Risk Factors Comparison 2024-03-19 to 2023-03-31 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks **and uncertainties** described below, ~~as well as~~ **together with all of** the other information **contained** in this ~~Quarterly~~ **Annual** Report **on Form 10-K** , including our **audited consolidated** financial statements and ~~the~~ related notes ~~thereto~~ **hereto,** ~~and the section of this Quarterly Report titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations "~~ before ~~you make an investment decision~~ **deciding to invest in our common stock** . The **risks and uncertainties** ~~occurrence of any of the events or developments~~ described below ~~could harm~~ **are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. We cannot assure you that any of the events discussed below will not occur. If any of the following risks actually occurs,** our business, **prospects, operating results and** financial condition **could suffer** ~~, results of operations and prospects. Additional risks and uncertainties not presently known to us or that we currently deem immaterial~~ **materially** ~~also may impair our business operations~~ . ~~As a result~~ **In such event** , the ~~market~~ **trading** price of our common stock could decline ~~,~~ and you ~~may~~ **might** lose all or part of your investment **. SUMMARY OF RISK FACTORS An investment** in our common stock ~~. The~~ **involves various** risks ~~described below~~ **, and prospective investors are urged to carefully consider the matters discussed in the section titled " Risk Factors " prior to making an investment in our common stock. These risks include, but** are not ~~intended~~ **limited** to **, the following: • We have incurred net losses every year since our inception and have no source of product revenue. We expect to continue to incur significant operating losses and may never become profitable. • Our business is highly dependent on the success of TOUR006 as well as any other potential future product candidates. If we are unable to successfully complete clinical development of, obtain regulatory approval for, or commercialize, TOUR006 or any other potential future product candidates, or if we experience delays in doing so, our business will** be ~~exhaustive~~ **materially harmed. • We will need significant additional capital to proceed with development and commercialization of TOUR006 and any potential future product candidates and our other operations. We may not be able to access sufficient capital on acceptable terms, if at all, and, as a result, we may be required to delay, scale back or discontinue development of such product candidates or other operations. • We have a limited operating history and no history of commercializing products, which may make it difficult for** ~~and~~ **an investor to evaluate the success of our business to date and to assess our future viability. • We will incur additional costs and increased demands upon management as a result of complying with the laws and regulations applicable to public companies. • We may not be able to obtain and maintain the relationships with third parties that are necessary to develop, commercialize, and manufacture TOUR006 and any potential future product candidates. • We rely completely on contract development and manufacturing organizations (" CDMOs ") for the manufacture and testing of TOUR006 and any potential future product candidates under current good manufacturing practices (" cGMP "), and we are subject to many manufacturing risks, any of which could substantially increase our costs and limit supply of any potential product candidates and any future products. Additionally, any difficulties in the transfer of drug substance or drug product to or from manufacturing facilities could materially adversely affect our business, financial condition, and results of operations. • Our manufacturing and testing of bulk drug substance for TOUR006 currently takes place in China through a global CDMO with facilities in China and around the world. Our manufacturing and testing of drug product for TOUR006 occurs in facilities in Austria and the U. S. Our drug product is packaged in Germany and the U. S. A significant disruption in the operation of these manufacturing facilities, a trade war, or political unrest could materially adversely affect our business, financial condition, and results of operations. • We may seek to establish business development arrangements (" BD Arrangements "), and, if we** are not **able to establish** ~~the~~ **them** ~~only~~ **on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans. • TOUR006 and any other of our future product candidates must undergo rigorous clinical trials before seeking regulatory approvals, and clinical trials may be delayed, suspended, or terminated at any time for many reasons, any of which could delay or prevent regulatory approval and, if approval is granted, commercialization of our product candidates. • If clinical trials of TOUR006 or any potential future product candidates fail to timely initiate, enroll, complete, or produce positive results, or if such clinical trials fail to demonstrate safety and efficacy to the satisfaction of the U. S. Food and Drug Administration (the " FDA ") or comparable health authorities or sufficiently to demonstrate differentiation from other approved therapies or therapies in development, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. • If we experience delays or difficulties in the enrollment of patients in clinical trials, development of TOUR006, or any potential future product candidates, may be delayed or prevented, which would have a material adverse effect on our business. • Even if we obtain approval to market TOUR006 or other potential future product candidates, these products may become subject to unfavorable pricing regulations, reimbursement practices from third- party payors or healthcare reform initiatives in the United States (" U. S. ") and abroad, which could harm our business. • We expect to expand our clinical development, manufacturing, and regulatory capabilities and potentially implement sales, marketing, and distribution capabilities, including significant growth in the number of our employees, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. • Healthcare reform may negatively impact our ability to profitably sell TOUR006 and any potential future product candidates, if approved. • Our international operations may expose us to business, regulatory, political,**

operational, financial, pricing, and reimbursement risks ~~facing~~ **associated with doing business outside of the U. S. • Product liability lawsuits against us could cause us to incur substantial liabilities and to limit development and commercialization of any products that we may develop. • Our relationships with healthcare providers, customers, and third- party payors will be subject to applicable anti- kickback, fraud and abuse, transparency, and** ~~the~~ **other healthcare laws** ~~Company. New risk factors can emerge from time to time,~~ and ~~it is~~ **regulations, which, if violated, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings. • Our business could be materially and adversely affected in the future by the effects of disease outbreaks, epidemics, and pandemics. • Our ability to use our U. S. net operating loss carryforwards and certain other U. S. tax attributes may be limited. • We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, we may** not ~~possible~~ **be able** to **accurately** ~~predict the impact that any factor or combination of factors may have on our~~ **or timely report our** ~~business, prospects,~~ financial condition or results of operations **, which may adversely affect our business. • Our internal control over financial reporting may not meet the standards required by Section 404 of the Sarbanes- Oxley Act, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and share price. • Failure or perceived failure to comply with laws, regulations, contracts, self- regulatory schemes, standards, and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could increase our costs and otherwise negatively affect our operating results and business** . Risks Related to ~~our Strategic Review Process~~ **Our Financial Condition and Capital Needs** We **have a limited operating history and no history of commercializing products which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability. We are a biotechnology company with a limited operating history and a single product candidate, TOUR006, in development to date. Legacy Tourmaline was formed in 2021 and commenced operations in 2022. To date, we have not yet demonstrated our ability to successfully complete pivotal clinical trials, obtain regulatory approvals, manufacture a product on a commercial scale or arrange for a third- party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization, and we** may not be successful in ~~identifying and implementing~~ **doing so in the future. Consequently,** any **predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, technical or regulatory challenges, or unanticipated delays in development timelines. We will eventually need to transition from a company with a clinical development focus to a company, if TOUR006 or any potential future product candidates are approved, capable of supporting commercial activities. We may not be successful in such a transition. We have no products approved for commercial sale and have not generated any revenue from product sales to date. Legacy Tourmaline has incurred losses in each year since it commenced operations. We expect to continue to incur significant research and development (" R & D ") costs and other expenses related to our ongoing operations for the foreseeable future, particularly to fund R & D of, and seek regulatory approvals for, TOUR006 and any potential future product candidates. We also expect to continue to incur significant operating losses over the next several years as our research, development, manufacturing, preclinical study, clinical trial and related activities grow. We expect our accumulated deficit will also increase in future periods. The size of our future net losses will depend, in part, on the amount of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our stockholders' deficit and working capital. In addition, we will not be able to generate product revenue unless and until TOUR006, or any potential future product candidate, successfully completes clinical trials, receives regulatory approval, and is successfully commercialized or generates revenues through business development activities. We do not expect to receive product revenue from our product candidates for a number of years, if ever. Our ability to generate any product revenue from TOUR006 and any potential future product candidates also depends on a number of additional factors, including our ability, or the ability of any potential future third- party partner, to successfully: • complete research and clinical development of current and future product candidates and obtain regulatory approval for those product candidates; • establish and maintain supply and manufacturing relationships, and ensure adequate, scaled- up, and legally- compliant manufacturing of bulk drug substances and drug products to maintain sufficient supply; • launch and commercialize TOUR006 or any potential future product candidates for which marketing approval is obtained, if any, and, if launched independently by us without a partner, successfully establish a sales force and marketing and distribution infrastructure; • demonstrate the necessary safety data (and, if accelerated approval is obtained, verify the clinical benefit) post- approval to ensure continued regulatory approval; • obtain coverage and adequate product reimbursement from third- party payors, including government payors, for any approved products; • achieve market acceptance for any approved products; • enter into collaboration, partnering, licensing, or other similar arrangements on economically favorable terms; • establish, maintain, protect and enforce our intellectual property rights; and / or • attract, hire and retain qualified personnel. Because of the numerous risks and uncertainties associated with pharmaceutical product development, including that TOUR006 and any potential future product candidates may not advance through development or be approved for commercial sale, we are unable to predict if or when we will generate product revenue or achieve or maintain profitability. Even if we successfully complete development and obtain health authority approval for commercialization for any product candidates that we take forward, we anticipate incurring significant costs associated with launching and commercializing any products. If we fail to become profitable or do not sustain profitability on a**

continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or cease operations. Our future success and ability to generate revenue from TOUR006 or any potential future product candidates, which we do not expect will occur for several years, if ever, is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more product candidates. We have identified thyroid eye disease (" TED ") as the lead indication for TOUR006. We submitted an investigational new drug application (" IND ") in the U. S. to support initiation of a Phase 2b trial of TOUR006 in first- line TED. This IND was cleared by the FDA in August 2023, and we initiated the aforementioned Phase 2b trial in September 2023, which we refer to as the spiriTED trial. Further, we expect to commence a pivotal Phase 3 trial of TOUR006 in first- line TED in 2024. If TOUR006 encounters undesirable safety signals, insufficient efficacy results, development delays, regulatory issues or other problems, our development plans and business would be significantly harmed. Our second indication for TOUR006 is expected to be atherosclerotic cardiovascular disease (" ASCVD "). As previously announced in January 2024, we have reached alignment with the FDA on the ASCVD clinical development program, including a Phase 2 trial evaluating the reduction of C- reactive protein (" CRP "), a validated biomarker for inflammation, with quarterly and monthly dosing of TOUR006 in patients with elevated cardiovascular risk. This trial is targeted to commence in the first half of 2024. TOUR006 for ASCVD is in an earlier stage of development and will require substantial additional investment for clinical development, prior to potentially being submitted for regulatory review and approval in one or more jurisdictions. If our Phase 2 CRP biomarker trial is unsuccessful, our development plans for a Phase 3 ASCVD trial would be significantly harmed. We will need significant additional capital to proceed with the development and commercialization of TOUR006 and any potential future product candidates and our other operations. We may not be able to access sufficient capital on acceptable terms, if at all, and, as a result, we may be required to delay, scale back or discontinue development of such product candidates or other operations. Our operations have consumed substantial amounts of cash since inception, and we will require substantial additional capital to finance our operations and pursue our product development strategy, both in the short- and the long- term, and the amount of funding we will need depends on many factors, including: • the rate of progress in the development of TOUR006 and our other potential future product candidates; • the initiation, progress, timing, delays, costs, and results of preclinical studies and clinical trials for TOUR006 and any potential future product candidates; • the number and development requirements of product candidates that we may pursue; • the outcome, timing, and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign health authorities, including the potential for such authorities to require that we perform more studies than those that we currently expect; • the cost to establish, maintain, expand, enforce, 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 licensing, preparing, filing, prosecuting, defending, and enforcing any patents or other intellectual property rights; • the cost and timing of selecting and auditing a manufacturing site for later- stage clinical and commercial- scale manufacturing; • the cost and timing of performing manufacturing process validation sufficient to meet regulatory expectations and requirements; • the effect of products that may compete with TOUR006 and any potential future product candidates or other market developments; • market acceptance of any approved product candidates, including product pricing and product reimbursement by third- party payors; • the cost of potentially acquiring, licensing, or investing in additional businesses, products, product candidates and technologies; and • the cost of establishing sales, marketing, and distribution capabilities for TOUR006 and any potential future product candidates for which we may receive regulatory approval and that we decide to commercialize ourselves or in collaboration with partners. We believe that our working capital will be sufficient to fund our operating expenses and capital expenditure requirements for at least twelve months from the date of issuance of this Annual Report on Form 10- K. Moreover, based on our current development plans and related assumptions, we believe our cash, cash equivalents and investments are sufficient to fund our operations into 2027. We have based these estimates on plans and assumptions that may prove to be insufficient or inaccurate (for example, with respect to anticipated costs, timing, or success of certain activities), and we could utilize our available capital resources sooner than we currently expect. In addition, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward- looking statement that involves risks and uncertainties, and actual results could vary materially as a result of a number of factors. We plan to finance our future cash needs through public or private equity or debt offerings, BD Arrangements, or a combination of these potential financing sources. For example, we may seek BD Arrangements in the future to facilitate clinical development that requires significantly more capital and resources that may otherwise not be available to us on acceptable terms or at all, such as large cardiovascular outcome trials of TOUR006 in patients with ASCVD. Additional capital may not be available in sufficient amounts, on reasonable terms, or when we need it, if at all. In addition, our ability to obtain financing may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the U. S. and worldwide resulting from geopolitical tensions, such as the ongoing war in Ukraine and hostilities in the Middle East, global pandemics, inflation, rising interest rates, and liquidity concerns at, and failures of, banks and other financial institutions. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in economic growth, increases in inflation rates, higher interest rates and uncertainty about economic stability. If the financial market disruptions and economic slowdown deepen or persist, we may not be able to access additional capital on favorable terms, or at all, which could in the future negatively affect our financial condition and our ability to pursue our business strategy. If adequate funds are not available from public or private equity or debt offerings, or BD Arrangements on acceptable terms when needed, in order to continue the development of TOUR006 or any of our potential future product candidates we may need to: • seek strategic ~~transaction~~

alliances for R & D programs when we otherwise would not, at ~~and~~ **an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available; or • enter into BD Arrangements that could require us to relinquish, or license, on potentially unfavorable terms, our rights to intellectual property, product candidates, or products that we otherwise would develop or seek to commercialize ourselves. We may not be able to raise adequate additional capital on a timely basis, on acceptable terms or at all. If we are unable to do so, we may need to significantly delay, scale back or discontinue development of or abandon TOUR006 or** any **potential** ~~strategic transactions that we may consummate in the~~ future **product candidates, which** could have ~~negative consequences. In February 2023~~ **a material adverse effect on our business** , **financial condition, results of operations and prospects, or** we ~~announced~~ **may be required to cease operations altogether. We will incur significant legal, accounting and other expenses as a public company** that we ~~are undertaking~~ **did not incur as** a **private company** ~~comprehensive review of strategic alternatives focused on maximizing shareholder value~~ , including **costs associated with public company reporting obligations under the Exchange Act. Our management team consists of the executive officers of Legacy Tourmaline prior to the Merger** , ~~but~~ **some of whom have** not **previously managed** ~~limited to, an~~ **and operated** ~~acquisition, merger, possible business combinations and / or~~ a **public** ~~divestiture of the Company~~ **company** ~~' s cell therapy CMC capabilities~~ . ~~We expect~~ **These executive officers and other personnel will need** to devote substantial time **to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of these requirements. Any changes we make to comply with these obligations may not be sufficient to allow us 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 the board of directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms. Once we are no longer** ~~and~~ **an emerging growth company, a smaller reporting company, or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly, and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. However, as an emerging growth company, we may take advantage of exemptions from various requirements, such as an exemption from the requirement to have our independent auditors attest to our internal control over financial reporting under Section 404 of the Sarbanes- Oxley Act of 2002, as well as an exemption from the " say on pay " voting requirements pursuant to the Dodd- Frank Act. After we no longer qualify as an emerging growth company, we may still qualify as a " smaller reporting company, " which may allow us to take advantage of some of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Even after we no longer qualify as an emerging growth company, we expect to still qualify as a " smaller reporting company, " as such term is defined in Rule 12b- 2 under the Exchange Act, in at least the near term, which will allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act and reduced disclosure obligations regarding executive compensation in periodic reports and proxy statements. Once we are no longer an emerging growth company, a smaller reporting company, or otherwise qualify for these exemptions, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could face additional costs to remedy those deficiencies, the market price of our stock could decline, or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management** resources **. Risks Related** to ~~exploring strategic alternatives~~ **Our Dependence on Third Parties We may not be able to obtain and maintain the relationships with third parties** that **are necessary to develop, commercialize and manufacture TOUR006 and any potential future product candidates. We expect to depend on third parties, including contract research organizations (" CROs "), clinical data management organizations, clinical investigators, and CDMOs and other third- party partners and service providers to support our development efforts, to conduct our clinical trials and certain aspects of our research and preclinical studies, to manufacture clinical and commercial- scale quantities of our drug substances and drug products under cGMP and to market, sell and distribute any products we successfully develop and for which we obtain regulatory approval. Any problems we experience with any of these third parties could delay the development, manufacturing** ~~our~~ **or** ~~board~~ **commercialization** of ~~directors believes~~ **TOUR006 or any potential future product candidates, which could harm our results of operations. We cannot guarantee that we or, as applicable, any of our partners** will ~~maximize stockholder value~~ **be able to successfully negotiate agreements for, and maintain relationships with, third- party partners and service providers on favorable terms, if at all** . ~~Despite devoting~~ **If we or any of our partners are unable to obtain and maintain these agreements, we may not be able to clinically develop, manufacture, obtain regulatory approvals for or commercialize TOUR006 or any potential future product candidates, which will, in turn, adversely affect our business. If we or any of our partners need to enter into alternative arrangements, it could delay our product development and, if applicable, commercialization activities and such alternative arrangements may not be available on terms acceptable to us. We expect to continue to expend substantial time and effort to enter into relationships with third parties and, if we**

successfully enter into such relationships, to manage these relationships. In addition, our reliance on these third parties for development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that our clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and we remain responsible for ensuring that manufacturing activities are conducted under cGMP. However, we cannot control the amount or timing of resources our partners will devote to our programs, TOUR006 or potential future product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct their clinical trials or other R & D activities in accordance with regulatory requirements, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for TOUR006 or any potential future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize any approved products. In addition, we base our expense accruals related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf and, if their estimates are not accurate, it could negatively affect the accuracy of our financial statements. Any agreements we have or may enter into with third-party partners and service providers may give rise to disputes regarding the rights and obligations of the parties. Disagreements could develop over contract interpretation, rights to ownership or use of intellectual property, the scope and direction of our programs, the approach for regulatory approvals or commercialization strategy. Any disputes or commercial conflicts could lead to the termination of our agreements, delay progress of our product development programs, compromise our ability to renew agreements or obtain future agreements, lead to the loss of intellectual property rights, result in increased financial obligations for us or result in costly and time- consuming arbitration or litigation. We rely completely on CDMOs for the manufacture and testing of TOUR006 and any potential future product candidates under cGMP, and we are subject to many manufacturing risks, any of which could substantially increase our costs and limit supply of any potential product candidates and any future products. Additionally, any difficulties in the transfer of drug substance or drug product to or from manufacturing facilities could materially adversely affect our business, financial condition, and results of operation. We require the services of third- party CDMOs to provide process development, analytical method development, formulation development, and manufacturing. We do not have, and do not currently plan to acquire or develop, the facilities or capabilities to manufacture and test bulk drug substance or filled drug product for use in clinical trials or commercialization. As a result, we rely completely on CDMOs, which entails risks to which we would not be subject if we manufactured TOUR006 or any potential future product candidates or products ourselves, including risks related to reliance on third parties for availability of drug product to use in our clinical trials and for regulatory compliance and quality assurance with respect to such drug product, the possibility of breach of the manufacturing agreement by third parties because of factors beyond our control (including a failure to manufacture TOUR006 and any potential future product candidates or any products we may eventually commercialize in accordance with our specifications) and the possibility of termination or nonrenewal of agreements by third parties, based on their own business priorities, at a time that is costly or damaging to us. TOUR006 is a biologic, and the manufacture and testing of biologic products is complex, highly regulated and requires significant ~~efforts~~ **expertise and capital investment, including the development of advanced manufacturing techniques, process controls, and advanced analytical testing capability. As a result, the manufacture and testing of our product candidate is subject** to ~~identify~~ **many risks, including the following, some of which we may experience: • product loss or other negative consequences due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, shortages of qualified personnel or improper delivery or storage conditions; • difficulties with product yields, quality control release testing, including challenges related to analytical method development and the qualification and implementation of those methods for release testing, which can delay availability of clinical trial materials; • challenges with long- term stability of our product candidate and products at reasonable and expected storage conditions; • challenges with comparability of product made following changes in the manufacturing process such as a change in the manufacturing facility, scale- up, changes in the storage container used for drug product, or other changes; • the negative consequences of failure to comply with strictly enforced federal, state and foreign regulations; • major deviations from normal manufacturing processes, which may result in reduced production yields, product defects and other supply disruptions; • the presence of microbial, viral or other contaminants discovered in our product candidate or in the manufacturing facilities in which it is made, which can necessitate closure of facilities for** ~~and~~ **an** ~~evaluate potential~~ **extended period of time to investigate and eliminate the contamination; • the negative consequences of our CDMOs' failure to be approved for commercial production following an audit by regulatory authorities, by us or by our partners; • Our CDMOs' changing** ~~strategic~~ **strategies** ~~alternatives~~ **and business priorities , which can affect the availability of facilities where we intend to manufacture our product candidate; and • Our CDMOs' manufacturing facilities being adversely affected by labor, raw material and component shortages, turnover of qualified staff or financial difficulties of their owners or operators, including as a result of natural disasters, power failures, local political unrest or other factors. We cannot ensure that issues relating to the manufacture or testing of our product candidates, such as those described above, will not occur or continue to occur in the future. If we or our CDMOs experience any such issues** there **could be a shortage of drug substance or drug product for use in our clinical trials, which could delay clinical and regulatory timelines significantly and have an adverse effect on our business. In addition, to date, TOUR006 has been manufactured and tested by our drug substance and drug product CDMOs solely for clinical trials. We intend to continue to use CDMOs for these purposes, and also for the supply of larger quantities that may be required to conduct accelerated or expanded early clinical trials or larger, later clinical trials and for commercialization if we advance any of our product candidates**

through regulatory approval and to commercialization. These manufacturers may not have sufficient manufacturing capacity and may not be able to scale up the production of drug substance or drug product in the quantities we need and at the level of quality required in a timely or effective manner, or at all. In particular, there is increased competition in the biotechnology industry for CDMO manufacturing slots and other capabilities generally, which has had, and may continue to have, a negative impact on the availability of manufacturing capacity and therefore our ability to supply clinical trial materials for planned, ongoing or expanded clinical trials or commercialization. The scale up and validation of the manufacturing processes in the CDMOs' facilities to manufacture larger quantities or different formats such as a pre- filled syringe involve complex activities and coordination. Scale up and process validation activities entail risks such as process reproducibility and robustness, stability of in- process intermediates, product quality consistency and other technical challenges. We may be unable to scale up or validate our manufacturing processes, which can be **expensive and time- consuming and could delay the initiation or completion of our clinical trials. Similarly, we or our CDMOs may make changes to our manufacturing processes at various points in product development for many reasons, including changing manufacturing facilities, scaling up, facility fit, raw material or component availability, improving process robustness and reproducibility, decreasing processing times, changing the storage container, or others. In some circumstances, we may fail to demonstrate that the product from the new process is comparable to product from the prior process and we may be required to perform additional bridging studies, animal or human studies to demonstrate that the product used in earlier clinical trials are comparable to the product we intend to use in later trials or later stages of an ongoing trial. These efforts are expensive and there is** no assurance that ~~this~~ **they will be successful, which could impact our ability to continue or initiate clinical trials in a timely manner, or at all, and could require the conduct of additional clinical trials. Any future adverse developments affecting manufacturing operations or the scale up or validation of manufacturing processes for TOUR006 or any of our future product candidates may result in shipment delays, lot failures, clinical trial delays or discontinuations, or, if we are commercializing products, inventory shortages, product withdrawals or recalls or other interruptions in supply. We may also have to record inventory write- offs and incur other charges and expenses for drug substance or drug product that fail to meet specifications or cannot be used before its expiration date. In addition, for out of specification materials, we may need to undertake costly remediation efforts or manufacture new batches at considerable cost and time delays or, in the longer run, seek more expensive manufacturing alternatives. We currently have a single source of supply for our drug substance and for our drug product. Single sourcing minimizes our leverage with our CDMOs, who may take advantage of our reliance on them to increase the pricing of their manufacturing services or require us to change our intended manufacturing plans based on their** ~~strategic~~ **strategies** ~~review~~ **and priorities. Single sourcing also imposes a risk of interruption or delays in supply in the event of manufacturing, quality or compliance difficulties and / or other difficulties in timely supplying us with materials. We do not currently have arrangements in place for redundant supply for drug substance or drug product. If one of our suppliers fails or refuses to supply us for any reason or we otherwise choose to engage a new supplier for TOUR006 or any of our future product candidates, including a second- source supplier to mitigate the risks of single-source supply, it may take a significant amount of time and cost to implement and execute the necessary technology transfer to, and qualification of, a new supplier. The FDA or comparable foreign health authority must approve manufacturers of commercial drug substance and drug product. If there are any delays in qualifying new suppliers or facilities or a new supplier is unable to meet the requirements of the FDA or comparable foreign health authority for approval of production of our commercial supply, there could be a shortage of drug substance or drug product with respect to the affected product candidates. If our CDMOs are unable to source certain raw materials and components from their supplier and if they must obtain such materials from a different supplier, additional testing, and regulatory approvals, may be required, which may negatively impact manufacturing timelines. Any significant delay in the acquisition or decrease in the availability of these materials, components or other items, or failure to successfully qualify alternative materials or components, could considerably delay the manufacture of our product candidates, which could adversely impact the timing or completion of any ongoing and planned trials or the timing of regulatory approvals, if any, of our product candidates. In addition, our CDMOs' facilities and operations may be adversely affected by labor, raw material and component shortages, high turnover of staff and difficulties in hiring trained and qualified replacement staff and the operations of our CDMOs may be requisitioned, diverted or allocated by U. S. or foreign government orders such as under emergency, disaster and civil defense declarations. Changes in economic conditions, supply chain constraints, labor, raw material and component shortages and steps taken by governments and central banks could also lead to higher inflation than previously experienced or expected, which could, in turn, lead to an increase in costs. If any CDMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CDMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CDMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CDMOs for any reason, we will be required to verify that the new CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We would also need to verify, such as through a manufacturing comparability study, that any new manufacturing** process will **produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CDMO could negatively affect our ability to develop product candidates or commercialize our**

products in a timely manner or within budget. Furthermore, a CDMO may possess technology related to the manufacture of our product candidate that such CDMO owns independently. This would increase our reliance on such CDMO or require us to obtain a license from such CDMO in order to have another CDMO manufacture our product candidates. Our manufacturing and testing of bulk drug substance for TOUR006 currently takes place in China through a global CDMO with facilities in China and around the world. Our manufacturing and testing of drug product for TOUR006 occurs in facilities in Austria and the U. S. Our drug product is packaged in Germany and the U. S. A significant disruption in the operation of these manufacturing facilities, a trade war or political unrest could materially adversely affect our business, financial condition and results of operations. We currently contract manufacturing operations to third parties. TOUR006 bulk drug substance for clinical studies is manufactured by a third- party facility in China. TOUR006 drug product is manufactured in Austria and the U. S. and packaged in Germany and the U. S. Any disruption in production or inability of our manufacturers in those countries to produce adequate quantities to meet our needs, whether as a result **of a natural disaster or other causes, could impair our ability to operate our business on a day-to- day basis and to continue development of our product candidates. Furthermore, since bulk drug substance is produced** in ~~us pursuing~~ **China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the U. S. or Chinese governments, political unrest or unstable economic conditions in China. Any of these matters could materially and adversely affect our business and results of operations. In addition, manufacturing interruptions or failure to comply with regulatory requirements by** any ~~transaction~~ **of these manufacturers could significantly delay clinical development of potential products and reduce third- party or clinical researcher interest and support of proposed trials. Furthermore, any recall of the manufacturing lots or similar action regarding** ~~or~~ **our product candidates used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. These interruptions or failures could also impede commercialization of our product candidates and impair our competitive position. Further, we may be exposed to fluctuations in the value of the local currencies. Future appreciation of the local currencies could increase our costs. In addition, our labor costs could continue to rise as wage rates increase due to increased demand for skilled laborers and the availability of skilled labor declines in such countries. Additionally, we plan to transfer manufacturing and testing of TOUR006 bulk drug substance to a facility in the U. S.** that ~~any transaction~~ **is licensed for commercial production. We intend to use this U. S. facility to produce TOUR006 bulk drug substance for late- stage clinical studies and commercial supply. We may encounter difficulties transferring the manufacture and testing process. Furthermore, our process at the new facility may result in the production of TOUR006 that is not comparable to the current TOUR006 clinical trial material produced at the facility in China. Also, we plan to conduct manufacturing and testing of TOUR006 drug product at a facility in Europe that is licensed for commercial production, through a global CDMO. TOUR006 drug product produced at the commercial facility may not be comparable to the current TOUR006 drug product that is being used in our clinical studies. We may seek to establish BD Arrangements, and** , if ~~pursued, will be completed~~ **we are not able to establish them** on ~~attractive~~ **commercially reasonable** terms **,** or at all ~~. We~~ **, we may** have **to alter** ~~not set a timetable for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or~~ **our** ~~transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value or that we will make any additional cash distributions to our stockholders. The process of continuing to evaluate these strategic options may be very costly, time- consuming and complex and we have incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business. In addition, potential counterparties in a strategic transaction involving our company may place minimal or no value on our assets and our public listing. Further, should we resume the~~ development ~~of our~~ **and commercialization plans. Our** product ~~candidates, the~~ development **programs** and ~~any~~ **the** potential commercialization of **TOUR006** ~~our~~ **or any of our future** product candidates will require substantial additional cash to fund **expenses** ~~the costs associated with conducting the necessary preclinical and clinical testing and obtaining regulatory approval . Consequently,~~ **For TOUR006 or** any ~~potential counterparty in a strategic transaction involving our company may choose not to spend additional resources and continue development~~ of our **future** product candidates ~~and~~ **, we** may ~~attribute little~~ **decide to collaborate with pharmaceutical and biotechnology companies** ~~or~~ **for the development and potential commercialization of** ~~no value, in such a transaction, to~~ those product candidates. **We face significant competition** ~~In addition, any strategic business combination or other transactions that we may consummate~~ in **seeking appropriate collaborators. Whether** ~~the future could have a variety of negative consequences and~~ we **reach** ~~may implement~~ a **definitive agreement** ~~course of action or consummate a transaction that yields unexpected results that adversely affects our business and decreases the remaining cash available~~ for **a BD Arrangement will** ~~use in our business or the execution of our strategic plan. Any potential transaction would be dependent~~ --- **depend** ~~on a number of factors that may be beyond our control, including~~ , among other things, **upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s own evaluation of a potential collaboration. Such factors a potential collaborator will use to evaluate a BD Arrangement may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and** market conditions ~~, industry trends, the interest of third parties in~~ **generally. The collaborator**

