject to challenges asserting infringement of intellectual property of a third party. Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell our products and use our proprietary technologies without infringing the intellectual property rights of third parties. However, despite our efforts to avoid infringement, we may face infringement challenges by competitors, or from non- practicing entities which purchase intellectual property assets for the purpose of making assertions of infringement to extract settlements. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. Even if we believe an infringement challenge to be without merit, a court could find infringement, which could have a negative impact on the commercial success of our current and future products. We do not know the nature of claims contained in unpublished patent applications around the world and it is not possible to know which countries patent applicants may choose for the extension of their filings under the Patent Cooperation Treaty. Accordingly, third parties may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our product candidates. Additionally, our products include components that we purchase from vendors, and may include components that are outside of our direct control. Vendors from whom we purchase components may not indemnify us if our products incorporating their components are accused of infringing a third party' s patent or trademark or of misappropriating a third party' s trade secret. If we are found to infringe a third party' s intellectual property rights, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed. In addition, we could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product. In some cases, we could pursue a license to continue developing,

manufacturing and commercializing our products and technology. However, we may not be able to obtain a license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Further, we generally indemnify our customers with respect to infringement by our products of the proprietary rights of third parties. If third parties assert infringement challenges against our customers, these challenges may require us to initiate or defend litigation on behalf of our customers. If any of these challenges succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products. The cost to us of any infringement challenge, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of an infringement challenge more effectively because of their greater financial resources. In addition to absorbing significant financial resources, an infringement challenge may also consume management' s time. Consequently, there is no assurance that we will be able to develop or commercialize a product candidate in line with our business objectives in the event of an infringement challenge. Further, the outcome of any infringement challenge is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in patent infringement cases that may turn on the testimony of experts as to technical facts upon which the experts may reasonably disagree. We may be subject to challenges asserting misappropriation of intellectual property of a third party. We employ or contract with individuals who were previously employed elsewhere, including at other biopharmaceutical companies such as our competitors or potential competitors. Some of these employees, consultants or contractors may have executed proprietary rights, non- disclosure, or non- competition agreements in connection with such previous employment or contracting. In addition, we use proprietary information and materials from third parties which may be subject to agreements that include restrictions on use or disclosure. Although we strive to ensure proper safeguards, we cannot guarantee strict compliance with such agreements, nor can we be sure that our employees, consultants and advisors do not use proprietary information, materials, or know- how of others in their work for us. We may be subject to challenges that we or our employees, consultants, or contractors have inadvertently or otherwise used or disclosed proprietary information of our employees' former employers or other third parties. There is no guarantee of success in defending such challenges, and if we are not successful, we may be blocked from using the technology that is the subject of the misappropriation challenge. We may be subject to challenges to the inventorship or ownership of our intellectual property. We may in the future be subject to challenges by our former employees or consultants asserting an ownership right in our intellectual property, as a result of the work they performed on our behalf. Although we generally require all of our employees and consultants and any other partners or collaborators who have access to our proprietary know- how, information or technology to assign or grant rights to us regarding inventions related to our business, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. If we fail in defending any such challenges, we may lose valuable intellectual property rights, including the loss of exclusive ownership of, or right to use, such intellectual property. Additionally, we may be subject to a challenge from a third party challenging our ownership interest in intellectual property we regard as our own, based on assertions that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any such a challenge. It may be necessary or we may desire to enter into a license to settle any such challenge; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to a challenge fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the proprietary information of the former employer. An inability to incorporate technologies or features that are important or essential to our products may prevent us from selling our products. Third parties may obtain our proprietary information, which could harm our business and competitive position. If any of our proprietary information, including trade secrets and know- how, were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us and our competitive position would be harmed. We seek to maintain the confidentiality of our proprietary information, relying heavily on confidentiality provisions that we have in agreements with our employees, consultants, collaborators and others upon the commencement of their relationship with us. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our proprietary technology and processes and cannot guarantee that such agreements will not be breached. Moreover, these agreements can be difficult and costly to enforce or may not provide adequate remedies. We also seek to preserve the integrity and confidentiality of our data and other proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these security measures and systems, agreements or security measures may be breached. Detecting the disclosure or misappropriation of proprietary information and enforcing an assertion that a party illegally disclosed or misappropriated proprietary information is difficult, expensive and time- consuming, the outcome is unpredictable, there may not be an adequate remedy for breach, and many foreign countries do not have laws adequate to protect proprietary rights. The theft or unauthorized use or publication of our proprietary information could reduce the differentiation of our products and harm our business, the value of our investment in development or business acquisitions could be reduced, and if a third party' s proprietary information is disclosed we may face litigation by such third party. Any of the foregoing could materially and adversely affect our business and financial condition. Risks Related to Our Organizational Structure We are a holding company and our principal asset is our interest in Rani LLC. Accordingly, we will depend on distributions from Rani LLC to pay our taxes, expenses (including payments under the Tax Receivable Agreement) and

