Risk Factors Comparison 2024-03-28 to 2023-03-22 Form: 10-K

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Careful consideration should be given to the following risk factors, together with the other information contained in this Annual Report, including our financial statements and the related notes. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. This Annual Report also contains forward- looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward- looking statements as a result of a number of factors, including the risks described below. See " Special note regarding forward- looking statements. " Risks related to our business and strategy We **may not be successful in completing a strategic transaction within a reasonable timeframe, on attractive terms or at all. If we are unable to complete a strategic transaction, then we may cease all operations and seek stockholder approval to voluntarily dissolve and liquidate the Company. Since November 2023, we** have ~~realigned~~ **ceased substantially all of our research and development and manufacturing activities while our Board of Directors considers strategic alternatives. We may be unable to complete a strategic transaction within a reasonable timeframe, on attractive terms** ~~our~~ **or** ~~business~~ **at all, and market conditions, including the historical volatility in our common stock will likely limit our ability to raise capital on favorable terms, or at all, and the terms of any public or private offerings of debt or equity securities likely would be significantly dilutive to existing stockholders. There is no set timetable for the overall process given the anticipated timelines for different strategic alternatives may vary, and there can be no assurance that this process will result in us pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms or at all. Given these challenges, if we are unable to complete a strategic transaction, then we may cease all operations and seek stockholder approval to voluntarily dissolve and liquidate the Company. The completion of a strategic transaction or the voluntary dissolution and liquidation of the Company each would have a material adverse effect on our growth** strategy ~~to focusing on developing tests that decentralize testing primarily in the women' s~~ and ~~sexual health markets, which~~ **our results of operations and financial condition. Commercialization of the Talis One system** will require pursuing marketing authorization through the FDA' s standard 510 (k) clearance process. We may not be able to obtain marketing authorization for these tests, which would adversely affect our business, financial condition and results of operations. ~~We have~~ **Our historical research and development efforts** focused ~~our efforts~~ on the development of the Talis One system for FDA clearance or other marketing authorization as a point- of- care testing system for infectious diseases **pursuant** ~~. Prior~~ to ~~the COVID- 19 pandemic, we focused our research and development efforts on developing the Talis One point- of- care system for use in women' s health and STI tests, including CT / NG / TV. However, during the COVID- 19 pandemic, we developed and received an EUA for the stand- alone Talis One COVID- 19 test. Following our revocation request, the EUA was revoked by the FDA in August 2022. We have focused our resources on our multiplex products primarily in the women' s and sexual health markets, initially on a CT / NG / TV test on the Talis One system. In order to gain user experience and feedback on the Talis One system' s physical components, workflow and software, we have resumed IUO system evaluations of the Talis One system. We intend to submit~~ 510 (k) submissions to the FDA ~~for our future test menu. We may not receive clearance or if we receive clearance, there are numerous factors to consider that make it difficult to evaluate our future business prospects and, therefore, we may not be able to achieve our goals and strategy. Failure to achieve marketing authorization for these tests would adversely affect our business, financial conditions and result of operations~~ . Development of the data necessary to obtain marketing authorization of a diagnostic test is time- consuming and carries with it the risk of not yielding the desired results. The performance achieved in initial studies may not be repeated in later studies that may be required to obtain marketing authorizations. In addition, limited results from earlier- stage verification studies may not predict results from studies conducted to obtain marketing authorization. Unfavorable results from ongoing preclinical and clinical studies could result in delays, modifications or abandonment of ongoing analytical or future clinical studies, or abandonment of a product development program, or may delay, limit or prevent regulatory approvals or clearances or commercialization of our products, any of which may materially adversely affect our business, financial condition and results of operations. Furthermore, results that would be sufficient for regulatory approval or clearance may not demonstrate strong performance characteristics, limiting the market demand for the system, which would adversely affect our business. See " — Risks related to regulatory matters. We have no experience with the entire commercialization process for the Talis One system. We have gained some experience with the initial stages of the process, including demand generation, evaluations, and quoting, and we have recent commercialization experience selling and distributing the Antigen Tests as an authorized distributor. As a result, we have limited experience forecasting future financial performance for our products ~~, including any third- party products that we may offer, such as the Antigen Tests,~~ and our actual results may fall below our financial guidance or other projections, or the expectations of analysts or investors, which could cause the price of our common stock to decline ~~. In addition, we are continuing to evaluate the appropriate acquisition model for our Talis One system and cannot predict the proportion of customers that would procure the Talis One instrument through capital purchase versus our planned equipment leasing model. Our results of operations could fluctuate with high variability depending on the changes in the proportion of our customers who directly purchase as compared to renting the equipment which will make it challenging to predict our operating results, particularly during the early stages of any future commercial launch following marketing approval~~ . Future commercialization of the Talis One system in the United States will require pursuing 510 (k) clearance or another available approval path. The launch of new products is inherently uncertain and requires the completion