may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a ~~potential transaction~~ **BD Arrangement could be more attractive than one** with us ~~, obtaining stockholder approval and~~ **for our product candidate. The terms of any additional BD Arrangements or** ~~the~~ **other** ~~availability of financing~~ **arrangements that we may establish may not be favorable** to ~~third parties~~ **us. We may** in ~~a~~ **the future be restricted under our current BD Arrangements from entering into** potential ~~transaction~~ **future BD Arrangements on certain terms** with **potential collaborators. BD Arrangements are complex and time- consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate BD Arrangements on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to** us on ~~reasonable~~ **acceptable** terms **or at all** . ~~Any failure of such potential transaction~~ **If we do not have sufficient funds, we may not be able** to ~~achieve~~ **further develop our product candidates or bring** ~~the~~ **them** ~~anticipated results could significantly impair our ability~~ to **market and generate product revenue. In addition, any future BD Arrangements that we** enter into ~~any future strategic transactions and may significantly diminish or delay any future distributions to our stockholders. If we are not successful in setting forth a new strategic path for the Company, or if our plans are not executed in a timely fashion, this may cause reputational harm with our stockholders and the value of our securities may be adversely impacted. In addition, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to the future of the Company could cause our stock price to fluctuate significantly. Even if we successfully consummate any transaction from our strategic assessment, including, but not limited to, an acquisition, merger, a business combination and / or divestiture, we may fail to realize all of the anticipated benefits of the transaction, those benefits may take longer to realize than expected, or we may encounter integration difficulties. Our ability to realize the anticipated benefits of any potential business combination or any other result from our strategic assessment, are highly uncertain. Any anticipated benefits will depend on a number of factors, including our ability to integrate with any future business partner, our ability to obtain value for our cell therapy CMC capabilities, if divested, and our ability to generate future shareholder value in the technology platform we may elect to pursue. The process may be disruptive to our business and the expected benefits~~ may not be **successful** ~~achieved within the anticipated time frame, or at all~~ . The ~~failure to meet the challenges involved and to realize the anticipated benefits of any potential transaction could adversely affect our business and financial condition. If we are successful~~ --- **success** ~~in completing a strategic transaction, we may be exposed to other operational and financial risks. Although there can be no assurance that a strategic transaction will result from the process we have undertaken to identify and evaluate strategic alternatives, the negotiation and consummation~~ of ~~any such transaction will require significant time on the part of our management, and the diversion of management' s attention may disrupt our business. The negotiation and consummation of any such transaction may also require more time or~~ **our BD Arrangements** ~~greater cash resources than we anticipate and expose us to other operational and financial risks, including: • increased near- term and long- term expenditures; • exposure to unknown liabilities; • higher than expected acquisition or integration costs; • incurrence of substantial debt or dilutive issuances of equity securities to fund future operations; • write- downs of assets or goodwill or incurrence of non- recurring, impairment or other charges; • increased amortization expenses; • difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel; • impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership; • inability to retain key employees of our company or any acquired business; and • possibility of future litigation. Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects. If a strategic transaction is not consummated, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders~~ will depend heavily on the ~~timing~~ **efforts and activities** of ~~such liquidation as well as~~ **our collaborators. Collaborators generally have significant discretion in determining** the ~~amount of cash~~ **efforts and resources** that **they** will ~~need~~ **apply** to ~~be reserved~~ **these collaborations. Disagreements between parties to a BD Arrangement regarding clinical development and commercialization matters can lead to delays in the development process** ~~for~~ - **or** ~~commitments~~ **commercializing the applicable product candidate** and ~~contingent liabilities~~ **, in some cases, termination of the BD Arrangement** . ~~There~~ **These disagreements** can be **difficult to resolve if neither of the parties has final decision- making authority. BD Arrangements with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation. We have** no **experience in sales** ~~assurance that a strategic transaction will be completed. If a strategic transaction is not completed~~ , **marketing** ~~our board of directors may decide to pursue a dissolution and liquidation. In such an~~ **and** ~~event, the amount of cash available for~~ distribution ~~to our stockholders will depend heavily on the timing of such decision~~ and ~~,~~ **may have to enter into agreements** with **third parties to perform** ~~the~~ **these functions** ~~passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition~~ , **which** ~~if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would~~ **could prevent us from successfully commercializing TOUR006** ~~be required under Delaware corporate law to pay our~~ - **or** ~~outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making~~ any **potential** ~~distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related~~

~~to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up. Our ability to consummate a strategic transaction depends on our ability to retain our employees required to consummate such transaction. Our ability to consummate a strategic transaction depends upon our ability to retain our employees required to consummate such a transaction, the loss of whose services may adversely impact the ability to consummate such transaction. In connection with the evaluation of strategic alternatives and in order to extend our resources, we implemented a restructuring plan that included reducing our workforce by approximately one- third, with remaining employees primarily focused on maintaining the Company' s cell therapy CMC capabilities and executing FREEDOM- 3, each pending the outcome of our review of strategic alternatives. Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain certain of our remaining personnel. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of a strategic alternative as well as business operations. Our corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business. On February 15, 2023, in connection with the evaluation of strategic alternatives and in order to extend its resources, the Board of Directors of the Company approved a restructuring plan (the" Plan") that includes reducing the Company' s workforce by approximately one- third, with remaining employees primarily focused on maintaining the Company' s cell therapy CMC capabilities and executing FREEDOM- 3. In addition, the Plan includes a discontinuation of the Company' s FREEDOM- 1 and FREEDOM- 2 clinical development programs and further prioritization of the Company' s resources as it assesses strategic alternatives. The Company estimates that it will incur approximately $ 2. 9 million for retention, severance and other employee termination- related costs in the first and second quarters of 2023. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. Furthermore, our restructuring plan may be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences, such as increased difficulties in implementing our business strategy, including retention of our remaining employees. Employee litigation related to the headcount reduction could be costly and prevent management from fully concentrating on the business. Our workforce reduction activities may also yield unintended consequences, such as attrition beyond our reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction depends in part on our ability to retain certain of our remaining personnel. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of a strategic alternative as well as business operations. Any~~ future ~~growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, and loss of employees and reduced productivity among remaining employees. For example, the workforce reduction may negatively impact our clinical, regulatory, technical operations, and commercial functions, should we choose to continue to pursue them, which would have a negative impact on our ability to successfully develop, and ultimately, commercialize our~~ product candidates ~~. Our future financial performance and our ability to develop our product candidates or additional assets will depend, in part, on our ability to effectively manage any future growth or restructuring, as the case may be. We may become involved in litigation, including securities class action litigation, that could divert management' s attention and harm the company' s business, and insurance coverage may not be sufficient to cover all costs and damages. In the past, litigation, including securities class action litigation, has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in investigations by the SEC. We may be exposed to such litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management' s attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction. Risks Related to Our Business and Product Candidates Risks Related to Clinical Development Our business substantially depends upon the successful development and regulatory approval of FCR001, our lead product candidate. If we are unable to obtain regulatory approval for FCR001, our business may be materially harmed~~ . We currently have no **sales, marketing or distribution capabilities. To commercialize TOUR006 or any potential future product candidates we must either develop our own sales, marketing and distribution capabilities or make arrangements with third parties to perform these services for us. If we decide to market or distribute any of our** products ~~approved~~ **on our own, we will have to commit significant resources to developing a marketing and sales force and supporting distribution capabilities. If we decide to enter into arrangements with third parties** for ~~sale and~~ **performance of these services, we may find that they** are ~~investing substantially~~ **not available on terms acceptable to us, or at** all ~~of~~ **. If we are not able to establish and maintain successful arrangements with third parties** ~~our or efforts~~ **build our own sales** and **marketing infrastructure, we may not be able to commercialize our product candidates, which would adversely affect our business,** financial ~~resources in~~ **condition, results of operations and prospects. Risks Related to** the **Discovery,** ~~development~~ **Development and Regulatory Approval** of **Our Product Candidates TOUR006 and any other of** our **future** ~~Facilitated Allo- HSCT Therapy, specifically in our lead~~ product ~~candidate~~ **candidates must undergo rigorous clinical trials before seeking regulatory approvals** . ~~FCR001. Successful continued~~

~~development~~ and ~~ultimate~~ **clinical trials may be delayed, suspended or terminated at any time for many reasons, any of which could delay or prevent** regulatory approval **and, if approval is granted, commercialization** of ~~FCR001~~ **our product candidates. TOUR006 and any other product candidates we might develop are subject to rigorous and extensive clinical trials before we can seek regulatory approval from the FDA and comparable foreign health authorities such as the European Medicines Authority. Clinical trials may be delayed, altered, suspended or terminated at any time for reasons including but not limited to: • ongoing discussions with the FDA or comparable foreign health authorities regarding the scope or design of our clinical trials; • delays in obtaining, or the inability to obtain, required approvals from institutional review boards (" IRBs ") and ethics committees or other governing entities at clinical trial sites selected for participation in our clinical trials; • delays in reaching agreement on acceptable terms with clinical trial sites on clinical budgets and / or clinical trial agreements; • lack and / or loss of personnel at clinical trial sites to conduct our trials, including patient screening, patient visits and / or assessments, data entry of patient data into the clinical database and / or processing of patient samples; • institutional policies related to in- person patient visits resulting in delays to treatments or assessments being conducted, CRO and / or sponsor visits to conduct monitoring visits to verify data and / or site adherence to regulatory requirements; • delays in patient enrollment and other key trial activities; • delays in reaching agreement on acceptable terms with prospective CROs; • the failure of CROs, testing laboratories and other third parties to satisfy their contractual duties to us or meet expected deadlines; • deviations from the trial protocol by clinical trial sites and investigators, or failures to conduct the trial in accordance with regulatory requirements; • alterations in the size and scope of the trial; • lower than anticipated retention rates of participants in clinical trials, including patients dropping out due to protocol non- compliance, side effects or disease progression; • missing or incomplete data; • failure of enrolled patients to complete treatment or to return for post- treatment follow- up; • for clinical trials in selected patient populations, delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used to identify selected patients and test any patient samples; • implementation of new, or changes to, guidance or interpretations from the FDA or comparable foreign health authorities with respect to approval pathways for TOUR006 and any potential future product candidates we are pursuing; • the need to repeat or conduct additional clinical trials as a result of inconclusive or negative results, poorly executed testing or changes in required endpoints or other changes to the trial or analysis; • insufficient supply or deficient quality of drug substance, drug product or other clinical trial material necessary to conduct our clinical trials, as well as delays in the testing, validation, manufacturing and delivery to clinical trial sites of such material; • withdrawal of clinical trial sites or investigators from our clinical trials** for any **reason, including as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials; • unfavorable FDA or comparable foreign health authority inspection or review of a clinical trial site or records of any clinical or preclinical investigation; • drug- related adverse effects or tolerability issues experienced by participants in our clinical trials; • changes in government regulations or administrative actions; • lack of adequate funding to continue the clinical trials; • ability to hire and retain key R & D and other personnel; or • the placement of a clinical hold on a trial by the FDA or comparable foreign health authorities. We cannot guarantee that we will be able to successfully obtain FDA or other global health authority clearance to proceed with any planned clinical investigations of TOUR006 or any** potential ~~indications is critical to the~~ future ~~success of~~ **product candidates** ~~our~~ **or** ~~business~~ **to accomplish required regulatory and / or manufacturing activities or all of the other activities necessary to initiate and complete clinical trials in a timely fashion, if at all . ~~We~~ As a result, our preclinical studies and clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approvals or successfully commercialize our products. In addition, we have only limited experience in conducting late- stage clinical trials required to obtain regulatory approval. In any event, we do not know whether any of our clinical trials will begin as planned,** will need to **be restructured** ~~raise sufficient funds for~~ **or will be completed on schedule** , ~~and~~ **or at all. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to** successfully ~~enroll~~ **commercialize our product candidates** and **may harm our business, financial condition, results of operations and prospects. We or our partners' inability to timely** complete ~~, our~~ clinical development ~~programs of FCR001~~ **could result in additional costs to us** ~~for~~ **or** ~~severe autoimmune diseases~~ **impair our ability to generate product revenue or development, regulatory, commercialization and sales milestone payments and royalties on product sales. If clinical trials of TOUR006** or any **potential future** ~~additional indications. There is no guarantee that any of our~~ product candidates ~~will proceed~~ **fail to timely initiate, enroll, complete, or produce positive results or to demonstrate safety and efficacy to the satisfaction of the FDA or comparable health authorities or sufficient to demonstrate differentiation from other approved therapies or therapies** in ~~clinical~~ development **, we may incur additional costs** ~~or achieve regulatory approval. The process for~~ **or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. Before** obtaining marketing approval **from health authorities** for **the sale of TOUR006 or** any ~~product candidate is very long and risky and there will be significant challenges for us to address in order to obtain marketing approval as planned or, if at all. The~~ potential ~~regulatory approval of FCR001 or any other product candidate we may develop is subject to a number of risks, including the following: successful initiation and completion of clinical trials; successful patient enrollment in clinical trials; successful data from our clinical trials that supports an acceptable risk- benefit profile of our product candidates in the intended populations; and receipt and maintenance of marketing approvals from applicable regulatory authorities. Furthermore, negative results in the development of FCR001, such as the patient death in our FREEDOM- 1 trial, may impact our ability to obtain regulatory approval of FCR001 for other current and potential indications since the underlying platform, manufacturing process, development process, and cell therapy is the same for all of our current~~

programs in development. Accordingly, a failure in any one program may affect the ability to obtain regulatory approval to continue or conduct our other clinical programs. Specifically, in February 2023, we announced the termination of our FREEDOM- 1 and FREEDOM- 2 clinical trials evaluating FCR001' s ability to induce durable tolerance in LDKT recipients. This decision was primarily attributable to the pace of enrollment and the associated timeline to critical milestones in those programs. Should we continue clinical development of our product candidates, we may face enrollment challenges in our clinical trials, such as those faced in our LDKT trials. In addition, because we have limited financial and personnel resources and are placing significant focus on the development of our lead product candidate and our current indications, we may forgo or delay pursuit of opportunities with other future product candidates **, we** and indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and other future product candidates for **or** specific indications **our partners must conduct extensive preclinical studies and clinical trials to demonstrate its safety and efficacy in humans. Preclinical studies and clinical trials are expensive, take several years to complete and** may not yield **results that support further** any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular future product candidate or indication, we may relinquish valuable rights to those future product candidates or indications through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such future product candidates or indications. Many of these risks are beyond our control, including the risks related to clinical development , our **or product approvals** proprietary manufacturing process and the regulatory submission process . If we are unable to develop and receive regulatory **The design of a clinical trial can determine whether its results will support** approval **of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. There is a high failure rate** for **drugs and biologic** FCR001 for the indications we are developing it for, or if we experience delays as a result of any of these risks or otherwise, our business could be materially harmed. We may not successfully identify, develop or commercialize new indications for FCR001 or identify any additional product **products proceeding** candidates and may be unable to expand our product pipeline through acquisition or in- licensing. In the event that FCR001 does not receive regulatory approval or is not successfully commercialized in our currently planned indications, then the success of our business will depend on our ability to expand FCR001 into additional indications or our product pipeline to include other product candidates through our own internal research and discovery efforts, in- licensing or other acquisitions. We may be unable to identify relevant product candidates or indications. If we do identify such product candidates or indications, we may be unable to develop these programs for a number of reasons, including insufficient capital or other resources. Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and the inability to successfully and timely conduct clinical trials and obtain regulatory approval for our product candidates would substantially harm our business. We cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA; similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and clinical trials, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate to assure safety, purity and potency. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure **failure** can occur at any time during the **stage of testing. Because we have limited experience designing clinical trials, we may be unable to design and execute a** clinical trial process **to support regulatory approval . We may also not be successful in generating clinical data sufficient to differentiate TOUR006 from other products in the same therapeutic area. If our competitors' products are, or are perceived to be, more effective, more convenient, less costly or safer than TOUR006, or we are unable to demonstrate differentiation in any of those factors, we may not be able to achieve a competitive position in the market. In addition, data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In any event, it is impossible to predict when or if any of our** Product **product** candidates **will prove safe and effective** in later stages of **humans or will receive regulatory approval. If we are unable to successfully discover, develop or enable our partners to develop drugs that regulatory authorities deem effective and safe in humans, we will not have a viable business. We may not be able to file INDs, IND amendments, or clinical trial applications (" CTAs ") to commence** clinical trials **on** may fail to show the desired safety **timelines we expect,** and **even if we are able** efficacy traits despite having progressed through preclinical studies and clinical trials. The time required to **,** obtain approval by the FDA and **or** comparable **health** foreign regulatory authorities is unpredictable but typically takes many **may not permit us** years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the study designs and substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to **proceed** gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions . We have **may** not obtained regulatory approval **be able to file INDs or CTAs** for **TOUR006** any product candidate and it is possible that none of our existing product candidates or any future product candidates **on the timelines we expect, if at all. For example, we may experience, or our partners may experience, manufacturing delays or other delays with IND- enabling studies. Moreover, we cannot be sure that submission of an IND or CTA** will **result in the FDA or comparable health authority allowing initial or later- stage clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally,** ever **even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or CTA, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND or CTAs. Any failure to**

file INDs and CTAs on the timelines we expect or to obtain regulatory ~~approval~~ **approvals for our trials may prevent us** ~~. Our product candidates could fail to receive regulatory approval~~ from **completing** ~~the FDA or a comparable foreign regulatory authority for many reasons, including: disagreement with the design or conduct of~~ our clinical trials ~~; failure to demonstrate to the satisfaction of regulatory agencies that FCR001, our~~ **or** ~~lead~~ **commercializing our** ~~product~~ **products** candidate, is safe and effective,..... indications), may grant approval contingent on ~~the performance of costly post- marketing clinical studies, or may approve~~ a **timely basis** ~~product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. If we experience delays or difficulties in the enrollment of patients in clinical trials~~ , **if at all** ~~development of our product candidate may be delayed or prevented, which would have a material adverse effect on our business~~ . **We** ~~In February 2023, we announced the termination of our FREEDOM- 1 and FREEDOM- 2 clinical trials evaluating FCR001 in LDKT. This decision was primarily attributable to the pace of enrollment and the associated timeline to critical milestones. While we continue to believe FCR001 should be assessed in our FREEDOM- 3 clinical trial in severe scleroderma, we~~ may not be able to initiate or continue clinical trials for our product candidate if we **,** or a potential future sponsor **,** are unable to locate and enroll a sufficient number of eligible patients to participate in these continuing trials as required by the FDA or comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials ~~. In particular, because certain of our clinical trials are focused on indications with relatively small patient populations, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate~~ . Patient enrollment may be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, **at clinical trial sites participating in our clinical trials, or at clinical trial sites not participating in our clinical trials** and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. ~~Furthermore, because we are investigating the treatment of complex indications that require specialized medical care by means of an HSCT procedure, which is itself a complex procedure performed by specialized physicians and treatment centers, we face inherent challenges in recruiting clinical trial sites to participate in our trials and to complete our trials on a timely basis. For example, in LDKT, each site that participated in our trials needed to identify a lead clinician from each of the solid organ transplant and HSCT departments, who are willing and able to coordinate closely on the care and follow- up of our patients. We have historically relied on our relationships with transplant centers of excellence to assist in identifying eligible patients and carrying out our clinical trials, and any inability to secure or deterioration of those relationships could impede our ability to successfully enroll patients in a timely manner, if at all.~~ Patient enrollment may also be affected by other factors, including: ~~•~~ size and nature of the patient population; ~~•~~ severity of the disease under investigation; ~~•~~ **availability of approved therapies, other medicines, surgical procedures, or other therapies or interventions that would lead a patient to opt for that treatment or care approach instead of enrolling in our trial; •** patient eligibility criteria for the trial in question; ~~•~~ nature of the trial protocol; ~~•~~ our ability to recruit clinical trial investigators with the appropriate competencies and experience; ~~•~~ perceived risks and benefits of the product candidate under study; ~~•~~ the occurrence of adverse events attributable to our lead product candidate; ~~•~~ efforts to facilitate timely enrollment in clinical trials; **•** the number and nature of competing products or product candidates and ongoing clinical trials of competing product candidates for the same indication **at clinical trial sites participating in our clinical trials, or at clinical trial sites not participating in our clinical trials** ; ~~•~~ patient referral practices of physicians; ~~•~~ risk that enrolled subjects will drop out or die before completion; ~~•~~ competition for patients from other clinical trials **at clinical trial sites participating in our clinical trials, or at clinical trial sites not participating in our clinical trials** ; ~~•~~ the ability to monitor patients adequately during and after treatment; **•** ~~travel restrictions and other potential limitations by federal, state, or local governments affecting the workforce or affecting clinical research site policies implemented in response to the COVID- 19 pandemic; delays in or temporary suspension of the enrollment of patients in our ongoing and planned clinical trials due to the ongoing and evolving COVID- 19 pandemic;~~ proximity and availability of clinical trial sites for prospective patients; and ~~•~~ continued enrollment of prospective patients by clinical trial sites. Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than ~~we expect~~ **expected** , the development costs for our product candidates may increase and the completion of our trials may be delayed or our trials could become too expensive to complete. Any delays in completing our clinical trials will increase ~~our~~ costs, delay or prevent ~~our~~ product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue. Any delays in completing our clinical studies for our product candidates may also decrease the period of commercial exclusivity. Any of these occurrences may significantly harm our business, financial condition **, results of operations,** and prospects. **Success** ~~We face substantial competition, which may result~~ in ~~others discovering, developing~~ **preclinical studies or earlier- stage clinical trials** ~~or~~ **for TOUR006,** ~~commercializing products before~~ or **evidence** ~~more successfully than we do. We face competition~~ from ~~numerous pharmaceutical~~ **published observations, clinical studies, or other literature for other anti- IL- 6 or anti- IL- 6 receptor agents, may not be indicative of such results in future or ongoing clinical trials for TOUR006. To date, the data supporting our drug discovery** and ~~biotechnology enterprises~~ **development programs are derived in part from laboratory and preclinical studies and earlier- stage clinical trials conducted by Pfizer. Owing in part to the complexity of biological pathways, when used to treat human patients** , as well as **differences in the design** ~~from academic institutions, government agencies and private and public research institutions. Our commercial opportunities will be significantly impacted if our~~ **or conduct** ~~competitors develop and commercialize products that are safer, more effective, have fewer side effects, are less expensive or obtain more significant acceptance in the market than any product candidates that we develop. Additionally, our commercial opportunities will be significantly impacted if novel upstream products or changes in treatment protocols reduce the overall incidence or prevalence~~ of **clinical trials, TOUR006 might not demonstrate the biochemical** ~~diseases in our current or future target population. Competition could result in reduced sales~~ and ~~pricing pressure~~ **pharmacological properties we anticipate based** on **laboratory studies** ~~our~~ **or earlier** ~~product candidates, if approved by applicable regulatory authorities. In addition, significant~~

delays in the development of our product candidates could allow our competitors to bring products to market before us and impair any ability to commercialize our product candidates. While there are currently no FDA - **stage clinical trials** or European Medicines Agency (" EMA") approved cell- based therapies for the indications we are currently targeting , other approved or commonly used drugs and **it may interact** therapies for our current or future target diseases, such as nintedanib to slow the rate of decline in lung function in patients with **human biological systems or** scleroderma- associated interstitial lung disease, are more well established and are accepted by physicians, patients and third- party payors. Some of these drugs are branded and subject to patent protection, and other drugs **in unforeseen** are available on a generic basis. Insurers and other third- party payors may encourage the use of generic products or specific branded products. In addition , **ineffective** a number of companies, academic institutions and government agencies are seeking to address limitations of existing therapies that we are also seeking to address. For - **or harmful ways** example, a number of third parties, such as Jasper Therapeutics, Inc . **Success** , bluebird bio, Inc. and Magenta Therapeutics, Inc., are seeking to develop conditioning regimens for HSCT that have lower toxicities, morbidities and mortalities than the current standard of care. Similarly, Johns Hopkins University and the Fred Hutchinson Cancer Center have previously administered non- myeloablative conditioning treatments. A number of other companies are also seeking to decrease the incidence and severity of graft versus host disease (" GvHD ") in HSCT. If any of these endeavors prove to be successful, the anticipated advantages of our Facilitated Allo- HSCT Therapy in comparison to the then existing standard of care could be eliminated and the demand for our Facilitated Allo- HSCT Therapy could be materially impacted. We expect that, if our one- time investigational therapy is approved, it will be priced in a manner that will reflect its long- term clinical, economic, and humanistic value. Such a pricing model may entail a single upfront cost or multiple installments contingent upon demonstration of continued benefit that will likely be more expensive than the upfront cost or initial annual costs of competitive generic products that must be taken chronically. Absent differentiated and compelling clinical evidence, pricing premiums may impede the adoption of our products over currently approved or commonly used therapies, which may adversely impact our business. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will become as our products continue in clinical development. Many of our competitors or potential competitors have significantly greater market presence, financial resources and expertise in research and development, manufacturing, preclinical **studies** testing, conducting clinical trials, obtaining regulatory approvals and **earlier** marketing approved products than we do, and as a result may have a competitive advantage over us. Smaller or early - stage companies may also prove to be significant competitors, including through collaborative arrangements or mergers with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, commercial and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business. As a result of these factors, these competitors may obtain regulatory approval of their products before we are able to, which will limit our ability to develop or commercialize our product candidates. Our competitors may also develop products that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidates obsolete or noncompetitive before we can recover the expenses of development and commercialization. Delays in the clinical development or delays in or our ability to achieve regulatory approval, if at all, and commercialization of our product candidates, if approved, would have a material adverse effect on our business. We may experience delays in our ongoing or future clinical trials and we do not know whether clinical trials will begin or enroll subjects on time, will need to be redesigned or will be completed on schedule, if at all, such as on account of the ongoing COVID- 19 pandemic and its impact at clinical trials sites or on the third- party service providers on whom we rely. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as: delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on the design and implementation of clinical trials; delay or failure in obtaining authorization to commence a trial, including the delay or ability to generate sufficient preclinical data to support initiation of clinical trials, or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a trial; delay or failure in reaching agreement on acceptable terms with prospective 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; the inability of CROs to perform under these agreements, including due to impacts from the COVID- 19 pandemic on their workforce; delay or failure in obtaining institutional review board (" IRB ") approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site; withdrawal of clinical trial sites from our clinical trials or the ineligibility of a site to participate in our clinical trials; delay or failure in recruiting and enrolling suitable subjects to participate in a trial; delay or failure in subjects completing a trial or returning for post- treatment follow- up; inability to identify and maintain a sufficient number of trial sites, including because potential trial sites may not have the capabilities required for the indication that we are treating; failure of our third- party clinical trial managers to satisfy their contractual duties, meet expected deadlines or return trustworthy data; delay or failure in adding new trial sites, including due to changes in policies of the clinical research sites or local IRBs; interim results or data that are ambiguous or negative or are inconsistent with earlier results or data; feedback from the FDA, the IRB, data safety monitoring boards (" DSMBs ") or comparable foreign authorities, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol for a trial; unacceptable benefit / risk profile, unforeseen safety issues or adverse side effects; failure to demonstrate a benefit from using a product candidate; lack of adequate funding to continue a trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials or increased expenses associated with the services of our CROs and other third parties; or changes in governmental regulations or administrative actions, failure by us or third parties to comply with regulatory requirements, or lack of adequate funding to continue a clinical trial. Furthermore, clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, including as a result of clinical sites, investigators or other third parties deviating from the trial protocol,