dividends. Rani' s ability to make such distributions may be subject to various limitations and restrictions. We are a holding company and have no material assets other than our ownership of LLC Interests of Rani LLC. As such, we have no independent means of generating net sales or cash flow, and our ability to pay our taxes and operating expenses or declare and pay dividends in the future, if any, is dependent upon the financial results and cash flows of Rani LLC and distributions we receive from Rani LLC. Rani LLC may not generate sufficient cash flow to distribute funds to us and applicable state law and contractual restrictions, including negative covenants in our debt instruments, may not permit such distributions. In August 2021, in connection with the IPO and Organizational Transactions, we entered into a Tax Receivable Agreement with certain of the Continuing LLC Owners. See the risk factor below entitled " The Tax Receivable Agreement with certain of the Continuing LLC Owners requires us to make cash payments to them in respect of certain benefits to which we may become entitled. In certain circumstances, payments under the Tax Receivable Agreement may be accelerated and / or significantly exceed the actual tax benefits we realize. " We anticipate that Rani LLC will continue to be treated as a partnership for U. S. federal income tax purposes and, as such, generally will not be subject to any entity- level U. S. federal income tax. Instead, taxable income will be allocated to holders of LLC Interests. Accordingly, we will incur income taxes on our allocable share of any net taxable income of Rani LLC and will also incur expenses related to our operations, including payments under the Tax Receivable Agreement, which we expect could be significant. Furthermore, our allocable share of Rani LLC' s net taxable income will increase over time as the Continuing LLC Owners redeem or exchange their LLC Interests for shares of our Class A common stock. We intend, as its managing member, to cause Rani LLC to make cash distributions to the owners of LLC Interests, including us, in an amount sufficient to (i) fund their or our tax obligations in respect of allocations of taxable income from Rani LLC and (ii) cover our operating expenses, including payments under the Tax Receivable Agreement. However, Rani LLC' s ability to make such distributions may be subject to various limitations and restrictions, such as restrictions on distributions that would either violate any contract or agreement to which Rani LLC is then a party, including debt agreements, or any applicable law, or that would have the effect of rendering Rani LLC insolvent. In addition, for taxable years beginning after December 31, 2017, liability for adjustments to a partnership' s tax return can be imposed on the partnership itself in certain circumstances, absent an election to the contrary. Rani LLC could be subject to material liabilities pursuant to adjustments to its partnership tax returns if, for example, its calculations or allocations of taxable income or loss are incorrect, which also could limit its ability to make distributions to us. If we do not have sufficient funds to pay taxes or other liabilities or to fund our operations, we may have to borrow funds, which could adversely affect our liquidity and financial condition and subject us to various restrictions imposed by any such lenders. To the extent that we are unable to make payments under the Tax Receivable Agreement for any reason, such payments generally will be deferred and will accrue interest until paid; provided, however, that nonpayment for a specified period may constitute a material breach of a material obligation under the Tax Receivable Agreement and therefore accelerate payments due under the Tax Receivable Agreement. In addition, if Rani LLC does not have sufficient funds to make distributions, our ability to declare and pay cash dividends will also be restricted or impaired. Rani LLC may make distributions of cash to us substantially in excess of the amounts we use to make distributions to our stockholders and pay our expenses (including our taxes and payments under the Tax Receivable Agreement). To the extent we do not distribute such excess cash as dividends on our Class A common stock, the holders of units of Rani LLC would benefit from any value attributable to such cash as a result of their ownership of Class A common stock upon an exchange or redemption of their units of Rani LLC. We will receive a portion of any distributions made by Rani LLC. Any cash received from such distributions will first be used by us to satisfy any tax liability and then to make any payments required under the Tax Receivable Agreement. Subject to having available cash and subject to limitations imposed by applicable law and contractual restrictions (including pursuant to our debt instruments), the Rani LLC operating agreement requires Rani LLC to make certain distributions to us and the Continuing LLC Owners, pro rata, to facilitate the payment of taxes with respect to the income of Rani LLC that is allocated to us and them. These distributions are based on an assumed tax rate, and to the extent the distributions we receive exceed the amounts we actually require to pay taxes, Tax Receivable Agreement payments, and other expenses, we will not be required to distribute such excess cash. Our board of directors may, in its sole discretion, choose to use such excess cash for any purpose, including (i) to make distributions to the holders of our Class A common stock, (ii) to acquire additional newly issued LLC Interests, and / or (iii) to repurchase outstanding shares of our Class A common stock. Unless and until our board of directors chooses, in its sole discretion, to declare a distribution, we will have no obligation to distribute such cash (or other available cash other than any declared dividend) to our stockholders. No adjustments to the redemption or exchange ratio of LLC Interests for shares of our Class A common stock will be made as a result of either (i) any cash distribution by us or (ii) any cash that we retain and do not distribute to our stockholders. To the extent we do not distribute such cash as dividends on our Class A common stock and instead, for example, hold such cash balances, buy additional LLC Interests or lend them to Rani LLC, this may result in shares of our Class A common stock increasing in value relative to the LLC Interests. The holders of LLC Interests