of commercialization activities that are complex, costly, time- intensive and uncertain, and require us to accurately anticipate patients', providers' and, if applicable, payors' attitudes and needs, the future competitive landscape, and emerging technology and industry trends. This process is conducted in various stages, and each stage presents the risk that we will not achieve our goals on a timely basis, or at all. ~~Our commercial~~ **Commercial** success **of the Talis One system** depends, in part, on the acceptance of our diagnostic tests and services as being safe, accurate, and relatively simple for medical personnel to learn and use, clinically flexible, operationally versatile and, with respect to providers and payors, cost effective. We cannot predict how quickly, if at all, payors, providers, clinics and patients will accept future diagnostic tests and services or, if accepted, how frequently they will be used. These constituents must believe that our diagnostic tests offer benefits over other available alternatives. The degree of market acceptance of **the Talis One system** ~~our current and future diagnostic tests and services~~ depends on a number of factors, including: • whether our customers are willing to incur the upfront costs associated with purchasing Talis One instruments; • whether there is adequate utilization of our tests by clinicians, health systems and other target groups based on the potential and perceived advantages of our diagnostic tests over those of our competitors; • the convenience and ease of use of our diagnostic tests relative to those currently on the market or when our tests are launched; • the effectiveness of our sales and marketing efforts; • our ability to provide incremental data that show the clinical benefits and cost effectiveness, and operational benefits, of our diagnostic tests; • the coverage and reimbursement acceptance of our products and services; • pricing pressure, including from group purchasing organizations (GPOs), seeking to obtain discounts on our diagnostic tests based on the collective bargaining power of the GPO members; • negative publicity regarding our or our competitors' diagnostic tests resulting from defects or errors; • the performance of our tests relative to those of our competitors; • product labeling or product insert requirements by the FDA or other regulatory authorities; and • limitations or warnings contained in the labeling cleared or approved by the FDA or other authorities. Additionally, even if our diagnostic tests achieve widespread market acceptance, they may not maintain that market acceptance over time if competing diagnostic tests or technologies, which are more cost effective or are received more favorably, are introduced. Failure to achieve or maintain market acceptance and / or market share would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition and results of operations. ~~We~~ **Also, there** may ~~experience~~ **be** research and development, regulatory, marketing and other difficulties that could delay or prevent ~~our~~ **the** introduction of enhanced or new products and result in increased costs and the diversion of management' s attention and resources from other business matters. For example, any molecular diagnostic tests that we may develop or further enhance may not prove to be clinically effective, or may not meet our desired target product profile or be offered at acceptable cost and with the sensitivity, specificity and other test performance metrics necessary to address the relevant clinical need or commercial opportunity; our molecular diagnostic test performance in commercial settings may be inconsistent with our validation or other clinical data; we may not be successful in achieving market awareness and demand, whether through our own sales and marketing operations or entering into collaborative arrangements; the collaborative arrangements we enter into may not be successful or we may not be able to maintain those that are successful; healthcare providers may not use any tests that we may enhance or develop; or we may otherwise have to abandon a product, service ore development program in which we have invested substantial resources. An important factor in our ability to commercialize our products is collecting data that supports the value proposition of our products, and in particular that our tests are just as accurate and reliable as central lab testing. The data collected from any studies we complete may not be favorable or consistent with our existing data or may not be statistically significant or compelling to the medical community or to third- party payors seeking such data for purposes of determining coverage for our products. Any of the foregoing could have a negative impact on our ability to commercialize our future products, which could have a material adverse effect on our business, financial condition and results of operations. **It may not be possible to validate** ~~We rely on a significant number of third- party manufacturers~~ **manufacturing** ~~and suppliers~~ for ~~our instrument and cartridges, which has created and may continue to create delays due to~~ the ~~complexity of our manufacturing lines and supply chain, as well as exposure to manufacturing and supply limitations or interruptions and quality and quantity issues. We do not have any commercial- scale manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of the Talis One system and our tests, as well as for commercial supply for any approved products, if ever. The manufacturing of our~~ Talis One instrument and ~~cartridge~~ **cartridges at scale, which may have a material adverse effect on any efforts to commercialize our products. In order to commercialize our products, if approved, it** is **necessary to manufacture** ~~a complex process that involves over 500 raw materials, intermediates and subassemblies. The complexity of~~ the **Talis One** instrument and ~~cartridge designs and number of parts involved has presented manufacturing challenges for us and our third- party manufacturers. In addition, our reliance on these third- party manufacturers exposes us to significant risk that we will not have sufficient quantities of our products