~~failing to conduct the trial in accordance with regulatory and contractual requirements, and / or dropping out of a trial. In addition, disruptions caused by the COVID- 19 pandemic, including any current or future emerging variants of the virus, may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. 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 DSMB 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 including a suspected unexpected serious adverse reaction (" SUSAR"), such as the recent death of a patient in our FREEDOM- 1 trial, 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 trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Risks Related to the Results of our Preclinical Studies and / or Clinical Trials The results of preclinical studies or earlier clinical trials are not necessarily predictive of future results. Our existing product candidates in clinical trials, and any other product candidate we advance into clinical trials, may not have favorable results in later clinical trials or receive regulatory approval. Success in preclinical studies and earlier~~ clinical trials does not ensure that later clinical trials will generate ~~findings consistent with~~ **the same results** ~~our~~ **or** ~~earlier~~ **otherwise provide adequate or positive data to demonstrate the effectiveness and safety of our current and potential future product candidates. In this regard, the data supporting our drug discovery and development programs are derived from laboratory and preclinical studies, and future** clinical trials **in humans may show that one or more** ~~, including adequate data to demonstrate the efficacy and safety~~ of ~~FCR001 or~~ **our** ~~any of other~~ product candidates **are not safe and effective, in which event** we **may need to abandon development of such product candidates. In fact,** ~~may~~ **many** ~~develop. Likewise, a number of~~ companies in the pharmaceutical and biotechnology industries ~~, including those with greater resources and experience than us,~~ have suffered significant setbacks in **late- stage** clinical trials ~~,~~ even after ~~seeing~~ **achieving** promising results in ~~earlier~~ preclinical studies ~~or~~ **and earlier- stage** clinical trials. ~~Despite the~~ **Similarly, preliminary data and interim** results ~~reported~~ **from clinical trials may not be predictive of final results. As a general matter, there is also a substantial risk that Phase 3 trials with larger numbers of patients and / or longer durations of therapy will fail to replicate efficacy and safety results observed** in earlier **clinical trials. The impact of such differences may lead to a clinical trial (s) of TOUR006 failing to reproduce any positive efficacy, safety, or other findings from laboratory and** preclinical studies ~~or~~ **and earlier- stage** clinical trials for ~~our product candidates~~ **TOUR006. In addition** ~~, to date,~~ **the rationale supporting our drug discovery and development programs is also based upon published articles describing positive** results **from clinical** ~~may not be replicated in subsequent trials~~ **trial** ~~,~~ **(s)** and ~~we do not know whether~~ **/ or the clinical experience of physicians using tocilizumab (and** ~~the~~ **other inhibitors of IL- 6 or IL- 6 receptor) in various diseases. For example, part of the rationale supporting the development and investigation for TOUR006 in TED is from published articles describing the off- label use of tocilizumab in TED, which report observations of positive efficacy and safety results. Results from our future or ongoing** clinical trials ~~we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval~~ of **TOUR006 may differ significantly from those from published articles** ~~FCR001 or any future product candidates we develop. Inaccuracies~~ in **the literature of other molecules in the anti- IL- 6** ~~our~~ **or** ~~earlier~~ **anti- IL- 6R class. For example, differences in** clinical ~~data and deviations~~ **results may arise** from **differences between drug targets** ~~our~~ **or between molecules that inhibit the same drug target. In addition, there may be substantial differences, even if the same disease or indication, between** clinical trial **(s)** ~~protocols can impact the integrity~~ of **TOUR006** ~~those data, including safety data,~~ and **published literature (e** ~~could impact the ability of those data to support regulatory approval~~ ~~. Additionally~~ **g.** ~~, certain of~~ **case series** ~~our~~ **or reports** ~~clinical trial endpoints also may not be adequately powered in a particular subpopulation of our trial population. For example~~ ~~, our Phase 2 trial was a " single arm " trial for which there was no comparator arm to permit a comparison of our investigational therapy against standard of care treatment. Furthermore, all of our ongoing and planned~~ clinical trials ~~to~~ **, etc.) for other molecules in the anti- IL- 6 or anti- IL- 6R class based upon factors such as the clinical use setting, patient population being treated or investigated, assessments (e. g., efficacy, safety, pharmacodynamics, etc.),** ~~date~~ **data collection and handling, analysis, study conduct, or other factors. Bias may** have **also** been **introduced in the published clinical reports that led to an incorrect determination or overestimate of the efficacy and safety results** ~~or~~ **for** ~~will be~~ **TOUR006 because of the** open- label ~~trials~~ **nature and lack of controls or other robustness measures in these case series and uncontrolled clinical studies** ~~. This means~~ **There also can be publication bias, if only examples of successful cases of the clinical use of an anti- IL- 6 or anti- IL- 6R molecule (e. g., tocilizumab, satralizumab, sarilumab, siltuximab, ziltivekimab, etc.) may have been published, while treatment experiences for such molecules** that ~~both~~ **were unsuccessful and / or associated with adverse safety outcomes were not published. The impact of such differences may lead to a clinical trial (s) of TOUR006 failing to reproduce any positive efficacy, safety, or** ~~the~~ **other** ~~patient~~ **findings in relation to inhibition of IL- 6 or the IL- 6 receptor that were reported in publications of other molecules. If such** ~~and~~ ~~-~~ **an** ~~investigator know whether~~ **event was to occur,** ~~the~~ **there** ~~patient~~ is ~~receiving~~ **a risk that the TOUR006 development program in a particular indication (s)** ~~our~~ ~~-~~ **or** ~~FCR001 therapy~~ **all indications is terminated, longer** or ~~standard of care therapy. Open- label~~ **more expensive development programs (including larger, longer, and / or costlier** clinical trials ~~can~~ **) may** be ~~subject~~ **required** to ~~various limitations that may exaggerate any therapeutic effect, as patients in open- label clinical trials are aware when they are receiving treatment. Open- label clinical trials may be subject to a " patient bias. " Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition,~~

~~open- label clinical trials may be subject to an " investigator~~ **investigate TOUR006** ~~bias " where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Given that each of our planned and ongoing clinical trials include an open- label dosing design~~ . **TOUR006 is not approved** ~~while we believe our trials utilize objective assessment measures for measuring our primary endpoints and therefore are unlikely to be influenced in any manner~~ by ~~patient or investigator bias, our trials may utilize secondary endpoint patient reported outcome measures and, it is unknown whether the open- label design may not be predictive of future clinical trial results with this or other product candidates for which we conduct an open- label clinical trial when studied in a controlled environment or with only objective endpoints. In addition, clinical data obtained from a clinical trial with an allogeneic product candidate such as FCR001 may not yield the same or better results on certain relevant outcome measures as compared to an autologous product candidate. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, which risk may be heightened in open- label trials where outcomes are subject to patient and investigator bias, and many companies that believed their product candidates performed satisfactorily in such trials nonetheless failed to obtain FDA, EMA or other necessary regulatory agency approval. Even if we believe that we have adequate data to support an application for regulatory approval to market any of our product candidates, no therapies for inducing immune tolerance to a transplanted organ or restoring tolerance to self in an autoimmune disease have been approved to date, and~~ the FDA or other regulatory authorities ~~may~~ **, TOUR006 is** not ~~agree with~~ **reimbursed by payors** ~~our~~ **or** ~~interpretation and may require that we conduct additional clinical trials to support the~~ **other** ~~regulatory approval of~~ **similar bodies,** ~~our~~ **or** ~~product candidates~~ **there is limited or no success achieved in the commercialization of TOUR006** . ~~If we fail to obtain~~ **Preliminary, initial, or interim** results ~~in our planned and future preclinical and clinical activities and studies sufficient to meet the requirements of the relevant regulatory agencies, the development timeline and regulatory approval and commercialization prospects for any potential product candidate, and, correspondingly, our business and financial prospects, would be materially adversely affected. Interim, " top line " or preliminary data~~ from ~~our~~ clinical trials that we ~~may~~ announce **, present,** or **publish** ~~share with regulatory authorities~~ from time to time may **change as more data and information become available (or are updated based upon audit, validation and verification procedures of the data / information commonly performed for clinical trials) that could result in material changes in the final trial results. From time to time, we may announce, present or publish preliminary, initial, or interim data or other information from our clinical trials. Any such data and other results from our clinical trials may materially** change as more patient data **and information** become available **. Such data** and ~~are subject to~~ **information may also undergo significant change following subsequent** ~~audit~~ **auditing , validation** and **/ or** verification procedures that ~~could result in material changes in the final data. From time to time, we expect to announce clinical updates or share~~ -- **are commonly conducted in** ~~with regulatory authorities interim " top line " or preliminary data from our~~ clinical trials **. Thus** , **any** ~~which is based on a~~ preliminary ~~analysis of then- available~~ **, initial, or interim** data **or other information** ~~. The outcome of preclinical development testing and early clinical trials~~ may not be predictive of **final** ~~the success of later clinical trials, and interim~~ results ~~of a~~ **from the** clinical trial ~~do not necessarily predict final results. In particular, additional data from existing or subsequent patients may not be comparable or positive with respect to efficacy, safety or target engagement. For example, in June 2022, we announced interim results from our FREEDOM- 1 Phase 3 clinical trial, including limited efficacy~~ and ~~safety data for the first seven patients dosed. Subsequently, in October 2022, we reported that one of the first seven patients, who had experienced GvHD symptoms that were treatment responsive and resolved in June 2022, had been hospitalized with grade IV GvHD that was complicated by serious infections leading to respiratory and renal failure, and ultimately death. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. These data and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of interim," top line" or preliminary data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top- line or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. 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. 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. Preliminary or " top line " 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 announced. As a result, interim, " top- line, " and preliminary data~~ should be viewed with caution until the final data are available. ~~Adverse~~ **We may also arrive at different conclusions, or other determinations that may qualify such results, once we have received and fully evaluated the additional data.** ~~differences~~ **Differences** between preliminary, **initial** ~~" top- line, "~~ or interim ~~data~~ **results** and final ~~data~~ **results** could **lead to** ~~impact the regulatory approval of, and~~ significantly **different interpretations** ~~harm the prospects for~~ - **or conclusions of** ~~any product candidate that is impacted by~~ the ~~applicable data~~ **trial outcomes** . Further, others, including regulatory ~~agencies~~ **authorities and collaboration or regional partners** , 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 **TOUR006** ~~the particular program~~ , the approvability or commercialization of ~~the particular~~ **TOUR006 or any future** product ~~candidate~~ **candidates ,** ~~or product~~ and **us** ~~our business~~ 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 product candidate or our business~~ . If the **preliminary** ~~clinical updates~~ , **initial** or ~~the~~ interim ~~," top- line, " or preliminary~~ data that ~~we~~ **our** ~~report~~ **reports** 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~~ , **TOUR006 may be harmed, which could significantly harm** our business, ~~operating results, prospects or~~ financial condition ~~may be harmed. Risks Related to Potential Side Effects and the Safety and Efficacy Profile of our Product Candidates Our product candidates~~ , **results of operations and prospects. TOUR006** ~~or associated conditioning regimens or treatment protocols,~~ may cause undesirable side effects or **adverse events or** have other properties **or safety risks, which could terminate further development of this product candidate, result in a lack of product approval by the FDA or other regulatory authorities, delay the timing (and / or increase the cost) of a product approval by the FDA or other regulatory authorities, lead to a restrictive product label** that **significantly** ~~could delay or prevent their regulatory approval, limit~~ **limits prescribing** ~~the commercial profile~~ of an approved ~~label~~ **product, delay** or ~~result in~~ **preclude reimbursement by payors, or significantly limit or preclude the commercialization of TOUR006. A concerning safety signal (such as that involving serious adverse events, life- threatening adverse events, or deaths, or a nonserious adverse event that may occur at a high or concerning frequency and / or severity or if rare, leads to a** significant ~~negative consequences following any regulatory approval~~ **safety concern), tolerability concern (e . g.,** ~~Undesirable~~ **undesirable** side effects **that cannot be tolerated by patients, require suboptimal dosing alterations require additional monitoring and / or lead to patients missing or delaying doses) or other safety issue** caused ~~or risks exacerbated~~ by **TOUR006 may be observed in any future** ~~our~~ **or ongoing clinical trial of TOUR006. For example, dosing in the 200 mg arm of the prior Pfizer Phase 2 trial of TOUR006 in systemic lupus erythematosus was stopped for safety concerns based on an unblinded data review and recommendation from the internal review committee for that study. Prior safety (clinical and nonclinical) data for TOUR006, safety data and observations for other molecules in the anti- IL- 6 and anti- IL- 6R classes, and published safety data and observations for other molecules in the anti- IL- 6 and anti- IL- 6R classes used in the same disease or indication as that being investigated in TOUR006 clinical trial (s) may not be indicative of similar safety and tolerability results or profile for TOUR006 in future or ongoing clinical trials. For example, some potential therapeutics developed in the biopharmaceutical industry that initially showed therapeutic promise in early- stage trials have later been found to have a problematic safety or tolerability profile that prevented their further development. In addition, TOUR006 is a recombinant protein. Recombinant proteins can sometimes induce host immune responses that can cause the production of anti- drug antibodies (" ADAs "). ADAs may neutralize the effectiveness of the product candidate, can require that higher doses be used to obtain a therapeutic effect or can cross react with substances naturally occurring in a subject' s body, which can cause unintended effects, including potential impacts on efficacy and adverse events. For example, the ADAs may prevent the drug from offering a therapeutic benefit or lead to a less efficacious effect. ADAs may also cause hypersensitivity reactions (including anaphylaxis) that may require patients to stop taking that drug or can, in some cases, be serious, life- threatening, or fatal. If we determine that ADAs are causing safety or efficacy concerns for TOUR006, we may need to delay, halt, or terminate our clinical trials and the affected** product candidates **. TOUR006 may never obtain** ~~or associated conditioning regimens or treatment protocols 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~~ regulatory ~~authority~~ **authorities** . ~~As~~ **We cannot provide assurance that the detection of ADAs will not occur at** a **higher rate than what we have observed historically or that ADA will not lead to meaningful impacts upon efficacy or safety, or that the detection of ADAs will not otherwise** result ~~of~~ **in TOUR006 not being approved by the FDA or other regulatory authorities. If a** safety **signal, tolerability concern, ADA concern,** or ~~toxicity~~ **other safety** ~~issues~~ **issue** ~~that we may experience~~ **emerges from any future or ongoing clinical trial for TOUR006, or any other IL- 6 inhibitor product candidate, this could result in: • slowing of patient enrollment** in our clinical trials **or inability** ~~, we may not receive approval~~ to ~~market any product candidates,~~ **enroll the trials; • a meaningful rate of patients dropping out of trials (** which could ~~prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and incidence of side effects, or side effects outweighing the benefits of our product candidates. Such side effects could include known side effects or safety risks that are exacerbated by the combination of HSCT and LDKT in our clinical trials. In such an event, our trials could be delayed, suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Additionally, during the course of our product development programs, FDA or comparable foreign regulatory authority review teams may change and new agency personnel may view the risk- benefit profile of any product candidates we may develop differently than prior agency review teams. Any negative views as to the risk- benefit profile of FCR001 or any product candidates we may develop in the future could~~ lead ~~FDA or comparable foreign regulatory authorities~~ to **a delay in completing the** ~~require that we conduct additional clinical trials or could require more onerous~~ clinical trial ~~designs for~~ - **or** ~~any ongoing or future clinical trials. The drug- related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, while we note the summary of safety findings we have gathered to date, certain populations of patients receiving our Facilitated Allo- HSCT Therapy may experience side effects in greater frequency or severity than others who may receive our product candidates and additional clinical research is planned to more fully understand the safety profile of our product candidates in our patient populations and indications of focus. Furthermore, we or others may later identify undesirable side effects caused by our products, including during any long- term follow- up observation period, such as that involved in our previous trials of FCR001. In particular, LDKT and HSCT involve certain known potential post- procedure complications that may manifest several weeks or months after a transplant and which may be more common in certain patient populations. For example, up to 20 % of patients with inherited metabolic diseases treated with HSCT experience primary engraftment failure, resulting in severe complications,~~

~~including death. GvHD also accounts for approximately 10 % of deaths following allogeneic HSCT. In June 2022, we reported three cases of low- grade acute GvHD in our FREEDOM- 1 clinical trial, all of which had responded to treatment and were resolved. One of the three aGvHD patients was subsequently diagnosed with moderate chronic GvHD and was also responding to treatment at the time of the June 2022 update. In October 2022, we reported that the patient who had been diagnosed with chronic GvHD had died. The patient had been hospitalized with grade IV GvHD that was complicated by serious infections leading to respiratory and renal failure, and ultimately death. This event triggered a pre- specified, temporary stopping requirement and review by the FREEDOM- 1 DMC. After their review of this case, the DMC determined that trial enrollment and dosing could continue. We also reported the event and the DMC' s recommendation to the FDA. If these or other serious adverse~~ **adversely impact** ~~events, undesirable side effects, or unexpected characteristics are identified during the development of any of our product candidates, it may be difficult to determine whether these~~ -- **the** ~~complications were or were not related to our investigational therapy, and we may need to limit, delay or abandon our further clinical development of those product candidates, even if such events, effects or characteristics were potentially the result of HSCT, LDKT or related procedures generally, and not directly or specifically caused or exacerbated by our product candidates. All serious adverse events or unexpected side effects are continually monitored per the clinical~~ trial' s ~~approved protocol. If serious adverse events are determined to be directly or specifically caused or exacerbated by~~ **probability of success in observing a positive efficacy result); • a meaningful rate of patients missing** ~~our~~ - **or postponing** ~~product candidates, we would follow the~~ **their** trial ~~protocol' s requirements~~ **procedures (including but not limited to dosing** , **study visits and efficacy assessments)** which **in turn could lead** ~~include certain pre- specified stopping requirements, and which call for our DSMB~~ to ~~review all available~~ **a delay in completing the** clinical **trial or adversely impact** ~~data in making a recommendation regarding~~ the trial' s **probability of success in observing** ~~continuation. However, there may be~~ a ~~failure by trial sites~~ **positive efficacy result; • an inability** to ~~effectively execute~~ **use a dose that offers efficacy** ~~our~~ - **or necessitating the use of a lower dose that may offer only low or partial efficacy; • suspension of the** clinical trial ~~protocols~~ **by us** , ~~including during any long- term follow- up period~~ **the FDA or other regulatory authority, or local IRB or ethics committee; • termination of the clinical trial; • need** for **additional and /** ~~our~~ - **or larger** clinical ~~trials~~ -- **trial** ~~during~~ **(s) to further evaluate** the ~~conduct~~ **safety profile** of ~~future~~ **TOUR006; • abandonment of the development of TOUR006 for that particular indication being evaluated by the** clinical ~~trials~~ -- **trial or** ~~or~~ **for** ~~following any~~ **other indications or as a program altogether; • refusal by the FDA or other regulatory authority to grant** product approval **; • restrictions** ~~we may receive. In addition, HSCT is associated with an increased risk of cancer. Among the likely causes of this increased risk is the total body irradiation and high- dose chemotherapy used in myeloablative conditioning regimens. We believe non~~ - **on** ~~- myeloablative conditioning regimens have~~ the ~~potential to help obviate this increased risk, however, patients receiving Facilitated Allo- HSCT Therapy in clinical trials after non- myeloablative conditioning have developed cancer after transplant. For example, a patient, a lifelong smoker, in our Phase 2 clinical trial developed non- small cell carcinoma of the lung approximately four years after HSCT. Additionally, if any of our~~ product **labeling (** ~~candidates receives regulatory approval, and we or others later identify undesirable side effects caused or risks exacerbated by~~ such **as** ~~product,~~ a ~~number~~ **black boxed warning, warnings and precautions, limitations** of ~~potentially~~ **use, and / or narrowed and limited indication) that may** ~~significant~~ **significantly limit** ~~negative consequences could result. For example,~~ the ~~FDA could~~ **prescribing and usage of TOUR006; •** ~~require~~ **requirement** ~~us~~ to ~~adopt~~ **develop** a Risk Evaluation and Mitigation Strategy (" REMS ") ~~to ensure~~ **for TOUR006 in the U. S. or a similar strategy as required by a comparable foreign regulatory authority; • a view by healthcare professionals** that ~~the~~ **TOUR006 presents an unfavorable** ~~benefits~~ - **benefit- risk profile which in turn may significantly limit the prescribing and usage** of **TOUR006; • a meaningful rate of patients either choosing to not start TOUR006** treatment ~~with such product candidate outweigh~~ **or to prematurely discontinue usage of TOUR006; • use of additional monitoring by healthcare professionals, either on** ~~the~~ **their own or due to the recommendations of expert panels or treatment guidelines, in the use of TOUR006 that in turn may significantly limit the prescribing and usage of TOUR006; • a view by payors that TOUR006 presents an unfavorable benefit-** ~~risks~~ - **risk profile** ~~for each potential patient,~~ which ~~may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or engage~~ in **turn may** ~~similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone or with collaborators. Other potentially significant~~ **significantly limit** ~~negative consequences include that: we may be forced to suspend marketing of that product, or decide to remove~~ the **reimbursement of TOUR006** ~~product form the marketplace~~ ; **• a** ~~regulatory authorities may withdraw or change their approvals of that product; regulatory authorities may require~~ **requirement to conduct** additional ~~warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment; we may be required to create a medication guide outlining the risks of the product for patients, or to conduct~~ post- ~~marketing~~ --- **market** studies **, including clinical trials** ; **• lawsuit (s) that results in us being** ~~we may be required to change the way the product is administered; we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or to sued and~~ held liable for harm caused to ~~subjects~~ **trial participants** or **other** patients; and ~~/~~ **/ or • reputational injury to us. Any of** ~~the~~ **these occurrences could materially and adversely affect our business, financial condition, results of operations and prospects. TOUR006 is a** product **candidate within** ~~may become less competitive, and our reputation may suffer. Any of these~~ -- **the** ~~events~~ **IL- 6 inhibitor and IL- 6R inhibitor class and may be adversely impacted by results for other members in the class, which** could ~~diminish~~ **delay, terminate or increase the cost of development of TOUR006, delay or prevent approval by the FDA or** ~~the~~ **other** ~~usage~~ **regulatory authorities, lead to a restrictive product label that significantly limits prescribing, delay** or ~~otherwise~~ **preclude reimbursement by payors, or significantly** limit ~~the commercial success of our~~ - **or preclude the**

commercialization of TOUR006. TOUR006 is a member of the IL- 6 inhibitor and IL- 6R inhibitor class. There are other products and product candidates **within this class that are being developed or commercialized by third parties over which we have no control** and ~~prevent us~~ **for which we do not have any information beyond what is publicly available. It is possible that negative data or information may emerge** from ~~achieving~~ **one** or ~~maintaining~~ **more of these other products or product candidates related to a limitation or failure of efficacy, safety concern, negative publicity or other issue. Such an occurrence may adversely impact TOUR006 or its perceived product profile and could terminate further development of TOUR006, result in a lack of product approval by the FDA or other regulatory authorities, delay the timing (and / or increase the cost) of a product approval, lead to a restrictive product label that significantly limits prescribing, delay or preclude reimbursement by payors, or significantly limit or preclude the commercialization of TOUR006. We face significant competition from other biotechnology and pharmaceutical companies targeting autoimmune and cardiovascular disease indications. Our operating results will suffer if we fail to compete effectively. The** ~~market~~ **markets** ~~acceptance~~ **for autoimmune disease therapies are competitive and are characterized by significant technological development and new product introduction. For example, there are several large and small pharmaceutical companies focused on delivering therapeutics for TED or ASCVD. We anticipate that, if we obtain regulatory approval of TOUR006, we will face significant competition from other approved therapies or drugs that become available in the future for the treatment of our target indications. If approved, TOUR006 may also compete with unregulated, unapproved and** ~~of~~ **off** ~~the affected~~ **- label treatments. TOUR006 may also face biosimilar competition following loss of regulatory exclusivity and / or patent expiry. Even if an approved biosimilar product is less effective than TOUR006, a less effective biosimilar may be more quickly adopted by physicians and patients than our competing** product candidate **based upon cost. TOUR006 will have to compete with existing therapies, some of which are widely known and accepted by physicians and patients. To compete successfully in this market, we will have to demonstrate that the relative cost, safety and efficacy of our product** , if approved ~~by applicable~~ **, provides an attractive alternative to existing and other new therapies to gain a share of some patients' discretionary budgets and to gain physicians' attention within their clinical practices. Some of the companies that may offer competing products also have a broad range of other product offerings, large direct sales forces and long- term customer relationships with our target physicians, which could inhibit our market penetration efforts. Such competition could lead to reduced market share for our product candidate and contribute to downward pressure on the pricing of our product candidate, which could harm our business, financial condition, results of operations and prospects. We expect to face competition from agents with different mechanisms of action in both TED and ASCVD. For example, in January 2020, the FDA approved Amgen Inc.' s (formerly Horizon Therapeutics Public Limited Company) TEPEZZA (teprotumumab), an anti- IGF- 1R antibody, for the treatment of TED. In addition, there are multiple other agents in various stages of development for the treatment of TED, including Roche' s satralizumab, an anti- IL- 6R monoclonal antibody. The first line of treatment for patients with TED is generally immunosuppressive therapy, including high doses of corticosteroids. For ASCVD, several classes of therapies are routinely used, including statins, beta- blockers, ACE inhibitors, ARBs, aspirin, and other anti- platelet agents. Additionally, we are aware of two IL- 6 blockers currently being developed for the treatment of ASCVD. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining** regulatory ~~authorities~~ **approvals of those product candidates in the U** . ~~If~~ **S. and in foreign countries. Many of our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our competitors. Competition may reduce the number and types of patients available to us to participate in** clinical trials **because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one** of **our competitors. Due to varying regulatory requirements in certain foreign countries, there are many more products and procedures available for use to treat autoimmune diseases in some international markets than are approved for use in the U. S. In certain international markets, there are also fewer limitations on the claims that our competitors can make about the effectiveness of their products and the manner in which they can market their products. Our ability to compete successfully will depend largely on our ability to: • develop and commercialize therapies in our target indications that are competitive with other products in the market; • demonstrate through our clinical trials that TOUR006** ~~our~~ **or any potential future** product candidates ~~fail to demonstrate safety~~ **is differentiated from existing** and **future therapies; • attract and retain qualified scientific,** ~~efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce~~ **product** ~~positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the~~ development **, manufacturing** and ~~commercialization of such~~ **commercial personnel; • obtain patent or other proprietary protection for TOUR006 and any potential future** product candidates ~~. Before~~ **; •** ~~obtaining~~ **obtain required** regulatory ~~approval~~ **approvals , including approvals to market TOUR006** ~~for~~ **or any potential future** ~~the sale of our~~ product candidates ~~,~~ we ~~must conduct extensive clinical trials to demonstrate~~ **develop; • have commercial quantities of any approved product manufactured at acceptable cost and quality levels and in compliance with FDA and** ~~the~~ **other** ~~safety and efficacy of such~~ **regulatory requirements; • successfully commercialize TOUR006 or any potential future** product candidates ~~in humans. Clinical testing is expensive~~ , ~~difficult to design~~ **if approved; • obtain coverage** and ~~implement~~ **adequate reimbursement from** , ~~can take~~ **and negotiate competitive pricing with, third- party payors; and • avoid regulatory exclusivities or patents held by competitors that** ~~many~~ **may** ~~years~~ **inhibit our products' entry** to ~~complete and~~ the **market** ~~outcome is uncertain~~ . ~~Despite preclinical~~ **The availability of our competitors' products could limit the demand** and ~~early clinical trial data,~~ **the price we are able to charge for** any product candidate **we develop. The inability to compete**

with existing or subsequently introduced treatments would have ~~can~~ **an** ~~unexpectedly fail at~~ **adverse impact on our business, financial condition, results of operations and prospects. If the market opportunities for TOUR006 and** any ~~stage of further development. The historical failure rate for product candidates is high. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications. In particular, we have conducted a Phase 2 trial of FCR001 in LDKT. We do not know whether FCR001 will perform in our subsequent clinical trials, including in dSSc, as it has performed in our initial LDKT Phase 2 trial. In addition, if our clinical results are not successful, we may terminate clinical trials for a product candidate and abandon any further research or studies of the product candidate. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. Risks Related to Combination Therapies We intend to develop FCR001, and potentially~~ -- **potential** future product candidates ~~, in other indications and in combination with other therapies, which exposes us to additional risks. Combination therapies and additional indications involve additional complexity and risk that could delay or cause our programs to stall or fail; development of such programs may be more costly, may take longer to achieve regulatory approval and may be associated with unanticipated adverse events. We intend to develop FCR001, and may develop future product candidates, for use in combination with nonmyeloablative conditioning and related conditioning drugs. Clinical development and commercialization of combination therapies involve additional complexity and risk, including without limitation, those involving drug- drug interactions, dose selection, unanticipated adverse events, clinical design and approvals of regulatory bodies and therapeutic development networks of patient advocacy groups. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to bear the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. If we~~ are ~~unable to manage the additional complexities and risks of the development and commercialization of combination therapies, the development of FCR001 or any other current or future product candidate could be delayed, halted or otherwise fail to receive or maintain approval and may be less successful commercially. We may develop FCR001 or related product candidates for a number of different indications, including solid organ transplant, severe autoimmune diseases and other severe disorders for which allo- HSCT has previously been observed to provide potential clinical benefit. Depending on the indication, patients may manifest a variety of differing co- morbidities, may be more or less vulnerable to our conditioning regimen, and may be more or less susceptible to certain severe adverse events or complications in the near or longer term, including cancer, infection, blood disorders and other life- threatening conditions. If any of these conditions or complications were to affect a patient who is participating in one of our clinical trials, it may be difficult or impossible to determine whether these adverse events or complications are related to the original or underlying condition or to our Facilitated Allo- HSCT Therapy. Given that our trials enroll a relatively small number of patients, even a small number of severe adverse events or serious complications could result in the delay or halt of development of our product candidates in one or more of our targeted indications. Risks Related to Regulatory Matters and Approvals Our product candidates represent a novel therapeutic approach that could result in heightened regulatory scrutiny. The regulatory landscape that applies to our Facilitated Allo- HSCT Therapy is rigorous, complex, uncertain and subject to change. Given that our single- dose cell therapy represents a novel combination of nonmyeloablative conditioning, our investigational FCR001 product, and stem cell transplant- oriented treatment protocols, developing and commercializing our product candidates subjects us to a number of challenges, including obtaining regulatory approval from the FDA and other regulatory authorities, which have limited experience with regulating the development and commercialization of stem cell therapies. Regulatory requirements governing the development of cell therapy products have changed frequently and may continue to change in the future. In 2016, the FDA established the Office of Tissues and Advanced Therapies (" OTAT") within the Center for Biologics Evaluation and Research (" CBER"), to consolidate the review of cell therapy, and related products, and to advise the CBER on its review. In September 2022, the FDA announced retitling of OTAT to the Office of Therapeutic Products (" OTP") and elevation of OTP to a" Super Office" to meet its growing cell and gene therapy workload. Moreover, serious adverse events or developments in clinical trials of cell therapy product candidates conducted by others may cause the FDA or other regulatory bodies to initiate a clinical hold on our clinical trials or otherwise change the requirements for approval of any of our product candidates. Although the FDA decides whether individual cell therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation. Adverse developments in preclinical studies or clinical trials conducted by others in the field of cell therapy may cause the FDA, the EMA, and other regulatory bodies to amend the requirements for approval of any product candidates we may develop or limit the use of products utilizing cell therapies, either of which could harm our business. In addition, the clinical trial requirements of the FDA, the EMA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for product candidates such as ours can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates. Further, as we are developing novel potential treatments for conditions in which there is little clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, the EMA or other regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing cell therapies in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays, or other impediments to our research programs or the commercialization of resulting~~

products. Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA' s ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA' s ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for biologics or modifications to approved biologics to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In response to the COVID- 19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities while local, national and international conditions warrant. Since March 2020, when foreign and domestic inspections have largely been on hold, the FDA has been working to resume pre- pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre- approval inspections. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. Regulatory authorities outside the U. S. may adopt similar restrictions or other policy measures in response to the ongoing COVID- 19 pandemic and may experience delays in their regulatory activities. During the COVID- 19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications. We may not be able to maintain orphan drug designation for FCR001 or obtain orphan drug designation for our future product candidates, or to obtain and maintain the benefits associated with orphan drug designation. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs or therapies for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually in the United States. In the European Union, the prevalence of the condition must not be more than five in 10, 000. The FDA has granted FCR001 orphan drug designation for the prophylaxis of organ rejection without the need for chronic immunosuppression in patients receiving LDKT. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. If a product that has orphan drug designation from the FDA subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic for the same indication, for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan product exclusivity or if FDA finds that the holder of the orphan exclusivity has not shown that it can ensure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the product was designated. Even if we or our collaborators obtain orphan designation to a product candidate, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. The scope of exclusivity is limited to the scope of any approved indication, even if the scope of the orphan designation is broader than the approved indication. Additionally, exclusive marketing rights may be limited if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if a product obtains orphan drug exclusivity, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve a product with the same active moiety for the same condition if the FDA concludes that the later product is safer, more effective, or makes a major contribution to patient care. Furthermore, the FDA can waive orphan exclusivity if we or our collaborators are unable to manufacture sufficient supply of the product. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. Similarly, in Europe, a medicinal product may receive orphan designation under Article 3 of Regulation (EC) 141 / 2000. This applies to products that are intended for a life- threatening or chronically debilitating condition and either (1) such condition affects no more than five in 10, 000 persons in the E. U. when the application is made, or (2) the product, without the benefits derived from orphan status, would be unlikely to generate sufficient returns in the E. U. to justify the necessary investment. Moreover, in order to obtain orphan designation in the E. U. it is necessary to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the E. U. or, if such a method exists, the product will be of significant benefit to those affected by the condition. In the E. U., orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and applicants can benefit from specific regulatory assistance and scientific advice. Products receiving orphan designation in the E. U. can receive ten years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. An orphan product can also obtain an additional two years of market exclusivity in the E. U. for pediatric studies. However, the ten- year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets

~~the criteria for orphan designation- for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if: the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; the first applicant consents to a second orphan medicinal product application; or the first applicant cannot supply enough orphan medicinal product. If we do not receive or maintain orphan drug designation to product candidates for which we seek such designation, it could limit our ability to realize revenues from such product candidates. The incidence and prevalence of the target patient population for FCR001 are based on estimates and third- party sources. If the market opportunity for FCR001 or our other product candidates is~~ smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, **then** our revenue **potential** and ability to achieve profitability ~~might~~ **will** be ~~materially and~~ adversely affected. ~~Periodically, we make estimates regarding the incidence and prevalence of target patient populations based on various third- party sources and internally generated analysis. These~~ -- **The** ~~estimates may be inaccurate or based on imprecise data. For example, the~~ total addressable market opportunity for ~~FCR001 in~~ **TOUR006 and** any ~~given indication~~ **other potential future product candidates we may develop** will **ultimately** depend ~~on~~ **upon** , among other things, **the proportion of patients identified as sensitive to our treatments,** acceptance ~~of FCR001~~ by the medical community ~~and~~ , patient access, drug **and any related companion diagnostic** pricing and **their** reimbursement **. We intend to initially seek regulatory approval of TOUR006 as therapies for patients with TED and ASCVD** . The number of patients in ~~the addressable~~ **our targeted commercial** markets **and elsewhere** may turn out to be lower than expected, patients may not be otherwise amenable to treatment with ~~FCR001,~~ **our drugs** or new patients may become increasingly difficult to identify or gain access to, all of which **would adversely affect our results of operations and our business. In addition, we** may ~~significantly harm~~ **not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates, which may prove to be the wrong choice and may adversely affect** our business, financial condition, results of operations and prospects. We may **not successfully identify new** ~~never obtain FDA approval for any of our~~ product candidates ~~in~~ **to expand our development pipeline. The success of our business over the longer term depends upon our ability to identify and validate new potential therapeutics. Efforts to identify new product candidates require substantial technical, financial and human resources, and our methodology may not successfully identify medically relevant potential therapeutics to be developed as product candidates. Moreover, our research and business development efforts may identify molecules that initially show promise yet fail to yield product candidates for clinical development for multiple reasons. For example, potential product candidates may, on further study, be shown to have inadequate efficacy, harmful side effects, suboptimal drug profiles, suboptimal manufacturability or stability, or other characteristics suggesting that** ~~the~~ **they** ~~United States~~ **are unlikely to be commercially viable products. Our inability to successfully identify additional new product candidates to advance into clinical trials could have a material adverse effect on our business** , **financial condition, results of operations** and **prospects. Risks Related to the Marketing and Commercialization of Our Product Candidates** ~~even~~ **Even** if ~~we~~ **any of our current or future product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. If TOUR006 or any of our potential future product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. If our product candidates** do **not achieve an adequate level of acceptance** , we may ~~never~~ **not generate significant product revenues and we may not become profitable. The degree of market acceptance of our current or potential future candidates, if approved for commercial sale, will depend on a number of factors, including: • the efficacy, safety and potential advantages compared to alternative treatments, including pharmaceutical and nonpharmaceutical interventions; • the acceptance of our product candidates as front- line treatments for various indications; • the prevalence and severity of any side effects, in particular compared to alternative treatments; • limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities; • the size of the target patient population; • the willingness and ability of the target patient population to try new therapies and adhere or comply with taking such therapy as prescribed and of physicians to prescribe these therapies; • our ability to offer our products for sale at competitive prices; • our ability to protect our approved products from generic or biosimilar competition through the use of regulatory exclusivity or patents; • the convenience and ease of administration compared to alternative treatments; • the amount of clinical burden upon healthcare professionals or patients related to any additional monitoring or other measures needed in order for patients to initiate and / or continue receiving such products; • the strength of marketing, sales and distribution support; • publicity for our product candidates and competing products and treatments; • the availability of third- party payor coverage and adequate reimbursement; • the timing of any marketing approval in relation to other product approvals; • support from patient advocacy groups; and • any restrictions on the use of our products together with other medications. Even if we** obtain approval **to market TOUR006** ~~for~~ - **or other potential future** ~~or commercialize any of our~~ product candidates **, these products may become subject to unfavorable pricing regulations, reimbursement practices from third- party payors or healthcare reform initiatives** in ~~any other~~ -- **the** ~~jurisdiction~~ **U. S. and abroad** , which ~~would~~ **could** ~~limit~~ **harm** our ~~ability to realize their full~~ **business. The regulations that govern** ~~market~~ **marketing** ~~potential~~ **approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals** . In **many** ~~addition to regulations~~ ---- **regions** ~~in the United States~~ , **including** ~~to market and sell our product candidates in~~ the European Union **(" EU ")** , ~~many Asian~~ **Japan and Canada, the pricing of prescription drugs is controlled by the government and some** countries **require** ~~and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements, both from a clinical and manufacturing perspective. The~~ approval

~~procedure varies among countries and can involve additional testing and validation and additional administrative review periods. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all~~ of ~~the risks associated with obtaining FDA approval. Clinical trials accepted in one country may not be accepted by regulatory authorities in other~~ -- **the sale price of** ~~countries. In addition, many countries outside the United States require that~~ a **drug** ~~product be approved for reimbursement~~ before it can be **marketed. In many countries, the pricing review period begins after regulatory** ~~approved~~ **approval** for ~~sale~~ **the product is granted. Regulatory agencies** in **those countries could determine** that ~~country~~ **the pricing for our products should be based on prices of other commercially available drugs for the same disease, rather than allowing us to market our products at a premium as new drugs** . ~~A~~ **As a result, we might obtain marketing approval for a** product ~~candidate that has been approved for sale~~ in a particular country **, but then be subject to price regulations that delay or limit its commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. Adverse pricing limitations** may ~~not receive~~ **hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. Our commercial success also depends on coverage and adequate** reimbursement ~~approval in that country. We may not be able to obtain approvals from regulatory authorities or payor authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory or payor authorities in other countries or jurisdictions, and approval by one regulatory or payor authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any~~ of our product candidates by ~~regulatory or payor authorities in the European Union, Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized. Even if our product candidates receive regulatory approval, we will still face extensive ongoing regulatory requirements and continued regulatory review, which may result in significant additional expense, and our products may still face future development and regulatory difficulties. Even if we obtain regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-marketing information. These requirements include submissions of safety and other post- marketing information and reports, establishment registration and product listing, as well as continued compliance by us and / or any future contract manufacturing organizations (" CMOs ") and CROs for any post- approval clinical trials that we conduct. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a REMS, impose significant restrictions on a product' s indicated uses or marketing or impose ongoing requirements for potentially costly post- approval studies or post- market surveillance. In addition, manufacturers of cell therapies and their facilities are subject to initial and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices (" cGMP "), Good Clinical Practices (" GCP "), current good tissue practices (" cGTP "), and other regulations. For certain commercial prescription and biologic products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. If we or a regulatory agency discover 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, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may: issue warning letters or untitled letters; mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners, or require other restrictions on the labeling or marketing of such products; require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance; seek an injunction or impose civil or criminal penalties or monetary fines; suspend, withdraw or modify regulatory approval; suspend or modify any ongoing clinical trials; refuse to approve pending applications or supplements to applications filed by us; suspend or impose restrictions on operations, including costly new manufacturing requirements; or seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall. The occurrence of any event or penalty described above may inhibit our ability to successfully commercialize our products. Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U. S. Federal Trade Commission, the Department of Justice (" DOJ "), the Office of Inspector General (" OIG ") of the U. S. Department of Health and Human Services (" HHS "), state attorneys general, members of the U. S. Congress and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our products for unapproved or off- label uses, are subject to enforcement letters, inquiries and~~

~~investigations, and civil and criminal sanctions by the FDA or comparable foreign bodies. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions, or civil or criminal penalties. The FDA and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any current or future product candidate. 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 to 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. Non- compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties. Risks Related to Healthcare Legislation and Reform Our relationships with customers,~~ third- party payors, ~~physicians and~~ **including government payors, private** ~~healthcare~~ **health** ~~providers~~ **insurers, health maintenance organizations and other organizations, which may be difficult or time- consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. In the U. S. and markets in other countries, governments and private insurers closely examine medical products to determine whether they should be covered by reimbursement and, if so, the level of reimbursement that** will **apply** ~~be subject to applicable anti- kickback, fraud and abuse, and other laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits. Healthcare providers, physicians and third- party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Physicians, hospitals and third- party payors are often slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Additionally, third- party payors may not cover, or provide adequate reimbursement for, long- term follow- up evaluations required following the use of our products. Patients are unlikely to use our product candidates unless insurance coverage is provided, and reimbursement is adequate, to cover a significant portion of the cost of our product candidates because patients generally rely on third- party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities~~ . In the ~~United States~~ **U. S.** , the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services (" CMS "), an agency within the U. S. Department of Health and Human Services (" HHS "). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. ~~Factors~~ **Government authorities and other third- party** payors ~~consider in determining~~ **have attempted to control costs by limiting coverage and the amount of** reimbursement **for particular drugs. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drug products. We cannot be sure that coverage and reimbursement will be available for any product that we or our partners commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we or our partners obtain regulatory approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we and our partners may not be able to successfully commercialize any product candidate for which marketing approval is obtained. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign health authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including costs of research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U. S. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Our inability to promptly obtain coverage and profitable reimbursement rates from both government- funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, ability to raise capital needed to commercialize products and overall financial condition. Even if we are able to obtain regulatory approval for TOUR006 or any of our future product candidates, we may receive an undesirable label, including, but not limited to, a black boxed warning, which could impede our ability to successfully commercialize TOUR006 or any of our future product candidates or compete successfully. Even if we receive regulatory approval for any of our product candidates, the FDA may determine that labels for our product candidates may require safety restrictions such as a black boxed warning, warnings and precautions, limitations of use, and / or narrowed and limited indication that may significantly limit the prescribing and usage of TOUR006. Safety restrictions such as a black boxed warning may impede our ability to successfully market and commercialize our product candidates and our ability to compete successfully against our competitors. Two approved therapies in the IL- 6 class, tocilizumab (Actemra ®) and**

sarilumab (Kevzara ®) have received black boxed warning for risks of serious infections. Two approved therapies in the IL- 6 class, satralizumab (Enspryng ®) and siltuximab (Sylvant ®) have not. We cannot guarantee or ensure that TOUR006 will not get a black boxed warning or significant safety restrictions on its product labels, if approved. Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all. Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on **assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties. Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, the ability to gain market share and** whether **we own** the **commercial rights for that territory. If the number of our addressable patients is not as significant as our estimates, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. We face an inherent risk of** product ~~FDA or a comparable foreign health authority for many reasons,including:• disagreement with the design or implementation of our clinical trials;• failure to demonstrate that a product~~ candidate **,** is safe and effective **,or has a positive benefit / risk profile** for its proposed ~~indication~~ **indications** ; ~~•~~ failure ~~of results~~ of clinical trials to meet the level of statistical significance required for approval; ~~• failure to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks;•~~ disagreement with our interpretation of data from preclinical studies or clinical trials; ~~•~~ the insufficiency of data collected from clinical trials **of our product candidates** to support the submission and filing of a Biologics License Application (~~" "~~ BLA ~~" "~~) or other submission or to obtain regulatory approval; ~~•~~ failure to obtain approval of ~~the~~ **our** manufacturing processes **,our own manufacturing facility,** or facilities of third- party manufacturers with whom we **may in the future** contract for clinical and commercial supplies; ~~• unfavorable quality review~~ or ~~audit / inspection findings;or •~~ changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval. **This lengthy approval process,as well as the unpredictability of future clinical trial results,may result in our failing to obtain regulatory approval to market our product candidates,which would significantly harm our business,results of operations and prospects.** The FDA or a comparable foreign ~~health~~ **regulatory** authority may require more information,including additional preclinical or clinical data ~~,~~to support approval,which may delay or prevent approval and **our** commercialization **plans** ,or we may decide to abandon the development program ~~for other reasons~~ .If we **were to** obtain approval,regulatory authorities may approve ~~TOUR006 or~~ any ~~potential future~~ **of our** product candidates for fewer or more limited indications than we request **(including failing to approve the most commercially promising indications)** ,may grant ~~accelerated~~ approval ~~or conditional marketing authorization based on a surrogate endpoint and~~ contingent ~~on the successful~~ is (i) **for** a **rare disease or condition and** ~~covered benefit under the payor' s health plan;~~ (ii) **is approved for indication** ~~safe, effective and medically necessary;~~ (~~iii~~ **s**) ~~appropriate~~ for **such rare disease or condition. By limiting price negotiation exemption to products with only one orphan drug designation, the IRA may decrease our interest in pursuing orphan drug designation for our product candidates in multiple indications. The IRA also, among** ~~the~~ **other** ~~specific~~ **things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025 and 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. These provisions 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 the Medicare drug pricing negotiation program is currently subject to legal challenges. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the ACA, was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. There have been executive, judicial and congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive legislation repealing the ACA, such legislation may be reintroduced. Members of Congress have introduced legislation to modify or replace certain provisions of the ACA. It is unclear how these efforts to repeal and / or replace the ACA will impact the ACA and our business. For example, the Tax Cuts and Jobs Act (the " 2017 Tax Act "), repealed the tax- based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage that is commonly referred to as the " individual mandate. " 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. Prior to the U. S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA and IRA may be subject to judicial or Congressional challenges in the future. It is unclear how any additional healthcare reform measures may impact the ACA or IRA,**

increase the pressure on drug pricing or limit the availability of coverage and adequate reimbursement for TOUR006 and any potential future product candidates, which would adversely affect our business. There has also been increasing executive, legislative and enforcement interest in the U. S. with respect to drug pricing practices. There have been U. S. congressional inquiries, presidential executive orders and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient ~~;~~**programs and reform government program reimbursement methodologies for drugs. For example, in an executive order, the administration of President Biden expressed its intent to pursue certain policy initiatives to reduce drug prices and, in response, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to lower drug prices. Further, in response to the Biden administration' s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS, Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve the quality of care. It is unclear whether the models will be 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. We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any approved product and could seriously harm its future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenue from TOUR006 and any potential future product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. In many countries outside the U. S., government- sponsored healthcare systems are the primary payors for drugs. With increasing budgetary constraints and / or difficulty in understanding the value of medicines, governments and payors in many countries are applying a variety of measures to exert downward price pressure and we expect that legislators, policy makers and healthcare insurance funds in the EU Member States will continue to propose and implement cost cutting measures. These measures include mandatory price controls, price referencing, therapeutic- reference pricing, increases in mandates, incentives for generic substitution and biosimilar usage, government- mandated price cuts, limitations on coverage of target population and introduction of volume caps. Many countries implement health technology assessment (** ~~iv~~ **" HTA ") , procedures that use formal economic metrics such as** cost- **effectiveness to determine prices, coverage and reimbursement of new therapies. These assessments are increasingly implemented in established and emerging markets. In the EU, Regulation (EU) 2021 / 2282 on Health Technology Assessment, which will become** effective ~~;~~**on January 12, 2025, will allow EU member states to use common HTA tools, methodologies** and ~~(v) neither experimental~~ **procedures to conduct joint clinical assessments and joint scientific consultations whereby HTA authorities may provide advice to health technology developers. Each EU member state will, however, remain exclusively competent for assessing the relative effectiveness of health technologies and making pricing and reimbursement decisions. Given that the extent to which pricing and reimbursement decisions are influenced by the HTA process currently varies between EU member states, it is possible that our products may be subject to favorable pricing and reimbursement status only in certain EU countries. If we are unable to maintain favorable pricing and reimbursement status in EU member states that represent significant markets, including following periodic review, our anticipated revenue from and growth prospects for our products in the EU could be negatively affected. Moreover, in order to obtain reimbursement for our products in some EU member states, we may be required to compile additional data comparing the cost- effectiveness of our products to other available therapies. Efforts to generate additional data for the HTA process will involve additional expenses which may substantially increase the cost of commercializing and marketing our products in certain EU member states. We cannot predict the likelihood, nature** ~~nor~~ **or** ~~investigational~~ **extent of healthcare reform initiatives that may arise from future legislation or administrative action** . ~~Because~~ **However, it is possible that countries will continue taking aggressive actions to seek to reduce expenditures on drugs. Similarly, fiscal constraints may also affect the extent to which countries are willing to approve new and innovative therapies and / or allow access to new technologies. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance,** our product candidates **may lose any regulatory approval that may** have **been obtained** ~~a higher cost of goods than conventional therapies,~~ and **we** may ~~require long~~ **not achieve or sustain profitability. Our relationships with healthcare providers, customers and third** ~~term follow~~ **party payors will be subject to applicable anti** ~~up evaluations~~ **kickback , fraud and abuse, transparency, and** ~~the~~ **other healthcare laws** ~~risk that coverage~~ and ~~reimbursement rates may be inadequate~~ **regulations, which, if violated, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings. Healthcare providers, including physicians, and third- party payors, will play a**

primary role in the recommendation and prescription of any product candidates for **which we or** ~~us to achieve profitability may be greater. Based on these and other factors, hospitals, physicians and payors may decide that the benefits of this new therapy do not or~~ **our partner obtains marketing approval** ~~will not outweigh its costs~~. Our ~~current~~ **existing** and future arrangements **with healthcare providers, and any arrangements we enter into** with third- party payors and customers **,** may expose us to broadly applicable ~~federal and varied state~~ fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we ~~conduct~~ **currently** research ~~as well as~~ **, and in the future,** market, sell and distribute ~~our~~ products ~~. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or~~ **for which we or** ~~bill directly to Medicare, Medicaid or~~ **our** ~~other third- party payors,~~ **partner obtain marketing approval. Restrictions under** federal and state healthcare laws and regulations **that** ~~pertaining to fraud and abuse and patients' rights~~ are **or may** ~~, and will~~ be ~~,~~ applicable to **us,** ~~our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate~~ include ~~, but are not limited to,~~ the following: ~~•~~ the federal ~~healthcare~~ Anti- Kickback Statute ~~, which~~ prohibits **persons from** , among other things, ~~persons and entities from~~ knowingly and willfully soliciting, offering, receiving ~~, paying~~ or providing remuneration, directly or indirectly, ~~overtly or covertly,~~ in cash or in kind, to induce or reward, or in return for, ~~either~~ the referral of an individual for **the furnishing or arranging for the furnishing** , or the purchase, lease ~~,~~ **or** order, ~~arrangement, or arranging or for or recommendation --- recommending of purchase~~ , **lease or order, of** any good ~~, facility, item~~ or service ~~,~~ for which payment may be made ~~, in whole or in part,~~ under a federal healthcare program **,** such as ~~the~~ Medicare and Medicaid ~~programs~~. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal **FCA** ~~False Claims Act~~ or federal civil monetary penalties ~~. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers, among others, on the other~~ ; ~~federal~~ **• the FCA imposes criminal and** civil **penalties** ~~and criminal false claims laws~~ , including **through** ~~the False Claims Act, and the~~ civil ~~monetary penalties law~~ **whistleblower or qui tam actions** , **against** ~~which prohibit, among other things,~~ individuals or entities ~~from~~ **for** knowingly presenting, or causing to be presented, ~~false or fraudulent~~ **to the federal government,** claims for payment ~~to,~~ **that are false** or **fraudulent** ~~approval by, Medicare, Medicaid,~~ or ~~other federal healthcare programs, knowingly~~ making ~~, using or causing to be made or used~~ a false ~~record or~~ statement ~~material~~ to **avoid** ~~a false or fraudulent claim or obligation to pay or transmit money or property to the federal government~~ , **decrease** or ~~knowingly concealing --- conceal or knowingly and improperly avoiding or decreasing or concealing~~ an obligation to pay money to the federal government. Manufacturers can be held liable under the **FCA** ~~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. ~~In addition,~~ **The FCA also permits a private individual acting as a " whistleblower " to bring actions on behalf of** the **federal** government ~~may assert that a claim including items~~ **alleging violations of the FCA and to share in any monetary recovery; • HIPAA, imposes criminal liability** ~~or for services resulting~~ **knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing** from a ~~violation~~ **healthcare benefit program, willfully obstructing a criminal investigation** of **a healthcare offense or knowingly and willfully making false statements relating to healthcare matters. Similar to** the federal Anti- Kickback Statute ~~constitutes a false or fraudulent claim for purposes of the federal False Claims Act. The False Claims Act also permits a private individual acting as a " whistleblower " to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery; the federal beneficiary inducement statute, includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), 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 Health Insurance Portability and Accountability Act of 1996 (" HIPAA ") which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private) and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious, or fraudulent statements 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 the Health Information Technology for Economic and Clinical Health Act ~~of 2009~~ (" HITECH ") ~~and their respective implementing regulations~~ , **also** ~~including the Final Omnibus Rule published in January 2013, which impose~~ **imposes** ~~requirements~~ **obligations** on certain covered **entity** healthcare providers, health plans, and healthcare clearinghouses **, and** ~~as well as~~ their ~~respective~~ business associates ~~, independent contractors or agents of covered entities,~~ that perform **certain** services ~~for~~ **involving** ~~them~~ **the** ~~that involve the creation, maintenance, receipt,~~ use ~~,~~ or disclosure of ~~,~~ individually identifiable health information as well as their covered subcontractors ~~relating~~ **, including mandatory contractual terms, with respect** to **safeguarding** the privacy, security **, processing,** 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. In addition, there may be additional federal, state and non- U. S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the

same effect, thus complicating compliance efforts; ~~• the federal~~ **Sunshine** ~~transparency requirements under the Patient Protection and Affordable Care~~ Act, as amended ~~by the Health Care and Education Reconciliation Act (collectively, the " ACA "), including the provision commonly referred to as the Physician Payments Sunshine Act~~, and its implementing regulations, ~~which~~ requires 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 **HHS** ~~Centers for Medicare & Medicaid Services (" CMS ")~~ information related to **"** payments or other transfers of value **" made** to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), **other health care professionals (such as physician assistants and nurse practitioners)** and teaching hospitals, as well as **information regarding** ownership and investment interests held by physicians and their immediate family members ~~. As of January 1~~ **; and • analogous state and foreign laws and regulations** , ~~2022~~ **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 non- governmental third- party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with** ~~these~~ -- **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; state and local laws requiring the registration of pharmaceutical sales representatives; state and foreign laws that require drug manufacturers to** ~~reporting~~ --- **report information related** ~~obligations now extend~~ to ~~include~~ **payments and other** transfers of value ~~by manufacturers that are made~~ to ~~physician~~ **physicians** ~~assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists~~ and ~~certified nurse midwives~~ **other healthcare providers, marketing expenditures or pricing** ; ~~-~~federal ~~price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and / or discounts on approved products; Federal~~ consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and ~~analogous~~ state and foreign ~~law equivalents of each of the above federal laws, such as anti- kickback and false claims laws which may apply to items or services reimbursed by any third- party payor, including commercial insurers or patients; state~~ laws that ~~require pharmaceutical companies to comply with~~ **govern the privacy and security and** ~~the~~ **other** ~~industry' s voluntary~~ **processing of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating** compliance **efforts** ~~guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the licensure of sales representatives; 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 pricing information. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and / or the Pharmaceutical Research and Manufacturers of America' s Code on Interactions with Healthcare Professionals~~. Efforts to ensure that our ~~current and future~~ business arrangements with third parties ~~, and our business generally, continue to~~ comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices ~~do~~ **may** not comply with ~~any such laws and~~ **current or future statutes,** regulations ~~. If our~~ -- **or** ~~operations, including~~ **case law interpreting applicable fraud and abuse** ~~our~~ - **or** ~~arrangements with physicians and~~ other healthcare ~~providers,~~ **laws and regulations. If our operations** are found to be in violation of any ~~such~~ **of these** laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal **,** and administrative penalties, damages, fines, **disgorgement, additional regulatory oversight, litigation,** imprisonment ~~, reputational harm~~ , exclusion from government ~~–~~ funded healthcare programs, such as Medicare and Medicaid, ~~disgorgement, additional reporting requirements,~~ and ~~/ or~~ the curtailment or restructuring of our operations ~~, as well as additional reporting obligations oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws~~ . If any **of the** physicians or other healthcare providers or entities with whom we expect to do business ~~are~~ **is** found ~~to~~ not **to** be in compliance with applicable laws, ~~they~~ **that person or entity** may be subject to ~~similar~~ **criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Outside the U. S., interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti- bribery laws of EU member states, national sunshine rules, regulations, industry self- regulation codes of conduct, and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative** penalties **, fines, or imprisonment** . ~~Healthcare legislative measures aimed~~ **Changes in tax laws or regulations could adversely affect our business and financial condition. New tax laws, statutes, rules, regulations, or ordinances could be enacted** at ~~reducing healthcare costs~~ **any time. For instance, the IRA imposes, among other rules, a 15 % minimum tax on the book income of certain large corporations and a 1 % excise tax on certain corporate stock repurchases. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted differently, changed, repealed, or modified at any time. Any such enactment, interpretation, change, repeal, or modification could adversely affect us, possibly with retroactive effect. In particular, changes in corporate tax rates, the realization of our net deferred tax assets, the taxation of foreign earnings, and the deductibility of expenses under the 2017 Tax Act, as amended by the Coronavirus Aid, Relief, and Economic Security Act or any future tax reform legislation, could have a material impact on the value of our deferred tax assets, result in significant one- time charges, and increase our future tax expenses. As of December 31, 2023, we had U. S. federal net operating loss carryforwards of approximately $ 16. 7 million. Under current law, U. S. federal net operating loss carryforwards generated in taxable periods beginning after December 31, 2017,** may **be carried forward indefinitely, but the deductibility of such net operating loss carryforwards is limited to 80 % of taxable income. In addition, our U. S. federal net operating loss carryforwards and tax credits may be**

subject to limitations under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if we have undergone or undergo an " ownership change, " generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three- year period. We may have experienced such ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. Our net operating loss carryforwards and tax credits may also be impaired or restricted under state law. If we earn taxable income, such limitations could result in increased future income tax liability and our future cash flows could be adversely affected. We have recorded a valuation allowance related to our net operating loss carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets. Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations. Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the U. S. are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred frequently in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. Compliance with new accounting standards may also result in additional expenses. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. Risks Related to Our Business Operations, Employee Matters and Managing Growth Our internal control over financial reporting may not meet the standards required by Section 404 of the Sarbanes- Oxley Act, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes- Oxley Act, could have a material adverse effect on our business and **share price. Our management is required to establish and maintain an adequate internal control structure and procedures for financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. Any failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report our financial condition,** results of operations **or cash flows** . ~~In~~ **If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins our reporting on internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or** ~~the~~ **other** ~~United States~~ **regulatory authorities. Failure to remedy any material weakness 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. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that** there **is a reasonable possibility that a material misstatement of the annual or interim financial statements would not be prevented or detected on a timely basis. Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner commensurate with the financial reporting requirements of an SEC registrant. Prior to the completion of the Merger, we were a private company and therefore had not designed or maintained internal controls over financial reporting commensurate with the financial reporting requirements of an SEC registrant. Our management identified material weaknesses in our internal control over financial reporting primarily related to limited staffing levels within the finance and accounting departments that were not commensurate with our financial accounting and reporting requirements. We had to rely increasingly on outsourced service providers and specialists, without adequate resources to monitor such work and did not maintain appropriate segregation of duties. Based on this, we did not fully implement components of the COSO framework, resulting in material weaknesses either individually, or in the aggregate, in the control environment, risk assessment, control activities, information and communication, and monitoring components. There** have been **no historical financial statement adjustments resulting from the above material weaknesses. However, the material weaknesses described above could result in** a **future misstatement of one or more account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected. We are in the process of implementing measures designed to improve our internal control over financial reporting and remediate these material weaknesses. Such measures include, but are not limited to: hiring additional accounting personnel with expertise commensurate with our financial accounting and reporting requirements and that have the requisite experience to oversee outsourced service providers and specialists, upgrading our financial systems and implementing information technology general controls, establishing controls to identify, assess, and respond to the risks of material misstatement, and establishing controls to identify and account for certain non-routine, unusual or complex transactions in a timely fashion. While we are currently in the process of remediating the material weaknesses outlined above, we cannot assure you that these efforts will remediate the material weaknesses in a timely manner, or at all. We expect to expand our clinical development, manufacturing and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, including significant growth in the** number of ~~legislative~~ **our employees,** and **as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. As of March 15, 2024, we had 44 full- time employees, including 31 who are engaged in research and development activities, and no part- time employees. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical product**