may benefit from any value attributable to such cash balances if they acquire shares of Class A common stock in redemption of or exchange for their LLC Interests or if we acquire additional LLC Interests (whether from Rani LLC or from holders of LLC Interests) at a price based on the market price of our Class A common stock at the time ~~. The Tax Receivable Agreement with certain of the Continuing LLC Owners requires us to make cash payments to them in respect of certain benefits to which we may become entitled. In certain circumstances, payments under the Tax Receivable Agreement may be accelerated and / or significantly exceed the actual tax benefits we realize~~ . We are a party to the Tax Receivable Agreement with certain of the Continuing LLC Owners. Under the Tax Receivable Agreement, we will be required to make cash payments to certain of the Continuing LLC Owners equal to 85 % of the tax benefits, if any, that we are deemed to realize (calculated using certain assumptions) as a result of (i) increases in the tax basis of assets of Rani LLC resulting from (a) any future redemptions or exchanges of LLC Interests and (b) payments under the Tax Receivable Agreement and (ii) certain other tax benefits arising from payments under the Tax Receivable Agreement. While the actual amount and timing of any payments under the Tax Receivable Agreement, will vary

depending upon a number of factors, including the timing of exchanges, the price of shares of our Class A common stock at the time of the redemption or exchange, the extent to which such redemptions or exchanges are taxable, future tax rates, and the amount and timing of our taxable income (prior to taking into account the tax depreciation or amortization deductions arising from the basis adjustments), we expect that, as a result of the size of the increases in the tax basis of the tangible and intangible assets of Rani LLC attributable to our interests in Rani LLC, during the expected term of the Tax Receivable Agreement, the payments that we may make to certain of the Continuing LLC Owners could be significant. See the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources — Source of Liquidity " for further information. Payments under the Tax Receivable Agreement will be based on the tax reporting positions that we determine, and the Internal Revenue Service (" IRS "), or another tax authority may challenge all or part of the tax basis increases, as well as other related tax positions we take, and a court could sustain such challenge. The Continuing LLC Owners who are parties to the Tax Receivable Agreement will not reimburse us for any payments previously made under the Tax Receivable Agreement if such basis increases or other benefits are subsequently disallowed, except that any excess payments made by us to the Continuing LLC Owners under the Tax Receivable Agreement will be netted against future payments that we might otherwise be required to make to the Continuing LLC Owners under the Tax Receivable Agreement. However, a challenge to any tax benefits initially claimed by us may not arise for a number of years following the initial time of such payment or, even if challenged early, such excess cash payment may be greater than the amount of future cash payments that we might otherwise be required to make under the terms of the Tax Receivable Agreement and, as a result, there might not be sufficient future cash payments against which the prior payments can be fully netted. The applicable U. S. federal income tax rules are complex and factual in nature, and there can be no assurance that the IRS or a court will not disagree with our tax reporting positions. Therefore, payments could be made under the Tax Receivable Agreement in excess of the tax savings that we realize in respect of the tax attributes with respect to the Continuing LLC Owners that are the subject of the Tax Receivable Agreement. In addition, the Tax Receivable Agreement provides that, upon certain mergers, asset sales or other forms of business combination or certain other changes of control our (or our successor' s) obligations with respect to tax benefits would be based on certain assumptions, including that we (or our successor) would have sufficient taxable income to utilize the benefits arising from the increased tax deductions and tax basis and other benefits covered by the Tax Receivable Agreement. Consequently, it is possible, in these circumstances, that the actual cash tax savings realized by us may be significantly less than the corresponding Tax Receivable Agreement payments. Our accelerated payment obligations and / or assumptions adopted under the Tax Receivable Agreement in the case of a change of control may impair our ability to consummate a change of control transaction or negatively impact the value received by owners of our Class A common stock in a change of control transaction. If we were deemed to be an investment company under the 1940 Act as a result of our ownership of Rani LLC, applicable restrictions could make it impractical for us to continue our business as contemplated and could adversely affect our business, results of operations and financial condition. Under Sections 3 (a) (1) (A) and (C) of the 1940 Act, a company generally will be deemed to be an " investment company " for purposes of the 1940 Act if (i) it is, or holds itself out as being, engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting or trading in securities or (ii) it engages, or proposes to engage, in the business of investing, reinvesting, owning, holding or trading in securities and it owns or proposes to acquire investment securities having a value exceeding 40 % of the value of its total assets (exclusive of United States government securities and cash items) on an unconsolidated basis. We do not believe that we are an " investment company, " as such term is defined in either of those sections of the 1940 Act. As the sole managing member of Rani LLC, we will control and operate Rani LLC. On that basis, we believe that our interest in Rani LLC is not an " investment security " as that term is used in the 1940 Act. However, if we were to cease participation in the management of Rani LLC, our interest in Rani LLC could be deemed an " investment security " for purposes of the 1940 Act. We and Rani LLC intend to conduct our operations so that we will not be deemed an investment company. However, if we were to be deemed an investment company, restrictions imposed by the 1940 Act, including limitations on our capital structure and our ability to transact with affiliates, could make it impractical for us to continue our business as contemplated and could adversely affect our business, results of operations and financial condition. ICL currently supports certain of our general and administrative corporate functions and we occupy space within facilities owned or leased by ICL pursuant to service agreements. If we were required to replicate or replace these services sooner than planned or if one or both of the service agreements is terminated, our operations could be adversely affected. Pursuant to the Rani LLC- ICL Service Agreement, ICL provides us certain general and