at an acceptable cost or quality, which has and could delay, prevent or impair our commercialization efforts when we commercialize. We are also susceptible to increased costs of good associated with rising inflation rates. While we do not have any commercial- scale manufacturing facilities, we have invested in the development of multiple automated assembly lines for production of the~~ test cartridges **in large quantities** . **We** ~~Prior to commercialization~~ , **or** ~~we will need to validate the lines which could cause us to incur substantial expenditures or~~ **our** ~~delays in order~~ **manufacturing partners, may be unable** to ~~achieve acceptable~~ **successfully increase the manufacturing capacity for any of our products in a timely or cost- effective manner, or at all. If we, or our manufacturing partners, are unable to successfully scale- up the manufacture of our products in sufficient** quality ~~, costs~~ and **quantity** ~~output. In addition , delays that may occur with one supplier could have a ripple effect with other suppliers. Such ripple effects could increase costs or obligate us to purchase materials before they~~ - **the development** ~~are required for commercial purposes which could increase costs~~ , ~~increase risk~~ **testing and clinical trials** of ~~scrap or~~ **our** ~~damage relationships with our suppliers. Such delays or required expenditures could further delay the launch of our Talis One system, which would adversely impact our business, financial condition and results of operations. As we have not yet completed process validation of our high- volume assembly lines with a cleared~~ women' s health ~~or STI test, in accordance with FDA~~

recommendations, it may be difficult to predict the cost of manufacturing our cartridges at scale. We are undertaking a number of initiatives designed to reduce the cost of manufacturing our instruments and diagnostic tests, including reducing the costs of supplies and restructuring our contract manufacturer relationships. However, there is no guarantee that we will be able to achieve planned cost reductions from such initiatives. For example, yield from the automated lines may be low resulting in many components to be scrapped or quality of final products may not meet our requirements, which may increase scrap and therefore, our costs. There have been unforeseen occurrences that have increased our costs for supplies used in manufacturing our cartridges and instruments, and there could be other unforeseen occurrences, such as increased prices of the components of our diagnostic tests, changes to labor costs or less favorable terms with third- party suppliers or contract manufacturing partners, including as a result of increased shipping costs caused by the substantial increase in fuel prices. As a result, even if our automated lines perform as anticipated, we may be unable to manufacture our products in a profitable manner. Almost all the materials, enzymes and reagents used in or with our instrument and cartridges are obtained from single source suppliers, which exposes us to significant supplier risk. In addition, we may purchase supplies through purchase orders and may not have long- term supply agreements with, or guaranteed commitments from, many of our suppliers, including single source suppliers. A loss of sufficient supply of such components could require us to expend significant time and resources to develop or license replacement technology and obtain additional marketing authorizations. While we are evaluating redundancy vendors for reagents and other materials there can be no assurance that we will successfully contract for such materials. Our third- party manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes, unstable political environments, health pandemics, inflation or epidemics or rising costs of labor, materials and transportation. If we are unable to procure sufficient supplies for our instruments and cartridges, at the level of quality we need, and at a commercially reasonable cost, we may be unable to manufacture our products in sufficient quantities and such event would have a material adverse effect on our business, financial condition and results of operations. If our third- party suppliers fail to deliver the required quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the potential future commercialization of our instrument and diagnostic tests, the supply of our instrument and diagnostic tests to customers and the development of any future diagnostic tests will be delayed, limited or prevented, which could have a material adverse effect on our business, financial condition and results of operations. Furthermore, all entities involved in the manufacture of our products are subject to extensive regulation. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with these regulations. In the event that any of our manufacturers fail to comply with such requirements or to perform their obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on commercially reasonable terms, if at all. Further, we may be unable to use the product produced by that manufacturer, or if the manufacturer has manufactured product for our commercial sale, if and when we obtain approval, we could be subject to a recall of such product. Any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our products may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturers in order to have another third- party manufacture our products. The process of changing manufacturers is time consuming, may involve substantial costs and is likely to result in delays or interruptions in the development of products and / or the commercialization of products, if approved. We are in the process of changing our manufacturer for the Talis One instrument, which could result in delays due to failure to sufficiently transfer knowledge from the prior manufacturer to the new manufacturer, as well as delays setting up a new production line with a new manufacturer. If we desire to or are required to change manufacturers for any reason, we will also be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop or deliver products in a timely or affordable manner. Our, or a third party' s, failure to execute on our manufacturing requirements, to do so on commercially reasonable terms and to comply with applicable regulations could adversely affect our business in a number of ways, including: • an inability to initiate or continue clinical trials of our products under development; • delay in submitting regulatory