development, business development, regulatory ~~changes~~ **affairs** and **, if TOUR006** ~~proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our~~ **or any potential future** product candidates **receives marketing** ~~, restrict or regulate post-~~ approval **, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our** ~~activities~~ **facilities** and **continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our choice to focus on multiple therapeutic areas may negatively** affect our ability to ~~profitably sell~~ **develop adequately the specialized capability and expertise necessary for operations. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. We must attract and retain highly skilled employees in order to succeed. If we are not able to retain our current management team or to continue to attract and retain qualified scientific, technical and business personnel, our business may suffer. To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. An important element of our strategy is to take advantage of the R & D and other expertise of our current management. The loss of** any **one of our executive officers, other senior members of the leadership team, or other key personnel could result in a significant loss in the knowledge and experience that we, as an organization, possess and could cause significant delays, or outright failure, in the development and further commercialization of TOUR006 and any potential future** product candidates **. There is intense competition** for **qualified personnel, including management, in the technical fields in** which we **operate and we may not be able to attract and retain qualified personnel necessary for the successful research, development and future commercialization, if any, of TOUR006 and any potential future product candidates. Our Executive Severance and Change in Control Plan with certain of our executive officers may require us to pay severance benefits to any of those persons who are terminated in connection with a change in control of us or otherwise, which could harm our financial condition or results. Certain of our executive officers are parties to our Executive Severance and Change in Control Plan that contains change in control and severance provisions providing for aggregate cash payments for (i) severance and other benefits and (ii) acceleration of vesting of stock options, in the event of a termination of employment in connection with a change in control of us. The accelerated vesting of options could result in dilution to our existing stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us. Our international operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the U. S. Our business is subject to risks associated with conducting business internationally. Some of our manufacturing and clinical trial sites are located outside of the U. S. Furthermore, if we or any future partner succeeds in developing TOUR006 or any of our potential future product candidates, we intend to market them in the EU and other jurisdictions in addition to the U. S. If approved, we or any future partner may hire sales representatives and conduct physician and patient association outreach activities outside of the U. S. Doing business internationally involves a number of challenges and risks, including but not limited to: • multiple, conflicting and changing laws and regulations, such as privacy and data protection regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses; • failure by us to** obtain **and maintain** regulatory ~~approval~~ **approvals** ~~. We expect~~ **for the use of our products in various countries; • rejection or qualification of foreign clinical trial data by the competent authorities of other countries; • delays or interruptions in the supply of clinical trial material resulting from any events affecting raw material or component supply or manufacturing capabilities abroad; • additional potentially relevant third- party patent rights; • complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property rights; • difficulties in staffing and managing foreign operations; • complexities associated with managing multiple payor reimbursement regimes, government payors or patient self- pay systems; • limits on our ability to penetrate international markets; • financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of inflation and local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations; • natural disasters, political, global geopolitical and economic instability, including geopolitical conflicts such as the ongoing war in Ukraine and hostilities in the Middle East, terrorism and political unrest, disease outbreaks, epidemics and pandemics; • export control and economic sanctions restrictions, which may restrict or prohibit altogether the sale or supply of certain of our product candidates to certain governments, persons, entities, countries and territories, including those** that ~~current~~ **are the target of comprehensive sanctions, unless there are license exceptions that apply or specific licenses are obtained; and • regulatory and compliance risks that relate to anti- corruption compliance and record- keeping that may fall within the purview of the U. S. Foreign Corrupt Practices Act, its accounting provisions or its anti- bribery provisions or provisions of anti-corruption or anti- bribery** laws **in other countries. Any of these factors could harm our ongoing international clinical operations and supply chain** , as well as **any future international expansion and operations and, consequently, our business, financial condition, prospects and results of operations. Disease outbreaks, epidemics and pandemics in regions where we may have clinical trial sites or** other ~~healthcare reform measures~~ **business operations could adversely affect our business, including by causing significant disruptions in our operations and / or in the operations of third- party manufacturers and CROs upon whom we rely. Disease outbreaks, epidemics and pandemics have negative impacts on**

our ability to initiate new clinical trial sites, to enroll new patients and to maintain existing patients who are participating in our clinical trials, which may include increased clinical trial costs, longer timelines and delay in our ability to obtain regulatory approvals of TOUR006 and any potential future product candidates, if at all. Disease outbreaks, epidemics and pandemics also could adversely impact clinical trial results for TOUR006 or other future potential product candidates, such as by diminishing or eliminating their efficacy or by producing a safety concern, either through direct biological effects or through confounding of the data collection and analysis. This adverse impact could terminate further development of TOUR006, result in a lack of product approval by the FDA or other regulatory authorities, delay the timing (and / or increase the cost) of a product approval by the FDA or other regulatory authorities, lead to a restrictive product label that **significantly limits prescribing of an approved product, delay or preclude reimbursement by payors, or significantly limit or preclude the commercialization of TOUR006. General supply chain issues** may be ~~adopted in~~ **exacerbated during disease outbreaks, epidemics and pandemics and may also impact** the **ability of our clinical trial sites to obtain basic medical supplies used in our trials in a timely fashion, if at all. If our CDMOs are required to obtain an alternative source of certain raw materials and components, for example, additional testing, validation activities and regulatory approvals may be required which can also have a negative impact on timelines. Any associated delays in the manufacturing and supply of drug substance and drug product for our clinical trials could adversely affect our ability to conduct ongoing and** future **clinical trials of TOUR006 on our anticipated development timelines. Likewise** , **the operations of our third- party manufacturers** may **be requisitioned, diverted or allocated by U. S. or foreign government orders. If any of our CDMOs or raw materials or components suppliers become subject to acts or orders of U. S. or foreign government entities to allocate or prioritize manufacturing capacity, raw materials or components to the manufacture or distribution of vaccines or medical supplies needed to test or treat patients in a disease outbreak, epidemic or pandemic, this could delay our clinical trials, perhaps substantially, which could materially and adversely affect our business. Unfavorable domestic or global economic conditions could adversely affect our business, financial condition, results of operations, or cash flows. Our results of operations could be adversely affected by general conditions in the domestic or global economy and in the domestic or global financial markets. Political developments impacting government spending and international trade, including current or potential government- imposed sanctions, potential government shutdowns and trade disputes and tariffs, may negatively impact markets and cause weaker macro-economic conditions. A severe or prolonged economic downturn could** result in **a variety of risks to our business, including, weakened demand for our current and future potential product candidates and our ability to raise** additional ~~reductions~~ **capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting** in ~~Medicare~~ **supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Our operations are vulnerable to interruption by fire, earthquake, power loss, telecommunications failure, terrorist activity** and other ~~healthcare funding~~ **events beyond our control** , ~~more rigorous coverage criteria~~ **which could harm our business. Our facilities may experience electrical blackouts as a result of a shortage of available electrical power. Future blackouts** , ~~new payment methodologies and~~ **which may be implemented by the local electricity provider** in **the face of high winds and dry conditions, could disrupt our operations. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major earthquake, fire, power loss, terrorist activity or other disasters and do not have a comprehensive recovery plan for such disasters. In** ~~additional~~ **addition** ~~downward pressure on the price~~ **, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business** that ~~we~~ **may occur** , ~~or~~ **and** any **losses or damages incurred by us could harm our business. We and the third parties with whom we contract use and generate materials that may expose us to material liability. Our clinical development activities require the use of hazardous materials, chemicals, and radioactive and biological materials. We contract with CDMOs,** ~~collaborators~~ **laboratories and other vendors that are subject to foreign** , **federal, state and local environmental and health and safety laws and regulations related to such hazardous materials and byproducts. We cannot completely eliminate the risks associated with the use, manufacture, handling, storage and disposal of hazardous materials and waste products, which could cause personal injuries or illnesses, accidental contamination of our raw materials, drug substance, and / or drug product, interruption of our development or manufacturing efforts, environmental damage resulting in costly cleanup, or liabilities under domestic or foreign laws and regulations. Also, we** may ~~receive~~ **incur significant costs to ensure our CDMOs, laboratories and other vendors comply with these current or future environmental and health and safety laws and regulations. In the event of an accident, an injured party may seek to hold us liable** for any ~~approved products~~ **damages that result** . ~~There have been~~ **Any liability could exceed the limits or fall outside the coverage of our applicable insurance** , and **we may not** ~~likely will continue to~~ be **able to maintain insurance on acceptable terms** , **if** ~~legislative and regulatory proposals~~ at **all. We currently carry no insurance specifically** ~~the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering~~ **covering environmental claims** ~~the cost of healthcare~~ . **We** ~~The implementation of cost containment measures or other healthcare reforms~~ may **be exposed** ~~prevent us from being able~~ to **litigation** ~~generate revenue~~ , ~~attain profitability~~ **including stockholder litigation** , **which** ~~or commercialize our product candidates. Such reforms~~ could have an adverse effect on ~~anticipated revenue~~ **our business and operations. We may be exposed to litigation** from **stockholders, suppliers and other third parties from time to time. Such litigation may have an adverse impact on our business and results of operations or may cause disruptions to our operations. In addition, in the past, stockholders have initiated class action lawsuits against biotechnology companies following periods of volatility in the market prices of these companies' common stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management' s attention and resources, which could have a material adverse effect on our**

business, financial condition and results of operations. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty and breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. Risks Related to Our Intellectual Property Our success depends in significant part upon our ability to obtain and maintain intellectual property protection for our products and technologies. Our success depends in significant part on our ability and the ability of our current or future licensors, licensees, partners and collaborators to establish and maintain adequate intellectual property rights covering the product candidates, products and technologies that we plan to develop. In addition to taking other steps designed to protect our intellectual property, we have applied for, and intend to continue applying for, patents with claims covering our technologies, processes and product candidates when and where we deem it appropriate to do so. However, the patent prosecution process is expensive and time- consuming, and we and our current or future licensors, licensees, partners or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current or future licensors, licensees, partners or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection for them. Pending and future patent applications filed by us or our current or future licensors', licensees', partners' or collaborators' may not result in patents being issued that protect our technology or product candidates, or products resulting therefrom, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. We have filed five provisional patent applications in the U. S. to obtain patent rights to our inventions, with claims directed to methods of use, combination therapy and other technologies relating to our product candidates. There can be no assurance that any of these patent applications will issue as patents or, for those applications that do mature into patents, whether the claims of the patents will exclude others from making, using or selling our product or product candidates, or products or product candidates that **are substantially similar to us for the same or similar uses. In countries where** we **have not and do not seek patent protection, third parties** may **be able to manufacture and sell products that are substantially similar or identical to our products or product candidates without our permission, and we may not be able to stop them from doing so. Similar to other biotechnology companies, our patent position is highly uncertain and involves complex legal and factual questions. In this regard, we cannot be certain that we or our current or future licensors, licensees, partners or collaborators were the first to make an invention, or the first inventors to file a patent application claiming an invention in our owned or licensed patents or pending patent applications. In addition, even if patents are issued, given the amount of time required for the development, testing and regulatory review of our product candidates, any patents protecting such candidates might expire before or shortly after the resulting products are commercialized. Moreover, the laws and regulations governing patents could change in unpredictable ways that could weaken the ability of us and our current or future licensors, licensees, partners or collaborators to obtain new patents or to enforce existing patents and patents we may obtain in the future. In any event, our patent rights and those of our current or future licensors, licensees, partners or collaborators may not effectively prevent others from commercializing competitive technologies and products. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology that we license from or license to third parties and may be reliant on our current or future licensors, licensees, partners or collaborators to perform these activities, which means that these patent applications may not be prosecuted or maintained, and these patents may not be enforced, in a manner consistent with the best interests of our business. If our current or future licensors, licensees, partners or collaborators fail to establish, maintain, protect or enforce such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current or future licensors, licensees, partners or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. In addition, the legal protection afforded to inventors and owners of intellectual property in countries outside of the U. S. may not be as broad or effective as that in the U. S. and we may be unable to acquire and enforce intellectual property rights outside the U. S. to the same extent as in the U. S., if at all. Accordingly, our efforts, and those of our licensors, licensees, partners and collaborators, to enforce intellectual property rights around the world may be inadequate to obtain a commercial advantage from the intellectual property that we own or license. We do not currently own or have a license to any issued patents that cover TOUR006, although this product candidate is disclosed and its use claimed in our pending U. S. non-provisional applications. The patent landscape surrounding TOUR006 is crowded, and there can be no assurance that we will be able to secure patent protection that would adequately cover the use of such product candidate, that we will obtain sufficiently broad claims to be able to prevent others from selling competing products for the same or similar uses, or that we will be able to protect and maintain any patent protection that we initially secure. Any changes we make to TOUR006 to cause it to have what we view as more advantageous properties may not be covered by its existing patent applications, and we may be required to file new patent applications and / or seek other forms of protection for any such altered product candidate. We are dependent on patents, know- how and technology, both our own and licensed from**

others. In particular, we are dependent on our license agreements with Pfizer and Lonza. Any termination, or reduction or narrowing, of these licenses could result in the loss of significant rights and could harm our ability to commercialize TOUR006 and any potential future product candidates. Disputes may also arise between us and our current licensor and future licensors regarding intellectual property subject to a license agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • whether and the extent to which our product candidates and technologies infringe intellectual property rights of the licensor that are not subject to the licensing agreement; • our right to sublicense patent rights and other rights to third parties under collaborative development relationships; • our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of TOUR006 and any potential future product candidates, and the activities that are deemed to satisfy those diligence obligations; • the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and • our payment obligations with respect to licensed intellectual property. Additionally, with regard to the Pfizer License Agreement, if we fail to cure a material breach, Pfizer has customary rights to terminate the Pfizer License Agreement. With regard to the Lonza License Agreement, Lonza has the right to terminate the Lonza License Agreement in the event of a change of control or if we contest the secret or substantial nature of the licensed know- how. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current or future licensing arrangements on acceptable terms, or if Pfizer or Lonza terminates their respective license agreement, we may be unable to successfully develop and **commercialize the** ~~for which we may obtain regulatory approval and may affect~~ **affected** ~~our overall financial condition and ability to develop~~ product candidates **and technologies** . **We** ~~For example, in March 2010, the Affordable Care~~ - **are** ~~Act (" ACA ")~~ **generally also subject to all of the same risks with respect to protection of intellectual property that we license,** ~~was~~ - **as** ~~enacted in~~ **it is for intellectual property that we own, which are described herein. If we, Pfizer, Lonza or any** ~~the~~ **other** ~~United States~~ **current or future licensors fail to adequately protect any licensed intellectual property, our ability to commercialize products could suffer. We may be unable to obtain intellectual property rights or technologies necessary to develop and commercialize TOUR006 or any potential future product candidates. Several third parties are actively researching and seeking and obtaining patent protection in the fields of TED and Cardiovascular Disease, and there are issued third- party patents and published third- party patent applications in these fields** . The ~~ACA includes measures~~ **patent landscape around our product candidate is complex, and we are aware of several third- party patents and patent applications containing claims directed to compositions- of- matter, methods of use and related subject matter, some of which pertain, at least in part, to subject matter** that ~~have significantly changed~~ **might be relevant to our product candidate. However** , **we may not be aware of all third- party intellectual property rights potentially relating to our product candidate** and **technologies, since patent applications** are **not published until eighteen months after** ~~expected to continue to significantly change, the~~ **their initial filing date** ~~way healthcare is financed by both governmental and private insurers~~ . ~~Among~~ **Therefore, we cannot know whether certain unpublished patent applications, if ultimately issued, may recover relevant uses of TOUR006 or** ~~the~~ **other** ~~provisions~~ **products** of **ours. Depending** ~~the ACA of greatest importance to the pharmaceutical industry are that the ACA: made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate~~ on **what patent claims ultimately issue** ~~average manufacturer price, or AMP, on most branded prescription drugs~~ and **how courts construe the issued patent claims** ~~adding a new rebate calculation for " line extensions " (i. e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products~~ , as well as ~~potentially impacting their~~ -- **the ultimate formulation and methods** ~~rebate liability by modifying the statutory definition~~ of ~~AMP; imposed~~ **use of our product candidate, we may need to obtain** a ~~requirement~~ **license to practice the technology claimed in such patents. There can be no assurance that such licenses will be available** on ~~manufacturers of branded drugs~~ **commercially reasonable terms, or at all. If we are unable** to ~~provide a 50 % point~~ **successfully obtain rights to required third** - ~~of~~ **party intellectual property rights or maintain the existing rights to third** - **party intellectual property rights we have** ~~sale discount (increased to 70 % pursuant to the Bipartisan Budget Act of 2018~~ , **we might be unable to develop and commercialize TOUR006 or any potential future product candidates, which could have a material adverse** ~~effective~~ --- **effect on our business** ~~as of January 1~~ , **financial** ~~2019) off the negotiated price of branded drugs dispensed to Medicare Part D beneficiaries in the coverage gap (i. e., " donut hole ") as a~~ condition ~~for a~~ **, results of operations and prospects. We could lose the ability to continue the development,** ~~manufacturer~~ - **manufacture** ~~' s outpatient drugs being covered under Medicare Part D; • extended a~~ **, and commercialization of TOUR006 or any potential future product candidates if we breach any license agreement with service providers and vendors related to those product candidates. Our commercial success depends upon our ability, and the ability of our current and future licensors, licensees, partners and collaborators, to develop,** ~~manufacturer~~ - **manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing** ~~' s Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; • expanded~~ the **proprietary rights of third parties. A third- party may hold intellectual property rights, including patent rights,** ~~entities eligible for discounts under the 340B Drug Discount Program; • established a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs~~ that are ~~inhaled, infused, instilled, implanted, or injected; • imposed an annual, nondeductible fee on any entity that manufactures or imports~~ **important** ~~certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs, and • established the Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for~~ - **or necessary to** ~~such research. The research conducted by~~ the **development of our product candidates and** ~~Patient- Centered Outcomes Research Institute may affect the market for certain pharmaceutical~~ products. ~~The ACA established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery~~

~~models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation through 2019. Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect that there will be additional challenges and amendments to the ACA in the future. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court' s decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business. In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted: • On August 2, 2011, the U. S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2 % per fiscal year, which remain in effect through 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID- 19 pandemic. Following the suspension, a 1 % payment reduction began April 1, 2022 and continued through June 30, 2022, and the 2 % payment reduction resumed on July 1, 2022. Due to the Statutory Pay-~~As **a ~~- You- Go Act of 2010, estimated budget deficit increases resulting~~ --- result ~~from the American Rescue Plan Act of 2021~~ , we are** ~~and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. • On January 2, 2013, the U. S. American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. • On April 13, 2017, CMS published~~ a **party** ~~final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. • On May 30, 2018, the Right~~ to ~~Try Act, was signed into law. The law, among other things, provides~~ a ~~federal framework for certain~~ **number of technology and** ~~patients~~ -- **patent licenses** ~~to access certain investigational new drug products that have completed a Phase 1 clinical trial and~~ that are **important to our business** ~~undergoing investigation for FDA approval. Under certain circumstances~~ , ~~eligible patients can seek treatment without enrolling in clinical trials~~ and ~~without obtaining FDA permission~~ **we expect to enter into additional licenses in the future. If we fail to comply with the obligations** under ~~the~~ **these** ~~FDA expanded access program~~ **agreements, including payment and diligence obligations, our licensors may have the right to terminate these agreements** . ~~There~~ **In the event of a termination of these agreements, we may not be able to develop, manufacture, market or sell any product that** is ~~no obligation~~ **covered by the intellectual property rights that are the subject of these agreements** ~~for~~ - **or** ~~a pharmaceutical manufacturer~~ to **engage in any** ~~make its drug products available to eligible patients as a result of the~~ **other** ~~Right~~ **activities necessary** to **our business that require** ~~Try Act. • On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans~~ the ~~option of using step therapy~~ **freedom- to- operate afforded by the agreements,** ~~for~~ - **or we may face** ~~Part B drugs beginning January 1, 2020. • On December 20, 2019, former President Trump signed into law the~~ **other penalties under the agreements** ~~Further Consolidated Appropriations Act (H~~ . **For example** ~~R. 1865)~~ , **in addition to the license agreements with Pfizer and Lonza described above we are party to license agreements with multiple vendors, under** which ~~repealed~~ **we license technology used to produce TOUR006. We are required to obtain prior consent from some of** ~~the~~ **these** ~~Cadillac tax,~~ **vendors to grant sub- licenses under** ~~the~~ **these agreements. Therefore** ~~health insurance provider tax~~ , ~~and the~~ **these vendors** ~~medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future. • On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100 % of a drug' s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms~~ may prevent us from **granting sub- licenses to third parties, which could affect our ability to use certain desired manufacturers in order to manufacture our current and future product candidates. In the event of a termination of any of our license agreements, our ability to manufacture or develop any product candidates covered by these agreements may be limited or halted unless we can develop or obtain the rights to technology necessary to produce these product candidates. Any of the foregoing could materially adversely affect the value of the product or product candidate** being **developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in having to negotiate new or amended agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs. We may become involved in lawsuits or other proceedings to protect or enforce our intellectual property rights, which could be expensive, time- consuming and unsuccessful, and have a material adverse effect on the success of our business. Third parties may infringe patents or misappropriate or otherwise violate intellectual property rights owned or controlled by us or our current or future licensors, licensees, partners or collaborators. In the future, it may be necessary to initiate legal proceedings to enforce or defend these intellectual property rights, to protect trade secrets or to determine the validity or scope of intellectual property rights that are owned or controlled by us or our current or future licensors, licensees, partners or collaborators. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. If we or our current or future licensors, licensees, partners or collaborators initiate legal proceedings against a third party to enforce a patent covering a product**

candidate, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the U. S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement during prosecution. In an infringement or declaratory judgment proceeding, a court may decide that a patent owned by or licensed to us or our current or future licensors, licensees, partners or collaborators is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent does not cover the technology in question. An adverse result in any litigation proceeding could put one or more of the patents at risk of being invalidated, narrowed, held unenforceable or interpreted in such a manner that would not preclude third parties from entering the market with competing products. Third parties may initiate legal proceedings against us or our current or future licensors, licensees, partners or collaborators to challenge the validity or scope of intellectual property rights we own or control. For example, generic or biosimilar drug manufacturers or other competitors or third parties may challenge the scope, validity or enforceability of patents owned or controlled by us or our current or future licensors, licensees, partners or collaborators. These proceedings can be expensive and time- consuming, and many of our adversaries may have the ability to dedicate substantially greater resources to prosecuting these legal actions than us. Accordingly, despite our efforts, we or our current or future licensors, licensees, partners or collaborators may not be able to ~~generate revenue~~ **prevent third parties from infringing upon or misappropriating intellectual property rights we own** , ~~attain profitability~~ **control or have rights to** , **particularly in countries where the laws may not protect those rights as fully as in the U. S. There is a risk that some of** ~~or~~ **our confidential information could be compromised by disclosure during litigation because of the substantial amount of discovery required. Additionally, many foreign jurisdictions have rules of discovery that are different than those in the U. S. and that may make defending or enforcing our patents extremely difficult. There also could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Third- party pre- issuance submission of prior art to the USPTO, opposition, derivation, revocation, reexamination, inter partes review or interference proceedings, or other pre- issuance or post- grant proceedings, as well as other patent office proceedings or litigation in the U. S. or other jurisdictions brought by third parties against patents or patent applications owned or controlled by us or our current or future licensors, licensees, partners or collaborators, may affect the inventorship, priority, patentability or validity of these patents or patent applications. An unfavorable outcome could leave our technology or current and future product candidates without patent protection and allow third parties to** commercialize **its technology** ~~our~~ **or** product **candidates without payment to us** . **Additionally, potential licensees, partners or collaborators could be dissuaded from collaborating with us to license, develop or commercialize current or future product candidates if the breadth or strength of protection provided by our patents and patent applications is threatened. Even if we successfully defend** ~~Such~~ **such** ~~reforms~~ **litigation or proceeding, we may incur substantial costs and we may distract our management and other employees. Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of the third- party intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Third parties may initiate legal proceedings against us or our current or future licensors, licensees, partners or collaborators alleging that we infringe their intellectual property rights. Alternatively, we may initiate legal proceedings to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, revocations, reexaminations, inter partes review or derivation proceedings before the USPTO or its counterparts in other jurisdictions. In this regard, we are aware of several third- party patents and patent applications containing claims directed to compositions- of- matter, methods of use and related subject matter, some of which pertain, at least in part, to subject matter that might be relevant to TOUR006. These proceedings can be expensive and time- consuming, and many of our adversaries may have the ability to dedicate substantially greater resources to prosecuting these legal actions than us. In addition, we may be subject to claims that we or our employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee' s former employer, or that third parties have an interest in our patents as an inventor or co- inventor. Likewise, we and our current and future licensors, licensees, partners and collaborators may be subject to claims that former employees, partners, collaborators or other third parties have an interest in our owned or in- licensed patents, trade secrets or other intellectual property as an inventor or co- inventor or an owner of rights via assignment from such an inventor or co- inventor. Litigation may be necessary to defend against these claims. Even if we believe third- party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. In order to successfully challenge the validity of any such U. S. patent in federal court, we would need to overcome a presumption of validity in favor of the granted third- party patent. This is a high burden, requiring us to present clear and convincing evidence as to the invalidity of any such U. S. patent claim. An unfavorable outcome in any such proceeding could require us and our current or future licensors, licensees, partners or collaborators to cease using the related intellectual property or developing or commercializing the product or product candidate, or to attempt to license rights to us from the prevailing party, which may not be available on commercially reasonable terms, or at all. Additionally, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing TOUR006 or any potential future product candidates or force us to**

cease some of our business operations, which could materially harm our business. Reliance on third parties requires us to share our proprietary information, which increases the possibility that such information will be misappropriated or disclosed. Because we rely on third parties for aspects of development, manufacture, or commercialization of TOUR006 and our technologies, or if we collaborate with third parties for the development or commercialization of our future product candidates and technologies, we must, at times, share proprietary information with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third- party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share confidential information increases the risk that such information become known by our competitors, is inadvertently incorporated into the technology of others, or is disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how, a competitor' s discovery of our know- how or other unauthorized use or disclosure could have an adverse effect on ~~anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect~~ our **business** ~~overall financial condition~~ and **results of operations. In addition, these agreements typically restrict the** ability ~~to develop product candidates. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost~~ of ~~prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. • At the federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration' s policy to (i) support legislative reforms that would lower the prices of prescription drugs and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and by supporting the development and market entry of lower- cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA' s implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for " best price " or~~ **our advisors** ~~Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs~~ , **employees** ~~CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented~~ , ~~importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. • On November 20, 2020, CMS issued an Interim Final Rule implementing the Most Favored Nation (" MFN ") Model under which Medicare Part B reimbursement rates would have been calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. However, on December 29, 2021, CMS rescinded the Most Favored Nations rule. • Additionally, on November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point- of- sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. This deadline was pushed back further to January 1, 2027 by the Bipartisan Safer Communities Act and could potentially be pushed back to January 1, 2032 by the Inflation Reduction Act. • Further, on December 31, 2020, CMS published a new rule, effective January 1, 2023, requiring manufacturers to ensure the full value of co- pay assistance is passed on to the patient or these dollars will count toward the Average Manufacturer Price and Best Price calculation of the drug. On May 17, 2022, the U. S. District Court for the District of Columbia granted the Pharmaceutical Research and Manufacturers of America' s (" PhRMA") motion for summary judgment invalidating the accumulator adjustment rule • The Inflation Reduction Act of 2022, or IRA includes several provisions that may impact our business to varying degrees, including provisions that reduce the out- of- pocket spending cap for Medicare Part D beneficiaries from $ 7, 050 to $ 2, 000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U. S. government to negotiate Medicare Part B and Part D price caps for certain high- cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The effects of the IRA on our business and the healthcare industry in general is not yet known. • In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA' s accelerated approval pathway. Although a number of these and~~