administrative corporate support services. In addition, pursuant to the Rani LLC- ICL Service Agreement and a separate service agreement dated January 1, 2021 originally between RMS and ICL but which was assigned by RMS to Rani LLC in April 2022 **and amended in March 2024** (the " RMS- ICL Service Agreement "), we sublease from ICL the office, laboratory and manufacturing space used for our operations (" Occupancy Services ") **. In March 2024, we entered into an amendment to the RMS- ICL Service Agreement to increase the Occupancy Services from 23, 000 square feet to 24, 000 square feet. In March 2024, we also entered into an amendment to the Rani LLC- ICL Service Agreement to extend the term of the Occupancy Services in Milpitas, California from February 2024 to August 2024 and to increase the payment for such Occupancy Services during the extension period** . Pursuant to the Rani LLC- ICL Service Agreement, we will wholly own intellectual property resulting from ICL' s development work that relates only to the oral delivery of sensors, small molecule drugs or biologic drugs and was developed by our team and using our resources. ICL has agreed to exclusively license certain intellectual property to us for use solely within the field of oral delivery of sensors, small molecule drugs and biologic drugs, but we may not obtain a license on favorable terms. The Rani LLC- ICL Service Agreement will automatically renew for successive one- year terms unless sooner terminated by either party. Termination of individual services under the Rani LLC- ICL Service Agreement or RMS- ICL Service Agreement requires 60 days' notice, and termination of Occupancy Services under the Rani LLC- ICL Service Agreement or RMS- ICL Service Agreement requires six months ' notice; except that the Occupancy

Services in Milpitas, California will expire in ~~February~~ **August** 2024, ~~with~~ **following** the **amendment entered into in March 2024** ~~potential for an annual renewal, subject to approval by ICL upon nine months' notice of renewal prior to the end of the lease term~~ . In the event the Rani LLC- ICL Service Agreement or RMS- ICL Service Agreement is terminated by us or ICL, we will need to replicate or replace certain functions, systems, equipment or facilities to which we will no longer have the same access. Such changes may be costly to implement and disruptive to our business **. In February 2024, we began to occupy a facility in Fremont, California. We intend to transition certain of our operations to that facility so that we will no longer need the Occupancy Services in Milpitas, California** . In addition, we may not be able to replace these services, systems, equipment or facilities or enter into appropriate third- party agreements therefor on terms and conditions, including cost, comparable to those that we receive from ICL under the Rani LLC- ICL Service Agreement or RMS- ICL Service Agreement, or in a time period that minimizes disruption to our operations. The loss of services or the use of systems, equipment or facilities under the Rani LLC- ICL Service Agreement or RMS- ICL Service Agreement or our inability to replace such services, systems, equipment or facilities in a timely or cost- effective manner could have an adverse effect on our operations and financial results. We are controlled by certain of the Continuing LLC Owners, whose interests may differ from those of our public stockholders. As of March ~~16~~ **10** , ~~2023~~ **2024** , certain of the Continuing LLC Owners controlled more than 80 % of the combined voting power of our common stock through their ownership of both Class A common stock and Class B common stock. These Continuing LLC Owners will, for the foreseeable future, have the ability to substantially influence us through their ownership position over corporate management and affairs, and will be able to control virtually all matters requiring stockholder approval. These Continuing LLC Owners are able to, subject to applicable law, elect a majority of the members of our board of directors and control actions to be taken by us and our board of directors, including amendments to our certificate of incorporation and bylaws and approval of significant corporate transactions, including mergers and sales of substantially all of our assets. The directors so elected will have the authority, subject to the terms of our indebtedness and applicable rules and regulations, to issue additional stock, implement stock repurchase programs, declare dividends and make other decisions. It is possible that the interests of these Continuing LLC Owners may in some circumstances conflict with our interests and the interests of our other stockholders, including you. For example, these Continuing LLC Owners may have different tax positions from us, especially in light of the Tax Receivable Agreement, that could influence our decisions regarding whether and when to dispose of assets, whether and when to incur new or refinance existing indebtedness, and whether and when we should terminate the Tax Receivable Agreement and accelerate its obligations thereunder. In addition, the determination of future tax reporting positions and the structuring of future transactions may take into consideration these Continuing LLC Owners' tax or other considerations, which may differ from the considerations of us or our other stockholders. The multi- class structure of our common stock may adversely affect the trading price or liquidity of our Class A common stock. The existence of three classes of our common stock could result in less liquidity for any such class than if there were only one class of our capital stock. In addition, S & P Dow Jones and FTSE Russell have announced changes to their eligibility criteria for inclusion of shares of public companies on certain indices that will exclude companies with multiple classes of shares of common stock from being added to such indices. Several stockholder advisory firms also have announced their opposition to the use of multiple class structures. As a result, the multi- class structure of our common stock may prevent the inclusion of our Class A common stock in such indices and may cause stockholder advisory firms to publish negative commentary about our corporate governance practices or otherwise seek to cause us to change our capital structure. Any such exclusion from indices could result in a less active trading market for our Class A common stock. Any actions or publications by stockholder advisory firms critical of our corporate governance practices or capital structure could also adversely affect the value of our Class A common stock. The multi- class structure of our common stock has the effect of concentrating voting control which will limit your ability to influence the outcome of important transactions, including a change in control. Our Class B common stock has ten votes per share, our Class A common stock has one vote per share and Class C common stock has no voting rights, except as required by law. As of March ~~16~~ **10** , ~~2023~~ **2024** , holders of our outstanding Class B common stock collectively held more than 80 % of the voting power of our