~~other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and / or impose price controls may adversely affect: • the demand for our product candidates, if we obtain regulatory approval; • our ability to set a price that we believe is fair for our products, if licensed; • our ability to generate revenue and achieve or maintain profitability; • the level of taxes that we are required to pay; and • the availability of capital. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. We expect that additional U. S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U. S. Federal Government will pay for healthcare drugs and services, which could result in reduced demand for our drug candidates or additional pricing pressures. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by~~ third- party ~~payors~~ **contractors, and consultants to publish data potentially relating to ~~or~~ our know- how. Despite our efforts to protect our know- how, we may not be able to prevent the unauthorized disclosure or use of our technical know- how by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors, and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or ~~other~~ others ~~restrictions~~ is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third- party illegally obtained and is using our proprietary information, like patent litigation, is expensive and time- consuming, and the outcome is unpredictable. In addition, courts outside the U. S. are sometimes less willing to protect proprietary information. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U. S. can be less extensive than those in the U. S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U. S., even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing its or its licensors' inventions in all countries outside the U. S., even in jurisdictions where we or our licensors pursue patent protection. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop its own competing products and, further, may export otherwise infringing products to territories where it has patent protection, but enforcement is not as strong as that in the U. S. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which** could ~~harm~~ **materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and** our business, financial condition, results of operations and prospects **may be adversely affected. In Europe, starting from June 1, 2023, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which is subject to the jurisdiction of the Unified Patent Court (the " UPC "). This is a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. It is our initial belief that the UPC, while offering a cheaper streamlined process, has potential disadvantages to patent holders, such as making a single European patent vulnerable in all jurisdictions when challenged in a single jurisdiction. We, our CROs, our CDMOs, service providers, our current and potential future partners or other third parties upon which we rely, could experience a security incident, system disruption or failure, data loss, cyberattack, or similar event that could compromise our systems and data (or those of the third parties upon whom we rely), result in material disruptions to our business operations, lead to regulatory investigations or actions, litigation, fines and penalties, affect our reputation, revenue or profits, or otherwise harm our business. We collect, store, receive, transmit, generate, use, transfer, disclose, make accessible, protect, secure, dispose, share and otherwise process (collectively, process) proprietary, confidential and otherwise sensitive information, including personal information (such as health- related data of clinical trial participants and employee information), in the course of our business. Our technology systems and the information and data processed and stored by us or by third parties upon whom we rely (e. g., research collaborators, partners, CROs, CDMOs, contractors, consultants and other third parties), are vulnerable to a variety of evolving online and offline threats that could result in security incidents, including unauthorized, unlawful, or accidental loss, damage, corruption, access, use, encryption, acquisition, disclosure, misappropriation, or other compromise of such systems or data. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to operate our business and may have other adverse effects. We and third parties on which we rely face threats that are constantly evolving and growing in frequency, sophistication, and intensity. For example, these threats may include (without limitation) malware (including as a result of advanced persistent threat intrusions), viruses, worms, software vulnerabilities and bugs, software or hardware**

failures, hacking, denial of service attacks, social engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing), credential harvesting, ransomware, personnel misconduct or errors, credential stuffing, telecommunications failures, loss or theft of devices, data or other information technology assets, attacks enhanced or facilitated by AI, earthquakes, fires, floods and other similar threats. Threats such as ransomware attacks, for example, are becoming increasingly prevalent and severe, and attackers are increasingly leveraging multiple attack methods to extort payment from victims, such as data theft and disabling systems. 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. Security incidents may result from the actions of a wide variety of actors with a wide range of motives and expertise, including traditional hackers, hacktivists, our personnel, or the personnel of the third parties we work with, sophisticated nation- states, nation- state-supported actors, and organized criminal threat actors. During times of war and other major conflicts, we, the third party upon which we rely, and our customers 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, sell and distribute our goods and services. Certain functional areas of our workforce work remotely on a full- or part- time basis outside of our corporate network security protection boundaries or otherwise utilize network connections, computers and devices outside of our premises or network, which imposes additional risks to our business, including increased risk of industrial espionage, phishing, and other cybersecurity attacks, and unauthorized dissemination of proprietary or confidential information, including personal information, any of which could have a material adverse effect on our business. 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 . In addition, ~~regional healthcare authorities~~ **we rely on third parties to operate critical business systems and process sensitive data in a variety of contexts, including, without limitation, cloud- based infrastructure, data center facilities, encryption and authentication technology, personnel email, and other functions. We also rely on third parties, including CROs, clinical trial sites and clinical trial vendors, to process sensitive data as part of our research activities. Our ability to monitor these third parties is limited, and these third parties may not have adequate information security measures in place and may expose us to cyberattacks and other security incidents. Supply- chain attacks have also increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third- party partners' supply chains have not been compromised. If our third- party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. We may be required to, or we may choose to, expend significant resources or modify our business activities (including our clinical trial activities) in** ~~and~~ **an effort** ~~individual hospitals are increasingly using bidding procedures~~ to ~~determine~~ **protect our information systems and data (including against security incidents), particularly where required by applicable data privacy and security laws or regulations or industry standards. While we have implemented security measures and processes designed to protect against security incidents, we cannot assure you** ~~what~~ **that** ~~pharmaceutical products and which suppliers~~ **these security measures that we or our service providers implement** will be ~~included~~ **effective** in ~~their prescription drug and~~ **preventing security incidents, disruptions, cyberattacks, or** other ~~healthcare~~ **similar events. 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, however, detect and remediate, all such vulnerabilities including on a timely and effective basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident. Any of the previously identified or similar threats could cause a security incident. A security incident could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to data. If our information systems or data, or that of the third parties on which we rely, are compromised or were perceived to be compromised, it could interrupt our operations, disrupt our development** programs **and have a material adverse effect** ~~. This could reduce the ultimate demand for our drugs or put pressure~~ on ~~our drug pricing, which could negatively affect~~ our business, financial condition ~~,~~ **and** results of operations ~~and prospects~~ . ~~Risks Related to Privacy and~~ **For example, the loss or corruption of clinical trial** ~~Data~~ **data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of TOUR006, to analyze clinical trial samples and to conduct clinical trials, and** ~~Security~~ **security** ~~Laws~~ **incidents experienced by these third parties could have a material adverse effect on our business. Actual or perceived security incidents affecting us or the third parties we rely on or partner with could result in substantial remediation costs and expose us to litigation (including class claims), regulatory enforcement action (for example, investigations, fines, penalties, audits and inspections), additional reporting requirements and / or oversight, fines, penalties, indemnification obligations, negative publicity, reputational harm, monetary fund diversions, diversion of management attention, interruptions in our operations (including availability of data), financial loss and other liabilities, and harms. Additionally, such incidents may trigger data privacy and security obligations requiring us to notify relevant stakeholders, such as individuals, regulators, and others, or take other remedial or corrective actions, and may subject us to liability. Such disclosures and remediation efforts may be costly, and related requirements or the failure to comply with them could lead to adverse consequences. 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 claims**

related to our data privacy and security obligations. Additionally, we cannot be certain that our insurance coverage will be adequate for data security liabilities actually incurred, will continue to be available to us on economically and commercially reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co- insurance requirements, could adversely affect our reputation, business, financial condition and results of operations. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information 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. Additionally, sensitive information of the Company could be leaked, disclosed, or revealed as a result of or in connection with our personnel' s, or vendors' use of generative AI technologies. We are subject to **rapidly changing and increasingly** stringent **foreign** and **domestic** ~~changing privacy and data security~~ laws **, regulations, and rules** , contractual obligations, **industry** ~~self- regulatory schemes, government regulation, and~~ standards ~~related~~ **, policies and other obligations relating** to **privacy,** data ~~privacy~~ **protection** and **information** security. The **restrictions imposed by these requirements or our** actual or perceived failure ~~by us, our collaborators, vendors or other relevant third parties~~ 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** ~~our~~ **or** ~~reputation~~ **profits** , **loss of customers** ~~subject us to significant fines and liability,~~ or ~~otherwise~~ **sales, and other** ~~adversely~~ **adverse** ~~affect our~~ business **consequences** ~~, operations and financial performance~~ . We **may** ~~collect, receive, store,~~ process **proprietary** , **confidential** ~~use, generate, transfer, disclose, make accessible, protect~~ and ~~share~~ **sensitive information, including** personal information **(including health- related data), which subjects us to numerous evolving and complex data privacy and security obligations, including various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts** and other **obligations that govern the processing of such** information ~~, including information we collect about patients and healthcare providers~~ in connection with ~~clinical trials~~ **our business** . ~~There are numerous federal~~ **Outside the U. S.** , ~~state, local and~~ **an** ~~international~~ **increasing number of** laws, regulations **,** and ~~guidance regarding~~ **industry standards govern data** privacy **and** ~~, information~~ security ~~and processing, the number and scope of which is changing, subject to differing applications and interpretations, and which may be inconsistent among jurisdictions, or in conflict with other rules, laws or data protection obligations. Data protection laws and data protection worldwide is, and is likely to remain, uncertain for the foreseeable future, and our failure or perceived failure to address or comply with these laws could: increase our compliance and operational costs; expose us to regulatory scrutiny, actions, fines and penalties; result in reputational harm; lead to a loss of customers; reduce the use of our products; result in litigation and liability; and otherwise result in other material harm to our business~~ . For example, ~~in the United States, HIPAA, as amended by HITECH, imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon " covered entities " (health plans, health care clearinghouses and certain health care providers), and their~~ **the European** ~~respective business associates, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity, as well as their covered subcontractors. HIPAA mandates the reporting of certain breaches of health information to HHS, affected individuals and, if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and / or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non~~ **Union ' s General Data Protection Regulation** ~~- compliance. Even when HIPAA does not apply~~ , ~~according to the Federal Trade Commission~~ (" ~~FTC~~ **EU GDPR** ") **and the United Kingdom** ~~, failing to take appropriate steps to keep consumers~~ ' **s GDPR, (" UK GDPR ") and the Swiss Federal Data Protection Act, (" Swiss FADP ") impose strict requirements for processing** personal information ~~secure constitutes unfair acts~~ **, and may apply to** ~~or~~ **our processing** ~~practices in or affecting commerce in violation~~ of ~~Section 5 (a) of the Federal Trade Commission Act (" FTCA "), 15 U. S. C. § 45 (a). The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC' s guidance for appropriately securing consumers'~~ personal information **from clinical trial participants** ~~is similar to what is required by the HIPAA security regulations. Additionally, U. S. States have begun introducing privacy legislation. For example, California recently enacted the California Consumer Privacy Act (" CCPA "), which creates new individual privacy rights for California consumers (as defined in the law)~~ and ~~places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA, which went into effect on January 1, 2020, requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt- out of certain sales or transfers of personal information. The CCPA also provides for civil penalties for violations, as well as a private right of action for data breaches that may increase our risk to data breach class action litigation. The CCPA will be expanded substantially on January 1, 2023, when the California Privacy Rights Act of 2020 (" CPRA ") becomes fully operative. The CPRA will, among~~ other ~~things, give California residents the ability to limit use of certain sensitive personal information, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA' s private right of action, and establish a new California Privacy Protection Agency to implement and enforce the new law. The CCPA and the CPRA could substantially impact our business. Additionally, some observers have noted that the CCPA and CPRA could mark the beginning of a trend toward more stringent privacy legislation in the U. S., which could increase our potential liability and adversely affect our business. Already, in the United States, we have witnessed significant developments at the state level.~~

~~For example, in 2021, Virginia and Colorado enacted state legislation that becomes effective January 1, 2023. In 2022, Utah and Connecticut also enacted privacy legislation. With bills proposed in many other jurisdictions, it remains quite possible that other states will follow suit. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and / or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country will make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. The increasing number and complexity of regional, country and U. S. state data protection laws, and other changes in laws or regulations across the globe, especially those associated with the enhanced protection of certain types of sensitive data could lead to government enforcement actions and significant penalties against us and could have a material adverse effect on our business, financial condition or results of operations. We may also be subject to additional privacy restrictions in various foreign jurisdictions around the world in which we operate or process personal information. The collection, use, storage, disclosure, transfer, or other processing of personal information regarding~~ individuals **located** in the European Economic Area (" EEA "), **the UK** ~~including personal health data~~, ~~is subject to~~ **or Switzerland and, if TOUR006 or any potential future product candidates are approved, our possible commercialization of** ~~the~~ **those** ~~General Data Protection Regulation 2016 / 679~~ **products in the EEA, the UK, or Switzerland** (~~"~~ **as applicable). Companies that violate the** GDPR **can face private litigation, regulatory investigations** ~~"). The GDPR is wide- ranging~~ and ~~imposes numerous requirements~~ **enforcement actions, prohibitions** on ~~companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding~~ data processing ~~activities~~, ~~implementing safeguards to protect the~~ **other administrative** ~~security and confidentiality of personal data, providing notification of data breaches, and taking certain~~ measures ~~when engaging third- party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union~~, **reputational damage** ~~including the United States,~~ and ~~permits data protection authorities to impose large penalties for violations of the GDPR, including potential~~ fines of up to ~~€~~ **the greater of** 20 million **Euros under the EU GDPR / 17. 5 million pounds sterling under the UK GDPR,** or 4 % of **their worldwide** annual ~~global revenues~~ **revenue, in either case**, whichever is greater. The **EU and UK** GDPR ~~also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time- intensive process that may increase our cost of doing business or~~ require us to ~~change our business practices~~, **among** ~~and despite those efforts, there~~ **other things: give detailed disclosures** ~~is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. In addition, further to the UK' s exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK' s European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but~~ **about how we collect** ~~subject to certain UK- specific amendments) into UK law~~, **use** ~~referred to as the UK GDPR. The UK GDPR~~ and **share personal information; contractually commit to** ~~the UK Data Protection Act 2018 set out the UK' s~~ data protection ~~regime, which is independent from but aligned to the EU' s~~ **measures in our contracts with vendors; maintain appropriate data security measures; notify regulators and affected individuals of certain personal data breaches; meet privacy governance and documentation requirements; and honor individuals'** data protection **rights, including** ~~regime. Non- compliance with the~~ **their rights** ~~UK GDPR may result in monetary penalties of up~~ to **access** ~~£ 17. 5 million or 4 % of worldwide revenue~~, **correct** ~~whichever is higher. Complying with these laws, if enacted, would require significant resources~~ and **delete their personal information** ~~leave us vulnerable to possible fines and penalties if we are unable to comply~~. In ~~addition, GDPR prohibits~~ the **ordinary course of business, we may** transfer ~~of~~ personal data from **Europe and** ~~the~~ **other** ~~EU~~ **jurisdictions** to the U. S **or** ~~, and~~ other countries ~~in respect~~ **. Certain jurisdictions have enacted data localization restrictions or laws and regulations restricting cross- border transfers** of ~~which~~ **personal information. In particular, regulators and courts in the EEA, the UK, and Switzerland have significantly restricted the transfer of personal information to the U. S. and** ~~the~~ **other countries that have not been declared " adequate " for data protection purposes by a relevant governmental authority. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross- border data transfer laws. Although there are currently mechanisms that may be used to transfer personal information from the EEA, the UK, or Switzerland to the U. S. in compliance with** European **data protection laws, such** ~~Commission or other relevant regulatory body has not issued a so- called " adequacy decision " (known~~ as ~~" third countries "), unless~~ the ~~parties to~~ **EEA standard contractual clauses,** the **UK' s International Data** ~~transfer~~ **Transfer Agreement / Addendum, and** ~~have implemented specific safeguards to protect the transferred personal data. One of the primary safeguards used for transfers of personal data to the U. S. was~~ the EU- U. S. **Data** Privacy ~~Shield framework~~ **Framework and** ~~administered by~~ the **UK extension thereto (which allows for transfers to relevant** U. S. **- based organizations who self- certify compliance and participate in** ~~Department of Commerce. However, certain recent EU court decisions cast doubt on the ability to use one of the primary alternatives to~~ the EU- U. S. **Data** Privacy ~~Shield~~ **Framework)** ~~, namely the~~ **these mechanisms are subject** ~~European Commission' s Standard Contractual Clauses,~~ to ~~lawfully~~ **legal challenges, and there is no assurance that we can satisfy or rely on these measures to** transfer personal data to the U. S. **If we are unable to implement a valid compliance mechanism for cross- border transfers of personal information, or if the requirements for a legally- compliant transfer are too onerous, we will face increased exposure to significant adverse consequences, including substantial fines, regulatory actions, as well as injunctions against the export** and **processing of personal information from the EEA, UK, Switzerland, or** other ~~third~~ countries **that** ~~. In addition, the European Commission has recently published new versions of the Standard Contractual Clauses, which must be used for all new transfers of personal data from the EEA to third countries (including the United States) as of September 2021, and all existing~~

transfers of personal data from the EU to third countries relying on the existing versions of the Standard Contractual Clauses must be replaced by December 2022. The implementation ----- **implement cross- border** of the new Standard Contractual Clauses will necessitate significant contractual overhaul of our data transfer arrangements **restrictions. Our inability to import personal information from the EEA, UK or Switzerland or other countries may also restrict or prohibit our clinical trial activities in those countries; limit our ability to collaborate** with customers **CROs** , sub **service providers, contractors and other companies subject to laws restricting cross** - **border** processors and vendors. Use of both the existing and the new Standard Contractual Clauses must now be assessed on a case- by- case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals, and additional supplementary technical, organizational and / or contractual measures and / or contractual provisions may need to be put in place. At present, there are few if any viable alternatives to the Standard Contractual Clauses, and there remains some uncertainty with respect to the nature and efficacy of such supplementary measures in ensuring an adequate level of protection of personal data **transfers; require us to increase our** . As supervisory authorities issue further guidance on personal data **processing capabilities in** export mechanisms (including circumstances where the **other** Standard Contractual Clauses can **countries at significant expense** and **may otherwise negatively impact** cannot be used) and / or **our business operations.** start taking enforcement action, we could suffer additional **Additionally** costs , **companies that** complaints and / or regulatory investigations or fines. In addition, if we are unable to transfer personal data between **out of the EEA** and among countries **UK to other jurisdictions, particularly to the U. S, are subject to increased scrutiny from regulators, individual litigants,** and regions **activist groups. We may also become subject to new laws** in **the EEA** which we operate and / or engage providers **other jurisdictions that regulate cybersecurity** and **non-** / or otherwise transfer personal data, **such** this could affect the manner in which we receive and / or provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results and generally increase compliance risk as a result **data collected through the internet of things. Depending on how these laws are interpreted, we may have to make changes to our business practices and products to comply with such obligations** . Additionally, other countries outside of Europe have enacted or are considering enacting similar cross- border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of **delivering our services and** operating our business. **Privacy and data security laws in** Furthermore, following Brexit, the relationship between the U. K **S** . and **at** the EEA in **federal, state and local level are increasingly complex and changing rapidly. For example, at the federal level, HIPAA, as amended by HITECH, imposes specific requirements** relation - **relating** to certain aspects **the privacy, security and transmission** of **individually identifiable health information. Additionally, at the state level, the privacy and** data protection **landscape is changing rapidly. Many states have enacted comprehensive privacy** law **laws** remains somewhat **— including California, Virginia, Colorado, Connecticut, and Utah — that impose** uncertain -- **certain** . In June 2021 **obligations on covered businesses** , the European Commission issued **including providing specific disclosures in privacy notices** an **and affording residents with certain rights concerning** adequacy decision under the GDPR which allows transfers (other - **their** than those carried out for the purposes of U. K. immigration control) of personal data from the EEA to the U . K. **As applicable, such rights may include the right** to continue without restriction **access, correct,** for - **or delete certain** a period of four years. After that period, the adequacy decision may be renewed only if the U. K. continues to ensure an adequate level of data protection. During these four years, the European Commission will continue to monitor the legal situation in the U. K. and could intervene at any point if the U. K. deviates from the level of data protection in place at the time of issuance of the adequacy decision. If the adequacy decision is withdrawn or not renewed, transfers of personal data **,** from the EEA to the U. K. will require a valid " transfer mechanism " and we may be required to **opt- out of certain data processing activities** implement new processes and put new agreements in place , such as **targeted advertising** Standard Contractual Clauses , **profiling, and automated decision- making. If these laws apply or were** to enable transfers **apply to us, the exercise** of **these rights may impact our business. Certain state laws also impose stricter requirements for processing sensitive personal information such as obligating covered businesses to conduct data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 (" CCPA "), applies to** personal data **of consumers, business representatives, and employees who are California residents, and requires certain businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines for noncompliance of up to $ 7, 500 per intentional violation, and a limited private right of action in connection with certain data breaches. While the CCPA and other comprehensive state privacy laws contain exemptions for certain personal information processed in connection with clinical trials, we may process other personal information that is or may become subject to these laws. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. The evolving patchwork of differing state and federal privacy and data security laws increases the cost and complexity of operating our business and increases our exposure to liability, including** from the EEA to the U. K. to continue, which could disrupt our operations. In addition, while the U. K. data protection regime currently permits data transfers from the U. K. to the EEA and other third **- party litigation** countries covered by a European Commission adequacy decision, and **regulatory investigations** currently includes a framework to permit the continued use of the existing version of the Standard Contractual Clauses for personal data transfers from the U. K. to third countries , **enforcement** this is subject to change in the future , **fines** and any such changes could have implications for our transfers of personal data from the U. K. to the EEA and other third countries. In particular , the U. K. Information Commissioner' s Office has stated that it is working on its own bespoke version of the Standard Contractual Clauses and **penalties** it is not clear whether the new Standard Contractual Clauses published by the European Commission will be accepted as a valid mechanism to permit the transfer of personal data from the U. K. to third countries and / or whether any U. K. version of the Standard Contractual Clauses will supersede the existing and / or new EU version of the Standard

~~Contractual Clauses. This could necessitate the implementation of both U. K. and EU versions of Standard Contractual Clauses, which would require significant resources and result in significant cost to implement and manage~~. We are also **bound by** ~~subject to the terms of our external and internal privacy and security policies, representations, certifications, standards, publications and frameworks, and~~ contractual obligations **related** to **data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies and provide notices regarding data privacy and security. If these policies or notices are 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. Our obligations related to data privacy and security (and individuals' data privacy expectations) are quickly changing in an increasingly stringent fashion and creating uncertainty. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Monitoring, preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time- related resources). These obligations may necessitate changes to our information technologies, systems and practices and to those of any** third parties **that process personal** ~~related to privacy,~~ information ~~security and processing~~ **on our behalf** . **In addition** ~~With applicable data protection laws~~, **these** ~~privacy policies and data protection~~ obligations ~~imposing complex and burdensome obligations, and with substantial uncertainty over the interpretation and application of these requirements, we have faced and~~ may **require us to** ~~face additional challenges in addressing and complying with them, and making necessary changes~~ -- **change aspects** ~~to our privacy policies and practices, and may incur material costs and expenses in an effort to do so, any~~ of ~~which could materially adversely affect~~ our business **model (such as where we conduct clinical trials)** ~~operations and financial results, and may reduce the overall demand for our products~~. ~~We strive~~ **Although we endeavor** to comply with applicable data ~~protection laws,~~ privacy ~~policies~~ and **security** ~~data protection~~ obligations ~~to the extent possible~~, ~~but~~ we may at times fail **(or be perceived to have failed)** to do so **. Moreover** , **despite** ~~or~~ **our efforts, our personnel or third parties upon whom we rely** may ~~be~~ **fail to comply with such obligations, which could negatively impact our business operations. If we (or third parties upon which we rely) fail, or are** perceived to have failed ~~to do so. Moreover~~ , ~~despite~~ **to address** ~~our~~ -- **or** ~~efforts, we may not be successful in achieving compliance if our personnel, collaborators or vendors do not~~ comply with ~~applicable~~ data **privacy,** protection ~~laws~~ **and security obligations** , **we could face significant consequences, including (without limitation): government enforcement actions (e. g., investigations, fines, penalties, audits, inspections and similar); litigation (including class- related claims) and mass arbitration demands; additional reporting requirements and / or oversight; bans on processing personal information; orders to destroy or not use personal information; and / or imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing** privacy **- related claims** ~~policies and data protection obligations. Any failure or perceived failure by us or our collaborators, service providers and contractors to comply with federal or foreign laws or regulation, our internal policies and procedures, representations or our contracts governing the processing of personal data could result in negative publicity, disruptions or interruptions in our operations, fines, penalties, lawsuits, liability, inability to process personal data, diversion of time and effort, proceedings~~ against **companies** ~~us by governmental entities~~ , **including class claims and mass arbitration demands. Some of these claims allow** ~~or for other~~ -- **the recovery of statutory damages** ~~adverse effects to our business. Risks Related to Our Dependence~~ on ~~Third Parties We are dependent on~~ a **per violation basis** ~~limited number of suppliers and~~ , ~~in some cases sole suppliers, for some of our components~~ and ~~materials used in our product candidates. Our manufacturing process~~ , **if** ~~like that of a number of other cell therapy companies, is characterized by limited numbers of suppliers, and in some cases sole source suppliers, with the manufacturing capabilities and know- how to create or source the reagents, materials and equipment necessary for the production of our product candidates. For example, like many other cell therapy companies, our manufacturing process for FCR001 depends on certain cell manipulation equipment and related reagents, all of which are available~~ --- **viable** ~~from Miltenyi Biotec (" Miltenyi") as the sole supplier. We cannot be sure that our suppliers will remain in business~~ , **carry** ~~or that they~~ -- **the** ~~will not be purchased by one of our competitors or another company that decides not to continue producing these materials for us. Additionally, during a public health emergency, there is a~~ potential for **monumental statutory damages** ~~certain manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950~~ , **depending on** ~~or equivalent foreign legislation, which may make it more difficult to obtain materials or reagents for our current and any future product candidates for our clinical trials or for commercial production, if approved, which could lead to delays in these~~ -- **the volume** ~~trials or issues with our commercial supply. Our use~~ of **data and the** ~~a sole or a limited~~ number of **violations** ~~suppliers of raw materials, components and finished goods exposes us to several risks, including disruptions in supply, price increases, late deliveries and an inability to meet customer demand. While we try to mitigate these risks by purchasing excess supplies, some of these components, such as reagents, typically expire after approximately four to six months. This short expiration period means that stocking the reagents in large quantities for future needs would not be an effective strategy to mitigate against the risk of shortage due to disruption of the supply chain or termination of our business relationship. We also pursue multiple sources for the critical components of our manufacturing process, but there are, in general, relatively few alternative sources of supply for these components and we may not be successful in securing these additional sources at all or on a timely basis. These vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. For example, the FDA or EMA could require additional supplemental data, manufacturing data and comparability data up to and including clinical trial data if we rely upon a new supplier~~ . Any ~~disruption in supply from any supplier or manufacturing location, including as a result of or impact from the COVID- 19 pandemic, could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects. If we are required to switch to a replacement supplier, the manufacture and delivery of our product candidates could be interrupted for an extended period, adversely affecting our business. Establishing~~

additional or replacement suppliers may not be accomplished quickly. While we seek to maintain adequate inventory of the components and materials used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to conduct our clinical trials and, if our product candidates are approved, to meet the demand of our customers and cause them to cancel orders. In addition, as part of the FDA's approval of our product candidates, the FDA must review and approve the individual components of our production process, which includes raw materials, the manufacturing processes and facilities of our suppliers and CMOs. Some of our current suppliers may not have undergone this process, and may not have had any components included in any product approved by the FDA. Our reliance on external suppliers subjects us to a number of risks that could harm our reputation, business, and financial condition, including, among other things: the interruption of supply resulting from modifications to or discontinuation of a supplier's operations; delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component; a lack of long- term commercial supply arrangements for key components with our suppliers; the inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms; difficulty and cost associated with locating and qualifying alternative suppliers for our components in a timely manner; production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications; a delay in delivery due to our suppliers prioritizing other customer orders over ours; and fluctuation in delivery by our suppliers due to changes in demand from us or their other customers. If any of these risks materialize, costs could significantly increase and our ability to conduct our clinical trials and, if our product candidates are approved, to meet demand for our products could be impacted. Some of these events could be the basis for FDA or other regulatory authority action, including injunction, recall, seizure, or total or partial suspension of production of our product candidates. We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an **a material** adverse effect on our **reputation,** business and prospects. We do not have the ability to conduct all aspects of our **or financial condition** clinical trials ourselves. As a result, we are, and expect to remain, dependent on third parties to conduct our ongoing clinical trials and any future clinical trials of our product candidates , including but not limited to **: loss of customers; interruptions or stoppages in our business operations** governmental agencies and university laboratories, CMOs, CROs, distribution and supply (**including** logistics) services organizations, contract testing organizations (" CTOs "), consultants or consultant organization with specialized knowledge- based expertise. The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Specifically, we expect CROs, clinical investigators, and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs, CTOs, and other third parties does not relieve us of our regulatory responsibilities. For example, we rely on a single third- party investigator to provide ongoing data from our Phase 2 clinical trial. We, our CROs and clinical sites are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for all of our current product candidates and any future product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs, and in particular, our single third- party investigator for our Phase 2 company- sponsored trial, or clinical trial sites fail to adhere to our clinical trial protocols or to comply with applicable GCP requirements, the data generated in our clinical trials **); inability** may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and / or repeat clinical trials, which would delay the marketing approval process **personal information** . Moreover, principal investigators for **or to operate in certain jurisdictions; limited ability to develop** our **or commercialize** clinical trials may serve as scientific advisors or **our** consultants to us from **products; expenditure of** time to time and **resources** receive compensation in connection with such services. Under certain circumstances, we may be required to **defend** report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA or comparable foreign regulatory authority 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 authority, as the case may be, and may ultimately lead to the denial of marketing approval of our product candidates. There is no guarantee that any **claim** such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our **or inquiry; adverse publicity;** development activities or perform as contractually required. Further, the performance of our **or revision** CROs has been, and may again in the future be interrupted by the ongoing COVID- 19 pandemic, including due to travel or quarantine policies, heightened exposure of CRO staff who are healthcare providers to COVID- 19 or prioritization of resources toward the pandemic. If any of these third parties fail to meet expected deadlines, adhere to our **or** clinical protocols **restructuring of** or **our** meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. In August 2022, a software vendor, which is responsible for providing logistics support for apheresed material from the donor to our manufacturing facility and back to the clinical site, shutdown operations . As there are few alternative vendors providing similar services, we may be required to utilize

a manual, paper- based chain of custody process that could add risk to our manufacturing process. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow- up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or comparable foreign regulatory authorities concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our current product candidates and any future product candidates. We may not realize the benefits of strategic alliances that we may form in the future or of potential future product acquisitions or licenses. We may desire to form strategic alliances, create joint ventures or collaborations, enter into licensing arrangements with third parties or acquire products or businesses, in each case that we believe will complement or augment our existing business. These relationships or transactions, or those like them, may require us to incur nonrecurring and other charges, increase our near- and long- term expenditures, issue securities that dilute our existing stockholders, reduce the potential profitability of the products that are the subject of the relationship or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic alliances and transactions and the negotiation process is time- consuming and complex and there can be no assurance that we can enter into any of these transactions even if we desire to do so. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate a positive risk profile. Any delays in entering into new strategic alliances agreements related to our product candidates could also delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. If we license products or acquire businesses, we may not be able to realize the benefit of these transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following an acquisition or license, we will achieve the financial or strategic results that would justify the transaction . Risks Related to **Our Common Stock The market price** Manufacturing Risks Related to our Manufacturing Facility We currently operate our own manufacturing facility which would require scale- up to appropriately address our anticipated commercial needs for FCR001, which will require significant resources. We may fail to successfully operate our facility, which could adversely affect our clinical trials and the commercial viability of our product candidates. We operate our own dedicated cGMP cell processing facility, located on the campus of the University of Louisville, where we manufacture our product candidates for our current and planned clinical trials. Although we are currently operating our manufacturing facility, our operations remain subject to review and oversight by the FDA, and the FDA could object to our use of our manufacturing facility or **our common stock is expected** the processes used therein. We had begun to scale- up our manufacturing and processing approaches to appropriately address our anticipated commercial needs for FCR001 for LDKT. While those scale- up efforts have been deferred, in order to scale- up our manufacturing capabilities and facility in the future to support our anticipated commercial needs, we will require substantial additional funds and will need to hire and retain significant additional personnel and comply with extensive cGMP regulations applicable to a commercial facility. If we fail to complete any construction in an efficient manner, recruit the required personnel and generally manage our growth effectively, the development and production of our product candidates could be **volatile** curtailed or delayed. Our manufacturing facility would also need to be licensed for the production of our product candidates by the FDA. Even if our manufacturing facility is approved by the FDA , we would be subject to ongoing periodic unannounced inspection by the FDA, corresponding state agencies and potentially third- party collaborators to ensure strict compliance with cGMPs and other -- **the market price of** government regulations. Our license to manufacture product candidates will be subject to continued regulatory review. We expect to use the same manufacturing process and starting material for future programs as those -- **the common stock** that we have used in our Phase 2 and Phase 3 trials of FCR001 for LDKT, except that our starting materials and process may **drop** be different for programs where we derive our component cells from a deceased donor. However, our use of this manufacturing process in our Phase 2 and Phase 3 trials may not be successfully replicated in subsequent trials, which could adversely affect our ability to scale- up our manufacturing processes or obtain or maintain the requisite licenses and approvals from the FDA to commercialize our product candidates. We believe that our manufacturing processes can be scaled- up to address our commercial needs. However, there can be no assurance that we will not encounter difficulties in scaling out our manufacturing processes. Significant scale- up of manufacturing may result in unanticipated technical challenges and may require additional FDA approvals. We may encounter difficulties in scaling out production, including problems involving raw material suppliers, production yields, technical difficulties, scaled- up product characteristics, quality control and assurance, shortage of qualified personnel, capacity constraints, compliance with FDA and foreign regulations, environmental compliance, production costs and development of advanced manufacturing techniques and process controls . The actual cost to manufacture and process our product candidates could also be greater than we expect and could materially and adversely affect the commercial viability of our product candidates. Any of these difficulties, if they occur and are not overcome to the satisfaction of the FDA or other regulatory agency, could lead to significant delays and possibly the termination of the development program for such product candidate. These risks become more acute as we scale- up for commercial quantities, where a reliable source of product becomes critical to commercial success. The commercial viability of any of our product candidates, if approved, will depend on our ability to produce our personalized cell therapy at a large scale. Failure to achieve this level of supply could jeopardize the successful commercialization of our therapy. The manufacture of a cell therapy is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products