outstanding capital stock. Because of the 10- to- 1 voting ratio between our Class B common stock and Class A common stock, the holders of our Class B common stock collectively control a majority of the combined voting power of our capital stock and therefore are able to control all matters submitted to our stockholders for approval so long as the shares of our Class B common stock represent more than 9 % of all outstanding shares of our Class A common stock and Class B common stock. These holders of our Class B common stock may also have interests that differ from other stockholders and may vote in a way which may be adverse to other stockholder interests. This concentrated control may have the effect of delaying, preventing or deterring a change in control of our company, could deprive our stockholders of an opportunity to receive a premium for their capital stock as part of a sale of our company and might ultimately affect the market price of our Class A common stock. The exchange of Class A units for Class A common stock will have the effect, over time, of increasing the relative voting power of those holders of Class B common stock who retain their shares in the long term. If, for example, Mir Imran, together with his affiliates, retains a significant portion of his holdings of our Class B common stock for an extended period of time, he could control a significant portion of the voting power of our capital stock for the foreseeable future. As a board member, Mir Imran owes a fiduciary duty to our stockholders and must act in good faith and in a manner to be in the best interests of our stockholders. As a stockholder, Mir Imran is entitled to vote his shares in his own interests, which may not always be in the interests of our stockholders generally. Risks Related to Our Class A Common Stock We do not know whether an active, liquid and orderly trading market will develop for our common stock. ~~We only recently completed our IPO, so there~~ **There** is limited history regarding the trading of our Class A common stock. An active trading market for our Class A common stock may not develop or be sustained. The lack of an active market may impair stockholders' ability to sell their shares at the time or price they wish to sell them. In addition, as described further in these " Risk Factors, " a substantial percentage of our Class A common stock will continue to be held by our executive officers and pre- IPO investors. As a result of these and other

factors, stockholders may be unable to resell their shares of our Class A common stock at or above the initial public offering price. Further, an inactive market may also impair our ability to raise capital by selling shares of our Class A common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of Class A common stock as consideration. Our stock price may be volatile and the value of our Class A common stock may decline. The market price of our Class A common stock may be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this " Risk Factors " section and elsewhere in this Annual Report on Form 10- K, these factors including: • our ability to obtain and maintain regulatory approvals for our current or any of our future product candidates; • changes in laws or regulations applicable to our current or any of our future product candidates; • adverse developments concerning any of our third- party collaborators and suppliers; • our inability to obtain adequate product supply for our current or any of our future product candidates or our inability to do so at acceptable prices; our ability to scale, optimize and expand automation of our manufacturing processes for our product candidates for the conduct of preclinical studies and clinical trials and, if approved, for successful commercialization; • the degree and rate of physician and market adoption of our current or any of our future product candidates; • announcements by us or our competitors of significant business developments, new technologies, acquisitions, or new offerings; • negative publicity associated with issues related to our technology or our product candidates; • our inability to establish collaborations, if needed; • future sales of our Class A common stock or other securities, by us or our stockholders; • changes in senior management or key personnel; • the trading volume of our Class A common stock; • performance or news releases by other companies in our industry including about adverse developments related to safety, effectiveness, accuracy and usability of their products, reputational concerns, reimbursement coverage, regulatory compliance, and product recalls; • general economic, regulatory and market conditions, including economic recessions or slowdowns; • changes in the structure of healthcare payment systems; • actual or anticipated fluctuations in our financial condition and results of operations, including as a result of anticipated or unanticipated demand based on seasonal factors; • variance in our financial performance from expectations of securities analysts or investors; • changes in our projected operating and financial results; • developments or disputes concerning our intellectual property or other proprietary rights; • significant lawsuits, including patent or stockholder litigation; • general political and economic conditions, including war, terrorism and other international conflicts, such as the conflict between Ukraine and Russia ~~as well as continued and any new sanctions against Russia by~~ , ~~among others, the European Union~~ and ~~the United States, which restrict a wide range of trade and financial dealings with Russia and Russian parties,~~ public health issues including health epidemics or pandemics ~~, such as COVID- 19~~ ; and • other events or factors, many of which are beyond our control. Broad market and industry fluctuations, as well as general economic, pandemic, political, regulatory, and market conditions, may negatively impact the market price of our Class A common stock. In addition, given the relatively small public float of shares of our Class A common stock on Nasdaq, the trading market for our shares may be subject to increased volatility. In the past, securities class action litigation has often been brought against companies that have experienced volatility or following a decline in the market price of its securities. This risk is especially relevant for us because medical device companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business. We are a " controlled company " within the meaning of the Nasdaq rules and, as a result, qualify for, and may rely on, exemptions and relief from certain corporate governance requirements. If we rely on these exemptions, our stockholders will not have the same protections afforded to stockholders of companies that are subject to such requirements. As of March ~~16~~ **10** , ~~2023~~ **2024** , our Chairman, Mir Imran beneficially owned more than 80 % of the combined voting power of our Class A and Class B common stock. As a result, we will continue to be a " controlled company " within the meaning of the Nasdaq corporate governance standards. Under these corporate governance standards, a company