often encounter difficulties in production, particularly in scaling out and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, shortages of raw materials, as well as compliance with strictly enforced federal, state and foreign regulations. For example, in late 2021, we were required to undertake an additional apheresis of a donor when quality testing revealed that the product prepared from that donor' s stem cells was contaminated. While there can be no assurance at what point the donor blood product was contaminated, whether at the point of apheresis or during the manufacturing process, we nonetheless have reviewed and enhanced our quality control procedures and believe the risk of future contamination to be low. Furthermore, if contaminants are discovered in our cell therapy or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot ensure that any stability or other issues relating to the manufacture of our product candidates will not occur in the future. We may fail to manage the logistics of collecting and shipping donor cell material to the manufacturing site and shipping the product candidate to the patient. Logistical and shipment delays and problems caused by us, our vendors or other factors not in our control, such as weather, could cause breakage or contamination of our products and prevent or delay the delivery of product candidates to patients. Additionally, we have to maintain a complex chain of identity and chain of custody with respect to donor material as it moves to the manufacturing facility, through the manufacturing process, and to the recipient. Failure to maintain chain of identity and chain of custody could result in patient death, loss of product or regulatory action. Though our supply chain has not been materially impacted by the COVID- 19 pandemic to date, our manufacturing capabilities could be affected by cost- overruns, resource constraints, unexpected delays, equipment failures, labor shortages or disputes, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy, jeopardize our ability to provide our product candidates to patients, and have a material adverse effect on our business, financial condition, results of operations and prospects. If our manufacturing facility is damaged or destroyed or production at our manufacturing facility is otherwise interrupted, our business would be negatively affected. Damage to our manufacturing facility or disruption to our operations for any reason, including due to natural disaster (such as earthquake, wildfires and other fires or extreme weather), power loss, communications failure, cyberattack, unauthorized entry or other events, such as a flu or other health epidemic (such as the COVID- 19 pandemic, including any current and future variants), could affect our manufacturing processes. In particular, our manufacturing facility, located on the Health Science Center campus of the University of Louisville, supplies all of our clinical needs, and any damage or disruption to that facility could cause a loss of products or materials or otherwise adversely affect our ability to manufacture our current and any future product candidates in support of our clinical trials. It may require substantial lead time to repair, and we may not have control over such repairs. The property damage and business interruption insurance coverage on our facility that we maintain might not cover all losses under such circumstances, and we may not be able to renew or obtain such insurance in the future on acceptable terms with adequate coverage or at reasonable costs. Any damage or disruption to the University of Louisville' s operations, including the foregoing events, may also adversely affect our business. For example, disruption to any of the utilities provided to our facility by University of Louisville (HVAC, electrical, water, etc.) could inhibit or prevent us from being able to manufacture our product candidates. Moreover, if we are unable to obtain key inputs used in our manufacturing process, disinfectants or other materials required to maintain " clean room " sterility in our manufacturing facility, we may be unable to manufacture products entirely. Any failure of our building systems could also adversely affect our operations, including but not limited to equipment malfunctions, failure to follow specific protocols and procedures, and issues relating to air handling and other utilities. Any significant disruption to our manufacturing facility or processes would likely have an adverse impact on our business. Any adverse developments affecting manufacturing operations for our current and any future product candidates may result in lot failures, inventory shortages, shipment delays, product losses or other interruptions in the supply of our product candidates for an undetermined period of time. We may also have to write off raw material and drug product inventory, incur other charges and expenses for key manufacturing inputs that fail to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. Inability to meet the clinical demand for our product candidates could damage our reputation and the reputation of our products among physicians, healthcare payors, patients or the medical community that supports our product development efforts, including hospitals and outpatient clinics. Our manufacturing process needs to comply with regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals. Further, as our preclinical and clinical programs and the manufacture of our product candidates are dependent on human donor material, we are or could be subject to additional regulations and requirements. The FDA, EMA and comparable foreign regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP, cGTP and similar jurisdictional standards. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA and comparable foreign regulatory agencies may also implement new standards at any time, or change their interpretations and enforcement of existing standards, including for the manufacture, packaging or testing of biological products. We may encounter difficulties in achieving quality control and quality assurance or meeting regulatory expectations. Our facilities are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP, cGTP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, packaging, or storage of our product candidates as a result of our failure to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our product candidates for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant non- compliance could also result in the imposition of sanctions, including warning or untitled

letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business. In addition, our clinical programs and the manufacture of our product candidates are dependent on human donor material. Procurement of certain human organs for transplantation is subject to the National Organ Transplant Act of 1984 (" NOTA "), which prohibits the acquisition, receipt, or transfer of any human organ for valuable consideration for use in human transplantation. We depend on third parties who arrange for living donor kidney transplants (" LDKT") to comply with applicable NOTA requirements and we do not know whether any failure by such third parties to comply with NOTA requirements could impact the integrity or usability of data in our clinical trials. 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 with a policy limit that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations 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, which could adversely affect our business, financial condition, results of operations and prospects. The process for treatment using cell therapies is subject to human and systemic risks. The " vein- to- vein " cycle for treating patients using our Facilitated Allo- HSCT Therapy and other cell- based targeted therapies typically takes approximately four to twelve weeks and involves a large number of steps, as well as human participants. In the United States, samples of the final product are subjected to several release tests which must fulfill specified criteria for the drug product to be released for infusion. These include sterility, identity, purity, potency and other tests. We are subject to stringent regulatory and quality standards in the course of our cell therapy treatment process. We cannot assure you that our quality control and assurance efforts will be successful or that the risk of human or systemic errors in these processes can be eliminated. Our cell therapies are uniquely manufactured for each recipient, so they must be administered only to the recipient matched to the donor from which the cellular source material was collected. While we implement specific identifiers, lot numbers and labels with cross checks for our products and operations from collection of cellular source material, through manufacture of drug product, transport of product to the clinical site up to thawing and administration of the product, it is possible that a product may be administered into the wrong patient. If our cell therapies were to be administered into the wrong recipient, the recipient could suffer harm, including experiencing a severe adverse immune reaction and this event, should it happen, could adversely affect our business, financial condition, results of operations and prospects. Risks Related to the Manufacturing of our Product Candidates Our product candidates are uniquely manufactured for each patient and we may encounter difficulties in production, particularly with respect to scaling our manufacturing capabilities. The manufacturing process used to produce our product candidates is novel and has not been validated for commercial production. Our product candidates comprise a composition of hematopoietic stem cells (" HSCs "), facilitating cells (" FCs ") and Alpha Beta T- cell Receptor Cells (" αßTCR T cells "), the dose of each of which is tailored to the recipient using our proprietary manufacturing process. Due to the personalized nature of the product candidate, we expect the cost to manufacture our product candidates to be high. Although we have qualified and obtained positive initial FDA feedback on our potency assays for each of our active cell components in FCR001, we must validate the potency assays prior to submission of a marketing application for FCR001. Potency assays have traditionally proven difficult to develop for cell- based products and must be validated prior to approval. There can be no assurance that we will be able to validate our potency assays to FDA' s satisfaction, or that FDA will not want us to develop different or alternative potency assays for FCR001 or other product candidates. Any such development could delay or prevent approval of FCR001 or our other product candidates. There is a risk of manufacturing issues associated with the differences in donor starting materials, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, and variability in product characteristics. Even minor deviations from our normal manufacturing processes could result in reduced production yields, lot failures, product defects, product delays, product recalls, product liability claims and other supply disruptions. If for any reason we lose a donor' s starting material or one of our custom- manufactured products at any point in the process, the manufacturing process for that recipient will need to be restarted and the resulting delay may adversely affect that recipient' s outcome. Because our product candidate is manufactured for each particular patient, we will be required to maintain a chain of identity with respect to materials as they move from the donor to the manufacturing facility, through the manufacturing process and on to the patient. Further, as our product candidate is developed through preclinical to later- stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered in an effort to optimize processes and results. If we make these types of changes, we may not achieve our intended objectives and any of these changes could cause our product candidates to perform differently than we expect, potentially affecting the results of clinical trials. Although we continually attempt to optimize our manufacturing process, doing

so is a difficult and uncertain task and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale- up, process reproducibility, stability issues, lot consistency and timely availability of reagents or raw materials. If we are unable to adequately validate or scale- up our manufacturing processes, we may encounter lengthy delays in commercializing our product candidates. We may continue to manufacture our product ourselves or we may ultimately decide to outsource our manufacturing to a third party CMO. We may not be successful in transferring our production system to such manufacturer, or the manufacturer (s) on whom we rely may not have the necessary capabilities to complete the implementation and development process. If we are able to adequately validate and scale- up the manufacturing processes for our product candidates with a contract manufacturer, we will still need to negotiate an agreement for commercial supply with that contract manufacturer and it is not certain we will be able to come to agreement on terms acceptable to us. As a result, we may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are approved and commercialized. The manufacturing process for any products that we may develop is subject to the FDA and foreign regulatory authority approval processes and, if we choose to outsource our commercial production, we will need to contract with manufacturers who we believe can meet applicable FDA and foreign regulatory authority requirements on an ongoing basis. If we are unable to reliably produce our cell therapy candidate to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize our products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or any CMOs we may contract with in the future will be able to manufacture the approved product to specifications and under cGMPs acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and growth prospects. Our future success depends on our ability to manufacture our products on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements. Our inability to do so could have a material adverse effect on our business, financial condition, prospects and results of operations. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change and we could need to replace, modify, design or build and install equipment, all of which would require additional capital expenditures. In addition, the FDA, the EMA and other foreign regulatory authorities may require us to submit samples of any personalized product lot, together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other foreign regulatory authorities may require that we not distribute a specific product lot until the relevant agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects. Problems in our manufacturing process could restrict our ability to meet market demand for our products. Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs. Our product candidate requires specific shipping, storage, handling and administration at the clinical sites, including cold- chain logistics, which could subject our product candidates to risk of loss or damage. Our product candidates are sensitive to temperature, storage and handling conditions. They must be stored at very low temperatures in specialized freezers or specialized shipping containers until immediately prior to use. For administration, the cryopreserved product container must be carefully removed from storage, and rapidly thawed under controlled temperature conditions in an area proximal to the patient' s bedside and administered into the patient. The handling, thawing and administration of the cryopreserved therapy product must be performed according to specific instructions, typically using specific disposables, specific bags and in some steps within specific time periods. Failure to correctly handle our product, including the potential breakage of the cryopreservation bags or to follow the instructions for thawing and administration and or failure to administer our product within the specified period post- thaw could negatively impact the efficacy and or safety of our product, or cause a loss of product. In addition, our product candidates must be cryopreserved / frozen using specialized equipment and following specific procedures in order to be stored without damage in a cost- efficient manner and without degradation. We may encounter difficulties in further optimization of freezing and thawing methodologies, and also in obtaining the necessary regulatory approvals for using such methodologies in treatment. If we cannot adequately demonstrate similarity of our frozen product to the unfrozen or thawed form to the satisfaction of the FDA, we could face substantial delays in our regulatory approvals. If we are unable to freeze FCR001 or other cell- based therapies we may develop for storage and shipping purposes, our ability to promote adoption and standardization of our products, as well as achieve economies of scale by centralizing production facilities, will be limited. Even if we are able to successfully freeze and thaw FCR001 without damage in a cost- efficient manner and without degradation to the satisfaction of the FDA to support regulatory approval, we will still need to scale- up a cost- effective and reliable cold- chain distribution and logistics network, which we may be unable to accomplish. Failure to effectively scale- up our cold- chain supply logistics, by us or third parties, could in the future lead to additional manufacturing costs and delays in our ability to supply required quantities for commercial supply. For these and other reasons, we may not be able to manufacture FCR001 or other cell- based therapies we may develop at commercial scale or in a cost- effective manner. The process of manufacturing cell therapies is inherently susceptible to contamination. If microbial, viral or other contaminations are discovered in any product candidate or in our manufacturing facility, our manufacturing facility may need to be closed for an extended period of time to allow us to investigate and remedy the contamination. Because our cell therapy product candidates are manufactured

from the cells of third- party donors, the process of manufacturing is susceptible to the availability of the third- party donor material. The process of developing products that can be commercialized may be particularly challenging, even if they otherwise prove to be safe and effective. The manufacture of these product candidates involves complex processes. Some of these processes require specialized equipment and highly skilled and trained personnel. The process of manufacturing these product candidates will be susceptible to additional risks, given the need to maintain aseptic conditions throughout the manufacturing process. Contamination with viruses or other pathogens in either the donor material or materials utilized in the manufacturing process or ingress of microbiological material at any point in the process may result in contaminated or unusable product. These types of contaminations could result in manufacturing delays which could result in delays in the development of our product candidates. These contaminations could also increase the risk of adverse side effects. Risks Related to Our Intellectual Property Risks Related to our Intellectual Property Licensed from ULRF We depend substantially on intellectual property licensed from the ULRF, and termination of this license could result in the loss of significant rights, which would materially harm our business. We depend substantially on the ULRF License for our intellectual property, data and know- how. The ULRF License imposes, and we expect that future license agreements will impose, various development, diligence, commercialization and other obligations on us. This license may be terminated upon certain conditions. Any termination of this license could result in the loss of significant rights and could harm our ability to commercialize our product candidate. In the future, we may also enter into additional license agreements that are material to the development of our product candidates. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those related to: the scope of rights granted under the license agreement and other interpretation- related issues; whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; our right to sublicense patent and other rights to third parties under collaborative development relationships; our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators. If disputes over intellectual property that we have licensed, or license in the future, prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. In addition, the resolution of any such disputes could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. We may rely on third parties from whom we license proprietary technology to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be related to our in- licensed intellectual property. For example, we cannot be certain that such activities by these licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third- party infringer of the intellectual property rights, or defend certain of the intellectual property that may be licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect such licensed intellectual property, our ability to commercialize products could suffer. Risks Related to our Intellectual Property Protection If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and manufacturing process, or if the scope of the intellectual property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be adversely affected. We rely upon a combination of patents, trademarks, trade secrets and confidentiality agreements that we own or possess or that are owned or possessed by our collaborators that are in- licensed to us under licenses, including the ULRF License, to protect the intellectual property related to our technology and product candidates. When we refer to " our " technologies, inventions, patents, patent applications or other intellectual property rights, we are referring to both the rights that we own or possess as well as those that we in- license, many of which are critical to our intellectual property protection and our business. For example, our product candidates and Facilitating Allo- HSCT Therapy are protected by patents or patent applications of ULRF that we have licensed and as confidential know- how and trade secrets. Additionally, our earlier stage product candidates are not yet protected by any patents or patent applications. If the intellectual property that we rely on is not adequately protected, competitors may be able to use our technologies and erode or negate any competitive advantage we may have. The patentability of inventions and the validity, enforceability and scope of patents in the biotechnology field is highly uncertain because it involves complex legal, scientific and factual considerations, and it has in recent years been the subject of significant litigation. Moreover, the standards applied by the U. S. Patent and Trademark Office (" USPTO ") and non- U. S. patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents. There is no assurance that all potentially relevant prior art relating to our patents and patent applications is known to us or has been found in the instances where searching was done. Further, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Thus, we may be unaware of prior art that could be used to invalidate an issued patent or prevent a pending patent application from issuing as a patent. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim of one of our patents or patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of such claim. As a consequence of these and other factors, our patent applications may fail to result in issued patents with

claims that cover our product candidates in the United States or in other countries. Even if patents have issued or do successfully issue from patent applications, and even if these patents cover our product candidates, third parties may challenge the validity, ownership, enforceability or scope thereof, which may result in these patents being narrowed, invalidated, circumvented, or held to be unenforceable. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable. Even if unchallenged, our patents and patent applications or other intellectual property rights may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. The possibility exists that others will develop products on an independent basis which have the same or similar effects as our product candidates and which do not infringe our patents or other intellectual property rights, or that others will design around the claims of patents that we have had issued that cover our product candidates. If the breadth or strength of protection provided by our patents and patent applications with respect to our product candidates is threatened, it could jeopardize our ability to commercialize our product candidates and dissuade companies from collaborating with us. We may also desire to seek a license from a third party who owns intellectual property that may be necessary or useful for providing exclusivity for our product candidates, or for providing the ability to develop and commercialize a product candidate in an unrestricted manner. There is no guarantee that we will be able to obtain a license from such a third party on commercially reasonable terms, or at all. Obtaining and enforcing biopharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain patents licensed from third parties. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third- party infringer of the intellectual property rights, or defend certain of the intellectual property that may be licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We and our collaborators have filed a number of patent applications covering our product candidates or methods of using or making those product candidates. We cannot offer any assurances about which, if any, patents will be issued with respect to these pending patent applications, the breadth of any such patents that are ultimately issued or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our collaborators were the first to file any patent application related to a product candidate. We or our collaborators may also become involved in proceedings regarding our patents, including patent infringement lawsuits, interference or derivation proceedings, oppositions, reexaminations, and inter partes and post- grant review proceedings before the USPTO, the European Patent Office and other non- U. S. patent offices. Even if granted, patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent generally occurs 20 years after the earliest U. S. non-provisional application is filed. Although various extensions may be available if certain conditions are met, the life of a patent and the protection it affords is limited. If we encounter delays in our clinical trials or in obtaining regulatory approvals, the period of time during which we could exclusively market any of our product candidates under patent protection, if approved, could be reduced. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be vulnerable to competition from biosimilar products, as we may be unable to prevent competitors from entering the market with a product that is similar or identical to our product candidates. In the United States, a patent that covers an FDA- approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (" Hatch- Waxman Act "), which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. In the European Union, our product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial. In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh- Dole Act. The federal government retains a " nonexclusive, nontransferable, irrevocable, paid- up license " for its own benefit. The Bayh- Dole Act also provides federal agencies with " march- in rights ". March- in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a " nonexclusive, partially exclusive, or exclusive license " to a " responsible applicant or applicants. " If the patent owner refuses to do so, the government may grant the license itself. Some of our licensed patents are subject to the provisions of the Bayh- Dole Act. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, enforcing and defending patents on all of our product candidates in all countries throughout the world would be prohibitively expensive. Our intellectual property rights in

certain countries outside the United States may be less extensive than those in the United States. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we and our future collaborators may not be able to prevent third parties from practicing our inventions in countries outside the United States, or from selling or importing infringing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection or where we do not have exclusive rights under the relevant patents to develop their own products and, further, may export otherwise-infringing products to territories where we and our collaborators have patent protection but where enforcement is not as strong as that in the United States. These infringing products may compete with our product candidates in jurisdictions where we or our future collaborators have no issued patents or where we do not have exclusive rights under the relevant patents, or our patent claims and other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our collaborators to stop the infringement of our patents or marketing of competing products in violation of our intellectual property rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our future collaborators. We or our future collaborators may not prevail in any lawsuits that we or our collaborators initiate, and even if we or our collaborators are successful, the damages or other remedies awarded, if any, may not be commercially meaningful. In some jurisdictions, including European Union countries, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our future collaborators are forced to grant a license to third parties under patents relevant to our business, or if we or our future collaborators are prevented from enforcing patent rights against third parties, our competitive position may be substantially impaired in such jurisdictions. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and / or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and / or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non- U. S. patent agencies. The USPTO and various non- U. S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business. If we are unable to protect the confidentiality of our trade secrets and other proprietary information, the value of our technology could be materially adversely affected and our business could be harmed. In addition to seeking the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and other elements of our technology, discovery and development processes that involve proprietary know- how, information or technology that is not covered by patents. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, including by enabling them to develop and commercialize products substantially similar to or competitive with our product candidates, thus eroding our competitive position in the market. Trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements and invention assignment agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, collaborators, or outside scientific advisors might intentionally or inadvertently disclose our trade secrets or confidential, proprietary information to our competitors. In addition, our competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, the laws of certain foreign countries do not protect proprietary rights such as trade secrets to the same extent or in the same manner as the laws of the United States. Misappropriation or unauthorized disclosure of our trade secrets to third parties could impair our competitive advantage in the market and could materially adversely affect our business, results of operations and financial condition. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to

build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations. Risks Related to Potential Third Party Claims If we are sued for infringing the intellectual property rights of third parties, the resulting litigation could be costly and time- consuming and could prevent or delay our development and commercialization efforts. Our commercial success depends, in part, on us and our future collaborators not infringing the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation and other adversarial proceedings, both within and outside the United States, involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interference or derivation proceedings, oppositions, reexaminations, and inter partes and post- grant review proceedings before the USPTO and non- U. S. patent offices. Numerous U. S. and non- U. S. issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of third parties' patent rights, as it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable. For example, we are aware of certain issued patents that may cover some of our product candidates, and while we believe these patent claims are not valid and would not establish a basis for our operations to be enjoined, we may be subject to litigation and be obligated to pay reasonable royalties to the patent owners. In addition, many companies in intellectual property- dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. Third parties may assert infringement claims against us based on existing or future intellectual property rights, alleging that we are employing their proprietary technology without authorization. There may be third- party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacturing of our product candidates that we failed to identify. For example, patent applications covering our product candidates could have been filed by others without our knowledge, since these applications generally remain confidential for some period of time after their filing date. Even pending patent applications that have been published, including some of which we are aware, could be later amended in a manner that could cover our product candidates or their use or manufacture. After issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. In addition, we may have analyzed patents or patent applications of third parties that we believe are relevant to our activities and believe that we are free to operate in relation to any of our product candidates, but our competitors may obtain issued claims, including in patents we consider to be unrelated, which may block our efforts or potentially result in any of our product candidates or our activities infringing their claims. If we or our future collaborators are sued for patent infringement, we would need to demonstrate that our product candidates, products and methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving that a patent is invalid or unenforceable is difficult and even if we are successful in the relevant proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted from other activities. If any issued third- party patents were held by a court of competent jurisdiction to be valid and enforceable and cover aspects of our materials, formulations, methods of manufacture or methods for treatment, we could be forced, including by court order, to cease developing, manufacturing or commercializing the relevant product candidate until the relevant patent expires. Alternatively, we may desire or be required to obtain a license from such third party in order to use the infringing technology and to continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonably terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property licensed to us. Additionally, in the event of a successful intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent, or to redesign our infringing product candidates, which may be impossible or technically infeasible, or require substantial time and monetary expenditure. In addition to paying monetary damages, we may lose valuable intellectual property rights or personnel and the parties making claims against us may obtain injunctive or other equitable relief, which could impose limitations on the conduct of our business. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. As is common in the biotechnology and pharmaceutical industry, we employ individuals who are or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. In particular, our founder and Senior Scientific Advisor, Suzanne T. Ildstad, MD, is the Jewish Hospital Distinguished Professor of Transplantation Research, Director of the Institute for Cellular Therapeutics, and a Professor in the Department of Surgery with associate appointments in the Departments of Physiology & Biophysics and Microbiology & Immunology at the University of

Louisville School of Medicine. Our Chief Technology Officer, Michael Zdanowski, and certain other employees or consultants were previously employed at Medeor Therapeuties, Inc., which is developing a cell therapy similar to ours. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee' s former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. We may face claims that we misappropriated, or otherwise acted unjustly or in bad faith with respect to, the confidential information or trade secrets of third parties, including collaborators or former collaborators. If we are found to have misappropriated a third party' s trade secrets, or otherwise to have acted unjustly or in bad faith with respect to such trade secrets, we may be prevented from further using these trade secrets, which could limit our ability to develop our product candidates, or may be otherwise subject to monetary damages. We may face claims that we misappropriated, or otherwise acted unjustly or in bad faith with respect to, the confidential information or trade secrets of third parties, including collaborators or former collaborators. Defending against intellectual property claims could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle before a final judgment, any litigation could burden us with substantial unanticipated costs. Parties making claims against us may be able to sustain the costs of litigation more effectively than we can because they have substantially greater resources. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation and these announcements may have negative impact on the perceived value of our product candidates, programs or intellectual property. Any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. As a result of all of the foregoing, any actual or threatened intellectual property claim, including claims that we acted unjustly or in bad faith with respect to the intellectual property of others, could prevent us from developing or commercializing a product candidate, subject us to monetary damages, or force us to cease some aspect of our business operations. We cannot ensure that additional patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and / or unenforceable. We have issued and pending U. S. and foreign patent applications in our portfolio, however, we cannot predict: if and when additional patents may issue based on our patent applications; the scope of protection of any patent issuing based on our patent applications; whether the claims of any patent issuing based on our patent applications will provide protection against competitors; whether or not third parties will find ways to invalidate or circumvent our patent rights; whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; whether we will need to initiate litigation or administrative proceedings to enforce and / or defend our patent rights which will be costly whether we win or lose; and whether the patent applications that we own or in- license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. We cannot be certain that the claims in our pending patent applications directed to our product candidates and / or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the " prior art, " information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. The examination process may require us to narrow our claims, which may limit the scope of patent protection that we may obtain. Even if the patents are issued based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries. We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time- consuming and unsuccessful and have a material adverse effect on the success of our business. Third parties may infringe our patents or misappropriate or otherwise violate our intellectual property rights. Our patent applications cannot be enforced against third parties practicing the technology claimed in these applications unless and until a patent issues from the applications, and then only to the extent the issued claims cover the technology. In the future, we or our collaborators may elect to initiate legal proceedings to enforce or defend our or our collaborators' intellectual property rights, to protect our or our collaborators' trade secrets or to determine the validity, ownership, enforceability or scope of our intellectual property rights. Any claims that we or our collaborators assert against perceived infringers could also provoke these parties to assert counterclaims against us or our collaborators alleging that we or our collaborators infringe their intellectual property rights or that our intellectual property rights are invalid or unenforceable. Interference or derivation proceedings provoked by third parties, brought by us or our collaborators, or declared by the USPTO may be necessary to determine the priority of inventions or matters of inventorship with respect to our patents or patent applications. We or our collaborators may also become involved in other proceedings, such as reexamination or opposition proceedings, inter partes review, post- grant review or other pre- issuance or post- grant proceedings before the