of which more than 50 % of the voting power in the election of directors is held by an individual, group or another company is a " controlled company " and may elect not to comply with certain corporate governance requirements. For example, controlled companies are not required to have: • a board that is composed of a majority of " independent directors, " as defined under the Nasdaq rules; • a compensation committee that is composed entirely of independent directors; and • director nominations be made, or recommended to the full board of directors, by its independent directors, or by a nominations / governance committee that is composed entirely of independent directors. While we do not intend to rely on the exemptions relating to being a " controlled company " within the meaning of the Nasdaq rules, we may utilize these exemptions for as long as we continue to qualify as a " controlled company. " Accordingly, our stockholders may not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of the Nasdaq. Investors may find our Class A common stock less attractive as a result of our reliance on these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be more volatile. We may in the future engage in acquisitions, collaborations, or strategic partnerships, which may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks. We may engage in various acquisitions, collaborations, and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any acquisition, collaboration, or strategic partnership may entail numerous risks, including: • increased operating expenses and cash requirements; • volatility with respect to the financial reporting related to such arrangements; • assumption of indebtedness or contingent liabilities; • issuance of our equity securities which would result in dilution to our stockholders; • assimilation of operations, intellectual property, products, and product candidates of an acquired company, including difficulties associated with integrating new personnel; • diversion of our management' s attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership; • retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships; • risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing

products or product candidates and regulatory approvals; and • our inability to generate revenue from acquired intellectual property, technology, and / or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs. In addition, if we undertake such a transaction, we may issue dilutive securities, assume or incur debt obligations, incur large one- time expenses, and acquire intangible assets that could result in significant future amortization expense. Future sales and issuances of our Class A common stock in the public market could cause the market price of our Class A common stock to decline. Sales and issuances of a substantial number of shares of our Class A common stock in the public market, or the perception that these sales might occur, could depress the market price of our Class A common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales and issuances may have on the prevailing market price of our Class A common stock. We have registered all of the shares of Class A common stock currently issuable upon exercise of outstanding stock options, and upon exercise or settlement of any options or other equity incentives and we intend to register all shares or such Class A common stock that we may grant in the future, for public resale under the Securities Act. Accordingly, these shares will be able to be freely sold in the public market upon issuance as permitted by any applicable vesting requirements. Continuing LLC Owners are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. As a result of certain stockholders requesting such registration, in December 2022 we filed a registration statement on Form S- 3 to register 6, 009, 542 shares of our Class A common stock held by certain of our stockholders. Accordingly, these shares are freely tradeable without restriction under the Securities Act. Any sales of securities by the foregoing or other stockholders could have a material adverse effect on the trading price of our Class A common stock. Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval and may prevent other stockholders from influencing significant corporate decisions. As of March ~~16~~ **10** , ~~2023~~ **2024** , our named executive officers, directors, holders of 5 % or more of our capital stock and their respective affiliates beneficially held outstanding stock representing over 80 % of our voting power. Therefore, these stockholders have substantial influence and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This concentration of voting power could, among other things, delay or prevent an acquisition of our company on terms that other stockholders may desire, which in turn could depress our stock price and may prevent attempts by our stockholders to replace or remove the board of directors or management. These stockholders, acting together, will be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders. We do not intend to pay dividends for the foreseeable future and, as a result, your ability to achieve a return on your investment will depend on appreciation in the price of our Class A common stock. We have never declared or paid any cash dividends on our capital stock, and we do not intend to pay any cash dividends in the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and may be restricted by the terms of any then- current debt instruments. Accordingly, stockholders must rely on sales of their Class A common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. We incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance with our public company responsibilities and corporate governance practices. We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act and regulations regarding corporate governance practices. The listing requirements of the Nasdaq require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel devote a substantial amount of time to ensure that we comply with all of these requirements, and we **may** ~~will likely~~ need to hire additional accounting and financial staff with appropriate public company reporting experience and technical accounting knowledge. Moreover, the reporting requirements, rules and regulations ~~will~~ increase our legal and financial compliance costs and ~~will~~ make some activities more time consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to continue to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms. As a public company, and particularly after we are no longer an " emerging growth company, " we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes- Oxley Act of 2002, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq and other applicable securities rules and regulations impose various requirements on public companies. Furthermore, the senior members of our management team do not have significant experience with operating a public company. As a result, our management and other personnel need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time- consuming and costly. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs. Accordingly, we expect to continue to incur operating losses for the foreseeable future and we may not achieve profitability in the future and that, if we do become profitable, we may not sustain profitability. Our failure to achieve and sustain profitability in the future will make it more difficult to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations and cause the market price of our Class A common stock to decline. Provisions under Delaware law and California law could make an acquisition of our company more difficult, limit attempts by

our stockholders to replace or remove our current management and limit the market price of our common stock. Under our amended and restated certificate of incorporation, we have elected not to be governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any holder of at least 15 % of our capital stock for a period of three years following the date on which the stockholder acquired at least 15 % of our common stock. Because our principal executive offices are located in California, the anti- takeover provisions of the California Corporations Code may apply to us under certain circumstances now or in the future. We are an emerging growth company and a smaller reporting company and our compliance with the reduced reporting and disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our Class A common stock less attractive to investors. We are an " emerging growth company, " as defined in the JOBS Act, and we expect to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including the auditor attestation requirements of Section 404 reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved and extended adoption period for accounting pronouncements. We are also a " smaller reporting company, " as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non- voting common stock held by non- affiliates is less than $ 250. 0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year and our voting and non- voting common stock held by non- affiliates is less than $ 700. 0 million measured on the last business day of our second fiscal quarter. Anti- takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our Class A common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management. Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include: • a requirement that special meetings of stockholders be called only by holders of at least 25 % of the voting power of our Class A common stock and Class B common stock, voting together as a single class, the chairperson of the board of directors, the chief executive officer, or by a majority of the board of directors; • advance notice requirements for stockholder proposals and nominations for election to our board of directors; • a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two- thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors; • a requirement of approval of a majority of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation, with protective provisions in our certificate of incorporation requiring approval of a majority of the voting power of the Class B common stock then outstanding; • the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of Class A common stock; and • the authorization of three classes of common stock as described above. Under our amended and restated certificate of incorporation, we have elected not to be governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business antitakeover provisions. Other provisions in our amended and restated certificate of incorporation and amended and restated bylaws, could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then- current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our Class A common stock to decline. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forums for substantially all 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 employees. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf, (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders, (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers, or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, (iv) any action or proceeding to interpret, apply, enforce, or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws, (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware, and (vi) any action asserting a claim against us or any of our directors, officers, or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court' s having personal jurisdiction over the indispensable parties named as defendants. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation and our amended and restated bylaws further provide

that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and the provisions may not be enforced by a court in those other jurisdictions. These exclusive forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees and may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation or bylaws has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the exclusive forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could seriously harm our business. General Risk Factors As a public company, we are obligated to develop and maintain proper and effective internal control over financial reporting, and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our Class A common stock. We are required, pursuant to Section 404 of the Sarbanes- Oxley Act of 2002, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting on an annual basis. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, we will be required to obtain attestation as to the effectiveness of our internal control over financial reporting by an independent registered public accounting firm in our first annual report required to be filed with the SEC following the date we become an accelerated filer. If we are unable to conclude that our internal control over financial reporting is effective, or if we or our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our Class A common stock could decline, and we could be subject to sanctions or investigations by the SEC or comparable foreign regulatory authorities. Failure to remedy any material weakness or significant deficiency in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our Class A common stock. The preparation of our financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. If our assumptions underlying our estimates and judgments relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates or judgments, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our Class A common stock. Business disruptions could seriously harm our business, financial condition, and results of operations. Our operations, and those of our CROs, suppliers and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, public health pandemics or epidemics ~~(including, for example, the COVID- 19 pandemic)~~ , geopolitical events, including civil or political unrest (such as the ongoing conflict between Ukraine and Russia), terrorism, insurrection or war, recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures, and other natural or man- made disasters or business interruptions, for which we are predominantly self- insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our