USPTO or in non- U. S. jurisdictions relating to our intellectual property or the intellectual property of others. An unfavorable outcome in any of these proceedings could result in us losing our valuable intellectual property rights, require us or our collaborators to cease using the related technology and commercializing our product candidates, or require us to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our collaborators a license on commercially reasonable terms if any license is offered at all. Even if we or our licensors obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us or our collaborators. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Any intellectual property proceedings can be expensive and time- consuming. Our or our collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our collaborators can. Accordingly, despite our or our collaborators' efforts, we or our collaborators may not be able to prevent third parties from infringing upon or misappropriating our intellectual property rights, particularly in countries where the laws may not protect our rights as fully as in the United States. Even if we are successful in the relevant proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted from other activities. In addition, in an infringement proceeding, a court may decide that one or more of our patents is invalid or unenforceable, in whole or in part, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors view these announcements in a negative light, the price of our common stock could be **subject** adversely affected. Risks Related to **significant fluctuations.** Intellectual Property Laws and Regulations Some intellectual property has been discovered through government- funded programs and thus may be subject to federal regulations such as certain reporting requirements, a preference for U. S.- based companies, and the possibility of **the factors that may cause the market price of** " march- in " rights. Compliance with such regulations or **our** the inability **common stock** to **fluctuate include: •** obtain a waiver for meeting such requirements may limit our ability to contract with non- U. S. manufacturers, or, in the unlikely event of the government exercising their " march- in " rights, may limit our exclusive rights. Some of our intellectual property rights were generated through the use of U. S. government funding and are therefore subject to certain federal regulations. As a result **results of clinical trials and preclinical studies** , the U. S. government may have certain rights to intellectual property embodied in certain of our current or **and** future **potential** product candidates pursuant to the Bayh- Dole Act of 1980 (" Bayh- Dole Act "). These U. S. government rights in certain inventions developed under a government- funded program include a non- exclusive , non- transferable, irrevocable worldwide license to use inventions for **or** any governmental purpose. In addition, the **those of our competitors or our existing or future collaborators; • failure** U. S. government has the right, under certain limited circumstances, to require **meet or exceed financial and development projections we may provide to the public; • failure to meet or exceed the financial and development projections of the investment community; • failure of** us to grant exclusive **achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts; • announcements of significant acquisitions** , partially exclusive **strategic collaborations** , **joint ventures or capital commitments by us or** or **our competitors; • actions** non- exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken **by** to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations **regulatory agencies** (also referred to as " march- in rights "). To our knowledge, however, the U. S. government has, to date, not exercised any march- in rights on any patented technology that was generated using U. S. government funds. The U. S. government also has the right to take title to these inventions if we or the applicable grantee fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with **respect** which may require us to expend substantial resources. In addition, the U. S. government requires that any products embodying the subject invention or **our current and future** produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U. S. manufacturers may limit our ability to contract with non- U. S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U. S. government funding, the provisions of the Bayh- Dole Act may similarly apply. Changes in U. S. or foreign patent laws could diminish the value of patents in general, thereby impairing our ability to protect our products. Changes in either the patent laws or interpretation of the patent laws in the United States or non- U. S. jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy- Smith America Invents Act (the " America Invents Act "), enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could

therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates **, clinical studies, manufacturing process** or (ii) invent any of the inventions claimed in our **or sales and marketing terms; • disputes** our **or** licensor's **other developments relating to proprietary rights, including** patents **,** or patent applications. The America Invents Act also included a number of significant changes that affect the way patent applications are prosecuted and also affects patent litigation **matters**. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post- grant proceedings, including post- grant review and , inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or **our ability to obtain** in- licensed patent applications and the enforcement or defense of our owned or in- licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights **for our technologies; • additions or departures** of **key personnel; • significant lawsuits, including** patent **or stockholder litigation; • if securities or industry analysts do not publish research or reports about our business** owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on **or if we issue adverse or misleading opinions regarding our business and stock; • changes in the market valuations of similar companies; • general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors; • sales of securities by us or our securityholders in the** future **; • if we fail to raise** actions by the U. S. Congress, the federal courts, and **an adequate amount of capital** the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to **fund** protect and enforce our intellectual property in the **operations and continued development of our current and** future . Risks Related to Our Financial Condition and Capital Needs We are a late- stage clinical biotechnology company and we have incurred net losses since our inception. We anticipate that we will continue to incur significant net losses for the foreseeable future, and may never achieve or maintain profitability. We are a late- stage clinical biotechnology company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue to date, and we will continue to incur significant research and development and other expenses related to our clinical development and ongoing operations. As a result, we are not profitable and have incurred net losses in each period since our inception. Since our inception, we have devoted substantially all of our resources to developing our product candidate, FCR001, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. Our financial condition and operating results, including net losses, may fluctuate significantly from quarter to quarter and year to year. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance. Additionally, net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net loss was $ 73. 7 million and $ 47. 8 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $ 164. 5 million. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses and capital expenditures to continue to increase. We anticipate that our expenses will increase substantially if and as we: • continue to conduct clinical trials for our product candidate, FCR001; • seek to identify additional product candidates and initiate research, preclinical and clinical development efforts for any future product candidates; **• trading volume of** • seek regulatory approvals for FCR001 or **our** any future **common stock; • announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments; • adverse publicity relating to IL- 6 inhibitor and IL- 6R inhibitor** product candidates that successfully complete clinical development; • scale our in- house manufacturing process to address anticipated commercial needs; • seek to meet regulatory requirements for our in- house manufacturing process; • add operational, financial and management information systems and personnel, including personnel to help us comply with our obligations as a public company; • hire and retain additional personnel, such as clinical, quality control, scientific, manufacturing, commercial and administrative personnel, to support our product candidate development; • maintain, expand and protect our intellectual property portfolio; • establish sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure in the future to commercialize any product candidates for which we may obtain regulatory approval; • adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products; • add equipment and physical infrastructure to support our research and development; and • acquire or in- license other product candidates and technologies. Our expenses could increase beyond our expectations if we are required by the FDA or other regulatory authorities to perform clinical trials in addition to those that we

currently expect, if there are any delays in establishing appropriate manufacturing arrangements for our product candidates, or if we experience delays in the initiation or completion of our clinical trials or the development of any of our product candidates for any reason, including as a result of the COVID- 19 pandemic. We have not yet completed any registrational trials and have no history of commercializing products, which may make it difficult to evaluate the success of our business to date and to assess our future viability. We were first formed in February 2002 under the name Regenerex LLC, and engaged in operations with non- dilutive funding, or in collaboration with Novartis International AG (" Novartis ") from 2013 to 2016, until October 2018 when we closed our first external financing round, converted into a corporation and changed our name to Regenerex, Inc. and subsequently to Talaris Therapeutics, Inc. Since we commenced our operations, we have devoted substantially all of our resources to raising capital, organizing and staffing our company, business planning, conducting discovery and research activities, establishing and protecting our intellectual property portfolio, developing and progressing FCR001 and preparing for clinical trials, and manufacturing initial quantities of FCR001. As an organization, we have not yet demonstrated an ability to successfully complete any Phase 3 clinical trials, obtain regulatory approval, consistently 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 the successful commercialization of any of our product candidates. In addition, our Facilitated Allo- HSCT Therapy is novel and has only been evaluated in a limited number of patients to date. Any predictions about our future success, performance or viability, particularly in view of the rapidly evolving immunotherapy field, may not be accurate given the limits of our operating history and lack of approved products. In addition, given the limits of our operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a research and development focus to a company capable of supporting commercial activities and may not be successful in such a transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, our financial results for any quarterly or annual periods may not be indicative of future operating performance. We will require substantial additional funding to develop and commercialize our product candidates and identify and invest in new product candidates. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product discovery and development programs or commercialization efforts. Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time- consuming, expensive and uncertain process that takes years to complete. We expect to continue to spend substantial amounts of capital to continue the preclinical and clinical development of our current and future programs. If we are able to gain marketing approval for any product candidate we develop, including for any indication for which we are developing or may develop FCR001, we will require substantial additional funding in order to launch and commercialize such product candidates, to the extent that such launch and commercialization are not the responsibility of a collaborator that we may contract with in the future. We may also invest in preparations for launch and commercialization in advance of receiving regulatory approval for a product candidate, and such approval may not be received on a timely basis or at all. In addition, other unanticipated costs may arise in the course of our development efforts. Because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop. Additionally, any COVID- 19- related program setbacks or delays due to changes in federal, state, or local laws and regulations or clinical site policies could impact the timing and cost of the development of our product candidates. Under the terms of the ULRF License Agreement, we are also obligated to make payments upon the achievement of certain development, regulatory and commercial milestones. Our future capital requirements depend on many factors, including: the scope, progress, results and costs of researching and developing FCR001 for our current indication, as well as any other product candidates we may develop, including any COVID- 19- related delays or other effects on our development programs; the timing of, and the costs involved in, obtaining marketing approvals for FCR001 for our current indication, and any other product candidates we may develop; if approved, the costs of commercialization activities for FCR001 for any approved indications, or any other product candidate that receives regulatory approval to the extent such costs are not the responsibility of a collaborator that we may contract with in the future, including the costs and timing of scaling our manufacturing and establishing product sales, marketing, distribution and manufacturing capabilities; subject to receipt of regulatory approval, revenue, if any, received from commercial sales of FCR001 for any approved indications or any other product candidates; the extent to which we in- license or acquire rights to other products, product candidates or technologies; our headcount growth and associated costs as we expand our research and development, increase our office space, and establish a commercial infrastructure; the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and the ongoing costs of operating as a public company. As of December 31, 2022, we had cash, cash equivalents and marketable securities of approximately $ 181. 3 million. We cannot be certain that additional funding will be available on acceptable terms, or at all. Further, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID- 19 pandemic. If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Any of our current or future license agreements may also be terminated if we are unable to meet the payment or other obligations under the agreements. We believe that our cash, cash equivalents and marketable securities as of December 31, 2022 will be sufficient to fund our operating expenses and capital expenditure requirements through at least 12 months from the issuance date of this Annual Report on Form 10- K. Our estimate may prove to be wrong, and we could use our available capital resources earlier than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to

consume capital significantly faster than we currently anticipate, and we may need to seek additional funds earlier than planned. Raising capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on terms that are unfavorable to us. We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, including incurring additional debt, making capital expenditures, entering into licensing arrangements or declaring dividends. If we raise additional funds from third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that are not favorable to us. Market volatility resulting from the COVID- 19 pandemic or other factors may further adversely impact our ability to access capital as and when needed. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our product candidates, grant to others the rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves or take other actions that are adverse to our business. Risks Related to Our Business, Growth and Industry Risks Related to the COVID- 19 Pandemic Our business has been adversely affected by the ongoing COVID- 19 pandemic, and could be further adversely affected by the effects this and other of public health epidemics in regions where we, or third parties on which we rely have significant research, development or production facilities, concentrations of clinical trial sites or other business operations. Our business has been adversely affected by the ongoing COVID- 19 pandemic, and could be further adversely affected by this and other public health epidemics in regions where we, and third parties on which we rely, such as CROs or suppliers, have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of those third- parties, and adversely affect our business. For example, enrollment in our Phase 3 FREEDOM- 1 clinical trial, prior to being discontinued, consistently lagged both our original and revised enrollment projections, significantly limiting the data which we were able to report at periodic medical conferences. In November 2021, when we provided the first interim data in connection with the American Association of Nephrology meeting, we reported data on five dosed patients, only three of whom had met the three- month post- transplant milestone. We believe the COVID- 19 pandemic significantly impacted the ability of our clinical trial sites to attract and enroll clinical trial subjects, which contributed to our decision to discontinue the clinical trial. Furthermore, the performance of our CROs may also be delayed or disrupted by the ongoing COVID- 19 pandemic and current and future variants of the virus, including due to travel or quarantine policies, availabilities of staff, exposure of CRO staff to COVID- 19 or re- prioritization of CRO resources as a result of the pandemic. Quarantines, shelter- in- place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could impact personnel at our manufacturing facilities, including our ability to manufacture FCR001, or the availability or cost of materials, which would disrupt our supply chain. Any manufacturing supply interruption of materials could adversely affect our ability to conduct ongoing and future research and manufacturing activities. In addition, our clinical trials have been and may be further affected by the ongoing COVID- 19 pandemic, particularly as viral variants, such as the COVID- 19 omicron variant and associated sub- variants, continue to proliferate in areas where we have clinical trials. Clinical site initiation and patient enrollment has been and may be further delayed due to prioritization of healthcare system resources toward the ongoing COVID- 19 pandemic. For example, some of our patients may not be able to comply with clinical trial protocols and follow- ups if quarantines impede patient movement, interrupt healthcare services, reduce patient access to trial investigators, hospitals and trial sites, and limit on- site personnel support at various trial sites. Similarly, COVID- 19 and current and evolving variants may adversely impact our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID- 19, thereby adversely impacting our clinical trial operations and enrollment timelines. The spread of COVID- 19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID- 19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID- 19 could materially affect our business and the value of our common stock. The global ongoing COVID- 19 pandemic continues to rapidly evolve. The ultimate impact of the COVID- 19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these potential effects could have a material impact on our operations, and we will continue to monitor the COVID- 19 situation closely. Risks Related to Employee and Growth Matters We are highly dependent on our key personnel and anticipate hiring new key 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 ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel. While we expect to engage in an orderly transition process as we integrate newly appointed officers and managers, we face a variety of risks and uncertainties relating to management transition, including diversion of management attention from business concerns, failure to retain other key personnel or loss of institutional knowledge. In addition, the loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business. We conduct our main operations at our cell processing facility in Louisville, Kentucky, we maintain a corporate office in Wellesley, Massachusetts and a laboratory in Houston, Texas. Competition for skilled personnel, particularly in the rapidly growing cell and gene therapy (" CGT ") market, is intense, particularly in Massachusetts, which serves as headquarters to many other biopharmaceutical companies and many academic and research institutions, and may limit our ability to hire and retain highly qualified personnel

~~on acceptable terms or at all. Changes to U. S. immigration and work authorization laws and regulations, including those that restrain the flow of scientific and professional talent, can be significantly affected by political forces and levels of economic activity. Our business may be materially adversely affected if legislative or administrative changes to immigration or visa laws and regulations impair our hiring processes and goals or projects involving personnel who are not U. S. citizens. To encourage valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at- will employment, which means that any of our employees could leave our employment at any time, with or without notice. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid- level and senior managers as well as junior, mid- level and senior scientific and medical personnel. It may be difficult or time- consuming to recruit all the qualified personnel that we need in order to scale- up our manufacturing operations in Louisville. Our recent reduction in force may negatively impact employee morale and productivity. Further, uncertainties surrounding the future of our clinical programs may increase retention risk. In connection with the evaluation of strategic alternatives that we announced in February 2023, and in order to extend our resources, we implemented a restructuring plan that included reducing our workforce by approximately one- third. In order to retain remaining employees primarily focused on maintaining the Company' s cell therapy CMC capabilities and executing FREEDOM- 3, we offered assurance of severance arrangements and retention benefits to certain remaining personnel. There can be no assurance that these programs will allow us to retain the personnel necessary to implement our strategic assessment plans, or continue our FREEDOM- 3 clinical program and CMC manufacturing capabilities. In addition, we may take additional restructuring steps in the future as we seek to realize operating synergies, optimize our operations to achieve our target operating model and profitability objectives, respond to market forces or better reflect changes in the strategic direction of our business. Disruptions in operations may occur as a result of taking these actions. Taking these actions may also result in significant expense for us ~~, including with respect to ~~workforce reductions, as well as decreased productivity due to employee distraction~~ **other such products on the market; • the introduction of technological innovations or new therapies that compete with the products** and ~~unanticipated employee turnover~~ **services of ours; and • period- to- period fluctuations in our financial results** . **Moreover, the stock markets in general have experienced** ~~Substantial~~ **substantial** ~~expense~~ **volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of** ~~or~~ **our** ~~business disruptions~~ **common stock. In addition, a recession, depression or other sustained adverse market event** resulting from ~~restructuring and reorganization activities~~ **rising interest rates, inflation, global geopolitical conflict, or other macroeconomic conditions** could **materially and** adversely affect our ~~operating results~~ **business and the value of our common stock** . In ~~addition~~ **the past** , **following periods of volatility in the market price of a company' s securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism** if ~~there are unforeseen expenses associated~~ **we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict** with ~~such realignments in~~ our ~~business strategies~~ **strategic direction or seek** ~~, and we incur unanticipated charges~~ **changes in** ~~or liabilities, then~~ **the composition of** ~~we may not be able to effectively realize the expected cost savings or~~ **our board** ~~other benefits~~ of **directors** ~~such actions which~~ could have an adverse effect on our ~~business,~~ operating results and financial condition. **Provisions** ~~Our employees, principal investigators, consultants and collaborators may engage~~ in ~~misconduct or~~ **our charter documents** ~~other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation. We are exposed to the risk of employee and third- party fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions, litigation and serious harm to our reputation. It is not always possible to identify and deter employee and third- party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, financial condition and results of operations. Risks Related to Business Disruptions If our security measures are compromised now, or in the future, or the security, confidentiality or integrity or availability of our information technology, software, services, communications or data is compromised, limited, or fails, this could result in a materially adverse impact, including without limitation, damage to our reputation, significant financial and legal exposure, breach or triggering of data protection laws, privacy policies and data protection obligations, disruption to our clinical trial or administrative activities, or loss of customers or collaborators. We rely~~

~~on information technology systems that we or our third- party providers operate to process, transmit and store electronic information in our day- to- day operations. In connection with our business, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information, as well as intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other parties. Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors, consultants and relevant third parties are vulnerable to several threats, including without limitation damage from computer viruses, unauthorized access, terrorism, war, natural disasters, and telecommunication and electrical failures. We exercise little or no control over these third parties, which increases our vulnerability to problems with their systems. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, phishing attacks, denial- of- service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. Although we have not, to our knowledge, experienced a material security incident, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches. We may be required to expend significant resources, fundamentally change our business activities and practices, or modify our services, software, operations or information technology in an~~ **and** ~~effort to protect against security breaches and to mitigate, detect, and remediate actual and potential vulnerabilities. Applicable data protection laws, privacy policies and other data protection obligations may require us to implement specific security measures or use industry- standard or reasonable measures to protect against security breaches. If we, our service providers, collaborators, or other relevant third parties have experienced or in the future experience, any security incident (s) that result in any data loss, deletion or destruction, unauthorized access to, loss of, unauthorized acquisition or disclosure of, or inadvertent disclosure of sensitive information or compromise related to the security, confidentiality, integrity or availability of our (or their) information technology, software, services, communications or data, it may result in a material adverse impact, including without limitation, legal liability, government investigations an inability to conduct our clinical trials, regulatory investigations, enforcement actions, indemnity obligations, the disruption of our operations, delays to the development and commercialization of our product candidates, negative publicity and financial loss. A failure by us or relevant third parties to detect, anticipate, measure or detect such security incidents could result in similar material adverse impacts. Additionally, applicable data protection laws, privacy policies and data protection obligations may require us to notify relevant stakeholders of security breaches, including affected individuals, customer and regulators. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to material adverse impacts, including without limitation, negative publicity, a loss of customer confidence in our products or security measures or a breach of contract claim. There can be no assurances that the limitations of liability in our contract would be enforceable or adequate or would otherwise protect us from liabilities or damages. Failures or significant downtime of our information technology or telecommunication systems or those used by our third- party service providers could cause significant interruptions in our operations and adversely impact the confidentiality, integrity and availability of sensitive or confidential information. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of data from completed or future preclinical studies and clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. While we maintain general liability insurance coverage and coverage for errors or omissions, we cannot assure that such coverage will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or other material adverse impacts arising out of our privacy and security actions we may experience, or that such coverage will continue to be available on acceptable terms or at all. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or that results in changes to our insurance policies (including premium increases or the imposition of large deductible or co- insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim. Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our manufacturing 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, medical epidemics 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. Market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. Market conditions such as inflation, volatile energy costs, geopolitical issues, unstable global credit markets and financial conditions could lead to periods of significant economic instability, diminished liquidity and credit availability, diminished expectations for the global economy and expectations of slower global economic growth going forward. Our business and operations may be adversely affected by such instability, including any such inflationary fluctuations, economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on**

favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other collaborators may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn. Global economic uncertainty and weakening product demand caused by political instability, changes in trade agreements and conflicts, such as the conflict between Russia and Ukraine, could adversely affect our business and financial performance. Economic uncertainty in various global markets caused by political instability and conflict and economic challenges caused by the COVID- 19 pandemic has resulted, and may continue to result, in weakened demand for our products and services and difficulty in forecasting our financial results and managing inventory levels. Political developments impacting government spending and international trade, including current or potential government- imposed sanctions, potential government shutdowns and trade disputes and tariffs, may negatively impact markets and cause weaker macro- economic conditions. The effects of these events may continue due to potential U. S. government shutdowns and the transition in administrations, and the United States' ongoing trade disputes with China and other countries. The continuing effect of any or all of these events could adversely impact demand for our products, harm our operations and weaken our financial results. Risks Related to Laws and Regulations that May Affect our Business Legislation or other changes in U. S. tax law could adversely affect our business and financial condition. The rules dealing with U. S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof. Our ability to use our U. S. net operating loss carryforwards and certain other U. S. tax attributes may be limited. Our ability to use our U. S. federal and state net operating losses to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our net operating losses. Under current law, unused U. S. federal net operating losses generated for tax years beginning after December 31, 2017 are not subject to expiration and may be carried forward indefinitely. Such U. S. federal net operating losses generally may not be carried back to prior taxable years, except that, net operating losses generated in 2018, 2019 and 2020 may be carried back to each of the five tax years preceding the tax years of such losses. Additionally, the amount of net operating loss carryforwards generated in taxable years beginning after December 31, 2017 that we are permitted to deduct in a taxable year beginning after December 31, 2020, is limited to 80 % of our taxable income in each such taxable year to which the net operating loss carryforwards are applied. In addition, both our current and our future unused U. S. federal net operating losses and tax credits may be subject to limitations under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the " Code "), if we undergo an " ownership change, " generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three- year period. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. Our net operating losses and tax credits may also be impaired or restricted under state law. As of December 31, 2022, we had U. S. federal net operating loss carryforwards of approximately $ 96. 9 million, and our ability to utilize those net operating loss carryforwards could be limited by an " ownership change " as described above, which could result in increased tax liability to us. We are subject to U. S. anti- corruption laws and regulations and can face serious consequences for violations. We are subject to anti- corruption laws, including the U. S. domestic bribery statute contained in 18 U. S. C. 201, the U. S. Travel Act, and the U. S. Foreign Corrupt Practices Act of 1977, as amended. These anti- corruption laws generally prohibit companies and their employees, agents, and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to recipients in the public or private sector. We can be held liable for the corrupt or illegal activities of our agents and intermediaries, even if we do not explicitly authorize or have actual knowledge of such activities. Violations of anti- corruption laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. Likewise, any investigation of potential violations of anti- corruption laws could also have an adverse impact on our reputation, our business, results of operations and financial condition. If product liability lawsuits are brought against, we may incur substantial liabilities and may be required to limit commercialization of any products that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: decreased demand for any product candidates or products that we may develop; termination of clinical trial sites or entire trial programs; injury to our reputation and significant negative media attention; withdrawal of clinical trial participants; significant costs to defend the related litigation; substantial monetary awards to study subjects or patients; loss of revenue; exhaustion of any available insurance and our capital resources; diversion of management and scientific resources from our business operations; the inability to commercialize any products that we may develop; and a decline in our share price. We currently hold product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks,

but which may not be adequate to cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidate in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business. Risks Related to Ownership of Our Common Stock Risks Related to our Common Stock The price of our stock may be volatile, and you could lose all or part of your investment. The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various 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 Quarterly Report, these factors include: • actual or anticipated variations in quarterly operating results; • our cash position; • our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; • publication of research reports about us or our industry, or cell therapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts; • changes in the market valuations of similar companies; • overall performance of the equity markets; • sales of our common stock by us or our stockholders in the future; • trading volume of our common stock; • changes in accounting practices; • ineffectiveness of our internal controls; • disputes or other developments relating to intellectual property or proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; • significant lawsuits, including intellectual property or stockholder litigation; • changes in the structure of health care payment systems; • general political and economic conditions, including impacts from the COVID- 19 pandemic; and • other events or factors, many of which are beyond our control. In addition, the stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company' s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management' s attention and resources, which would harm our business, financial condition, results of operation and future prospects. Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant influence over matters subject to stockholder approval. Our executive officers, directors, and 5 % stockholders beneficially owned approximately 68. 7 % of our outstanding voting common stock as of December 31, 2022. The voting power of this group may increase to the extent they convert shares of non- voting common stock they hold into common stock. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders 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 may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. Our business is affected by macroeconomic conditions, including rising inflation, interest rates and supply chain constraints. Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties such as those resulting from the current and future conditions in the global financial markets. For instance, rising interest rates have impacted the Company' s net income. Recent supply chain constraints have led to higher inflation, which if sustained could have a negative impact on the Company' s product development and operations. If inflation or other factors were to significantly increase our business costs, our ability to develop our current pipeline and new therapeutic products may be negatively affected. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the operation of our business and our ability to raise capital on favorable terms, or at all, in order to fund our operations. Similarly, these macroeconomic factors could affect the ability of our third- party suppliers and manufacturers to manufacture clinical trial materials for our product candidates. Risks Related to our Filer Status We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors. We are an emerging growth company, as defined in the JOBS Act, enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002, as amended (the " Sarbanes- Oxley Act "), reduced disclosure obligations regarding executive compensation in this Annual Report and our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the completion of our offering in May 2021, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $ 1. 235 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock and non- voting common stock that are held by non- affiliates to exceed $ 700 million as of the prior June 30th, and (2) the date on which we have issued more than $ 1 billion in non- convertible debt during the prior three- year period. Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to not " opt out " of this exemption from complying with new or revised accounting standards and, therefore, we will adopt new or revised accounting standards at the time private companies adopt the new or

~~revised accounting standard and will do so until such time that we either (i) irrevocably elect to " opt out " of such extended transition period or (ii) no longer qualify as an emerging growth company. Even after we no longer qualify as an emerging growth company, we may still qualify as a " smaller reporting company, " which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions applicable to emerging growth companies and smaller reporting companies. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. Risks Related to our Certificate of Incorporation and Bylaws Anti- takeover provisions under our certificate of incorporation and bylaws and~~ Delaware law could ~~delay or prevent a change of control, which could limit the market~~ -- **make** ~~price of our common stock and~~ - **an acquisition of us more difficult and** may ~~prevent or frustrate~~ **discourage any takeover** attempts ~~by our~~ stockholders **may consider favorable, and may lead** to **entrenchment of** ~~replace or remove our current~~ management. ~~Our~~ **Provisions of our** amended and restated certificate of incorporation **, as amended,** and ~~our~~ amended and restated bylaws ~~contain provisions that~~ could delay or prevent ~~a change~~ **changes** ~~of~~ **in** control ~~of our company~~ or changes in ~~our~~ **management without the consent of the** board of directors ~~that our stockholders might consider favorable~~ . ~~Some of these~~ **These** provisions **will** include **the following** : ~~•~~ a board of directors divided into three classes serving staggered three- year terms, such that not all members of the board will be elected at one time; ~~•~~ a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders; ~~•~~ a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office; ~~•~~ 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 not less than two- thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our **charter** ~~certificate of incorporation~~ ; and ~~•~~ 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 common stock. In addition, ~~because we are incorporated in Delaware, we are governed by the~~ **these** provisions **would apply even if we were to receive an offer that some** ~~of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with~~ stockholders **may consider beneficial** ~~owning 15 % or more of our outstanding voting stock~~ . ~~These~~ **We will also be subject to the** anti- takeover provisions ~~and~~ **contained in Section 203 of the DGCL. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15 % or more of its capital stock unless the holder has held the stock for three years or, among** other **exceptions, the** ~~provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our~~ board of directors **has approved** ~~or initiate actions that are opposed by the then~~ - **the** ~~- current board of directors and could also delay or impede a merger, tender offer, or proxy contest and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control~~ transaction ~~or changes in our board of directors could cause the market price of our common stock to decline~~ . Our bylaws **provide that** ~~designate certain courts as~~ the ~~sole and~~ **Court of Chancery of the State of Delaware is the** exclusive forum for ~~certain types of actions~~ **substantially all disputes between us** and ~~proceedings that may be initiated by~~ our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers ~~,~~ or **other** employees. Our bylaws provide that ~~, unless we consent in writing to an alternative forum,~~ the Court of Chancery of the State of Delaware **is** ~~will be~~ the sole and exclusive forum for any ~~state law claims for (i) any~~ derivative action or proceeding brought on our behalf, ~~(ii)~~ any action asserting a ~~claim of~~ breach of fiduciary duty ~~owed by any of our directors~~ , ~~officers, and employees to us or our stockholders, (iii)~~ any action asserting a claim **against us** arising pursuant to any ~~provision~~ **provisions** of the **DGCL** ~~Delaware General Corporation Law~~ , our ~~amended and restated~~ certificate of incorporation or ~~our amended and restated~~ bylaws **,** or ~~(iv)~~ any action asserting a claim **against us** that is governed by the internal affairs doctrine ~~, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein (the " Delaware Forum Provision ")~~ . The ~~Delaware~~ **exclusive** ~~Forum~~ **forum** ~~Provision~~ **provision** ~~will~~ **does** not apply to ~~any causes of action~~ **actions** arising under the ~~Securities Act or the~~ Exchange Act. ~~Our~~ **The** amended and restated bylaws ~~further~~ **will also** provide that ~~, unless we consent in writing to the selection of an alternative forum,~~ the federal district courts of the ~~United States shall~~ **U. S will** be the ~~sole and~~ exclusive forum for ~~resolving~~ **the resolution of** any complaint asserting a cause ~~or causes~~ of action ~~arising~~ under the Securities Act ~~(the " Federal Forum Provision "). In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder~~ . The ~~Delaware Forum Provision~~ **provision** ~~and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, the forum selection clauses in our amended and restated bylaws~~ may limit ~~our~~ **a** ~~stockholders~~ - **stockholder** ' **s** ability to bring a claim in a **judicial** forum that ~~they~~ **it** ~~find~~ **finds** favorable for disputes with us or our directors, officers or **other** employees, which may discourage such lawsuits against us and our directors, officers and **other** employees ~~even though~~ **. Alternatively, if a court were to find the choice of forum provision contained in the certificate of incorporation and bylaws to be inapplicable or unenforceable in** an action ~~, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require~~

~~claims under the Securities Act be brought in federal court were " facially valid " under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable~~ , we may incur additional costs associated with resolving such **action in** ~~matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would~~ other ~~courts~~ **jurisdictions** , **which** ~~including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders. General Risk Factors Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non- performance by financial institutions or transactional counterparties,~~ could **materially and** adversely affect **our** ~~the Company' s current and projected~~ business **,** ~~operations and its~~ financial condition and results of operations ~~. Adverse developments involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (" SVB"), was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (" FDIC "), as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. The Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money, including funds held in uninsured deposit accounts, after only one business day of closure. The U. S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $ 25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. There is no guarantee, however, that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion~~ . We do not ~~hold cash deposits or securities at SVB and have not experienced any adverse impact to our liquidity or to our current and projected business operations, financial condition or results of operations. However, uncertainty remains over liquidity concerns in the broader financial services industry, and our business, our business partners, or industry as a whole may be adversely impacted in ways that we cannot predict at this time. Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the Company, the financial institutions with which the Company has credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which the Company has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets and termination of cash management arrangements and / or delays in accessing or actual loss of funds subject to cash management arrangements. In addition, widespread investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations. In addition, a critical vendor, CDMO, or business partner could be adversely affected by any of the liquidity or other risks that are described above as factors, which in turn, could have a material adverse effect on our current and / or projected business operations and results of operations and financial condition. Any CDMO, business partner, or supplier bankruptcy or insolvency, or any breach or default by a CDMO, business partner, or supplier, or the loss of any significant supplier relationships, could result in material adverse impacts on our current and / or projected business operations and financial condition. Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations. Our results of operations could be adversely affected by economic and political changes in the location in which we, or our suppliers and vendors, maintain operations. For example, our business may be generally exposed to the impact of political or civil unrest or military action, including the current conflict between Russia and Ukraine and, while we do not have direct exposure to Ukraine, we do have interests in securing regulatory approval in Europe. The approval process may be impacted based upon the events taking place there. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives. As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We are~~

subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the " Exchange Act "), which will require, among other things, that we file with the Securities and Exchange Commission (the " SEC "), annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes- Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Global Market to implement provisions of the Sarbanes- Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd- Frank Wall Street Reform and Consumer Protection Act (the " Dodd- Frank Act ") was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd- Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as " say on pay " and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of our initial public offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time- consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers. Actions of activist stockholders could cause us to incur substantial costs, divert management' s attention and resources, and have an adverse effect on our business. Stockholder activism, which could take many forms or arise in a variety of situations, has been increasing recently. From time to time, we may be subject to proxy solicitations or proposals by activist stockholders urging us to take certain corporate actions, or otherwise effect changes or assert influence on our board of directors and management. For example, volatility in the price of our common stock or other reasons may in the future cause us to become the target of stockholder activism. If activist stockholder activities ensue, our business could be adversely affected because responding to proxy contests and reacting to other actions by activist stockholders can be costly and time- consuming, disrupt our operations and divert the attention of management and our employees. For example, we may be required to retain the services of various professionals to advise us on activist stockholder matters, including legal, financial and communications advisors, the costs of which may negatively impact our future financial results. In addition, perceived uncertainties as to our future direction, strategy or leadership created as a consequence of activist stockholder initiatives may result in the loss of potential business opportunities, harm our ability to enter into strategic transactions, harm our ability to attract new investors, customers, employees and joint venture partners and cause our stock price to experience periods of volatility or stagnation. If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time- consuming effort that needs to be re- evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We have begun the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes- Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting. We have begun recruiting additional finance and accounting personnel with certain skill sets that we will need as a public company. Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our service to new and existing customers. We do not intend to pay dividends on our common stock, so any returns will be limited to the value of our stock. We currently anticipate that we will **pay** retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends **for in** the foreseeable future. **The current expectation is** In addition, we may enter into agreements that **prohibit us from we will retain our future earnings, if any, to fund the growth of our business as opposed to** paying **cash** dividends **. As a result** without prior written consent from our contracting parties , **capital appreciation, if any,** or which other terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock **will be our** . Any return to stockholders **' sole source** will therefore be limited to the appreciation of **gain** their stock, which may never occur. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. In the event one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these -- **the foreseeable future** analysts ceases coverage of our

~~company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline~~. ~~We may be at an increased risk of securities class action litigation. Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.~~ ~~90~~