business and the business of our suppliers of APIs or drug substances and the raw materials or components for our RaniPill capsule could be materially and adversely affected by the risks, or the public perception of the risks, related to a pandemic or other health crisis ~~, such as the COVID- 19 pandemic~~ . A significant outbreak of contagious diseases in the human population could result in a widespread health crisis that could adversely affect our planned operations. Such events could result in the complete or partial closure of one or more manufacturing facilities which could impact our supply of APIs, drug substances, and critical materials for manufacturing our RaniPill capsules. In addition, an outbreak or other business disruption near where our clinical trials occur could impact our ability to recruit subjects, delay our clinical trial, and could affect our ability to complete our clinical trials within the planned time periods. In addition, business disruptions of the kind noted above, including geopolitical events like the ongoing conflict between Ukraine and Russia or disruptions to bank deposits and lending commitments due to bank failures, could impact economies and financial markets, resulting in economic worsening and / or inflation that could impact our ability to raise capital, increase the costs of goods and services, cause us to have to de- prioritize or stop certain business activities, diminish potential partnering opportunities, and have an adverse effect on our results of operations. Unanticipated changes in effective tax rates or adverse outcomes resulting from examination of our income or other tax returns could adversely affect our results of operations and financial condition We are or may be subject to taxes by the U. S. federal, state, local and foreign tax

authorities, and our tax liabilities will be affected by the allocation of expenses to differing jurisdictions. Our future effective tax rates could be subject to volatility or adversely affected by a number of factors, including: • changes in the valuation of our deferred tax assets and liabilities; • expected timing and amount of the release of any tax valuation allowances; • tax effects of ~~equity~~ **stock** - based compensation; • changes in tax laws, regulations or interpretations thereof; or • future earnings being lower than anticipated in countries where we have lower statutory tax rates and higher than anticipated earnings in countries where we have higher statutory tax rates. In addition, we may be subject to audits of our income, sales and other transaction taxes by U. S. federal, state, local and foreign taxing authorities. Outcomes from these audits could adversely affect our business, results of operations and financial condition. Our failure to meet Nasdaq' s continued listing requirements could result in a delisting of our Class A common stock. If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our Class A common stock. Such a delisting would likely have a negative effect on the price of our Class A common stock and would impair a stockholder' s ability to sell or purchase our Class A common stock when they wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our Class A common stock to become listed again, stabilize the market price or improve the liquidity of our Class A common stock, prevent our Class A common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non- compliance with the listing requirements of Nasdaq. We are subject to U. S. and certain foreign export and import controls, sanctions, embargoes, anti- corruption laws and anti- money laundering laws and regulations. We can face criminal liability and other serious consequences for violations, which can harm our business. We are subject to export control and import laws and regulations, including the United States Export Administration Regulations, United States Customs regulations, and various economic and trade sanctions regulations administered by the United States Treasury Department' s Office of Foreign Assets Controls, and anti- corruption and anti- money laundering laws and regulations, including the Foreign Corrupt Practices Act (" FCPA "), the United States domestic bribery statute contained in 18 U. S. C. § 201, the United States Travel Act, the USA PATRIOT Act, and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct or may in the future conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other third- party collaborators from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties outside of the United States to sell our products internationally once we enter a commercialization phase, and / or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other third- party collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses engage in practices that are prohibited by the FCPA or other applicable laws and regulations. To that end, our internal control policies and procedures and employee training and compliance programs designed to deter prohibited practices ultimately may not be effective in preventing our employees, contractors, business partners, intermediaries or agents from violating or circumventing our policies and / or the law. Responding to any enforcement action or related investigation may result in a significant diversion of management' s attention and resources and significant defense costs and other professional fees. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. If securities or industry analysts do not publish research or publish unfavorable or inaccurate research about our business, our Class A common stock price and trading volume could decline. Our stock price and trading volume will be heavily influenced by the way analysts and investors interpret our financial information and other disclosures. If securities or industry analysts do not publish research or reports about our business, delay publishing reports about our business or publish negative reports about our business, regardless of accuracy, our Class A common stock price and trading volume could decline. The trading market for our Class A common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We expect that only a limited number of analysts will cover our company. If the number of analysts that cover us declines, demand for our Class A common stock could decrease and our Class A common stock price and trading volume may decline. Even if our Class A common stock is actively covered by analysts, we do not have any control over the analysts or the measures that analysts or investors may rely upon to forecast our future results. Over- reliance by analysts or investors on any particular metric to forecast our future results may result in forecasts that differ significantly from our own. Regardless of accuracy, unfavorable interpretations of our financial information and other public disclosures could have a negative impact on our stock price. If our financial performance fails to meet analyst estimates, for any of the reasons discussed above or otherwise, or one or more of the analysts who cover us downgrade our Class A common stock or change their opinion of our Class A common stock, our stock price would likely decline.