applications, or receiving regulatory approvals, for our products; • delay in optimizing the use of our automated manufacturing lines; • requirements to cease development or to recall batches of our products; and • even in the event of approval to market and commercialize our products, an inability to meet commercial demands for our products or any other future products. We may be unable to validate our manufacturing for the Talis One instrument and cartridges at scale, which may impact our ability to support our research and development pipeline and future commercialization. In order to commercialize our products, if approved, we will need to manufacture the Talis One instrument and test cartridges in large quantities. We, or our manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our products in a timely or cost- effective manner, or at all. If we, or our manufacturing partners, are unable to successfully scale- up the manufacture of our products in sufficient quality and quantity, the development, testing and clinical trials of our women's health and STI products may be delayed or become infeasible, and marketing approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business . We have experienced delays related to the manufacture of the instrument and cartridges due to the complexity of the process. This has subsequently delayed our progress in developing future products by reducing access to material and requiring us to divert significant internal resources to focus on stabilizing the manufacturing process with our manufacturing partners. Also, due to the insufficient supply of instruments and cartridges and implementation

~~of required design changes, our ability to commence formal reliability studies to determine product reliability when produced at scale has been delayed, and may continue to be delayed or paused, if we encounter any additional manufacturing issues. The COVID- 19 pandemic has and could continue to materially adversely affect our business, financial condition and results of operations. The global outbreak of COVID- 19 across many countries around the globe, including the United States, has significantly slowed global economic activity, caused significant volatility in financial markets, supply chain disruptions and increased costs associated with rising inflation rates. Although the FDA has approved therapies and vaccines for distribution, there remain uncertainties as to the overall efficacy of the vaccines, especially as new strains of the coronavirus continue to emerge, and the level of resistance these new strains have to the existing vaccines, if any. Certain states and cities have taken and may re- institute measures to prevent or slow the spread of COVID- 19, and its variants including by instituting quarantines, vaccination mandates, and testing requirements restrictions on travel," stay- at- home" rules, restrictions on types of business that may continue to operate and / or restrictions on the types of construction projects that may continue. While vaccine availability and uptake has increased, the longer- term macro- economic effects on global supply chains, inflation, labor shortages and wage increases continue to impact many industries. The COVID- 19 pandemic presents material uncertainty and risk with respect to our financial condition and development efforts, including: • interruption of or delays in receiving products and supplies from the third parties we rely on to, among other things, manufacture components of our instruments, due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, which may impair our ability to sell our products and consumables; • limitations on our business operations by the local, state, or federal government that could impact our ability to sell or deliver our instruments and consumables; • delays in customers' purchasing decisions and negotiations with customers and potential customers; • business disruptions caused by workplace, laboratory and office closures, travel limitations, cyber security and data accessibility limits, or communication or mass transit disruptions; and • limitations on employee resources that would otherwise be focused on the conduct of our activities, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people~~ . If our products do not perform as expected, including due to errors, defects or reliability issues, our reputation and market acceptance of our products could be harmed, and our operating results, reputation and business will suffer. Our success depends on physician and customer confidence that we can provide reliable and highly accurate diagnostic tests and enable better patient care. We believe that physicians and other healthcare providers are likely to be particularly sensitive to defects, errors or reliability issues in our products, including if our products fail to accurately diagnose infections with high accuracy from patient samples, and there can be no guarantee that our products will meet their expectations. There is no guarantee that the accuracy and reproducibility we have demonstrated to date will continue as our product deliveries increase and our product portfolio expands. Our products use a number of complex and sophisticated biochemical and bioinformatics processes, many of which are highly sensitive to external factors. For example, the Talis One system, comprised of a compact instrument, universal single- use test cartridges and software, including a central cloud database, may contain undetected errors or defects when first introduced or as new versions are released. Our diagnostic tests may contain errors or defects or be subject to reliability issues, and while we have made efforts to test them extensively, we cannot assure that our current diagnostic tests, or those developed in the future, will not have performance problems. An operational, technological or other failure in one of these complex processes or fluctuations in external variables may result in sensitivity or specificity rates that are lower than we anticipate, thus affecting the accuracy of a diagnostic result, or result in longer than expected turnaround times or they may cause our products to malfunction. Due to the complexity of our instrument and cartridge, it may be difficult or impossible to identify the reason for such performance. Performance issues would increase our costs in the near- term and accordingly adversely affect our business, financial condition and results of operations. In addition, failure to maintain high- quality customer support, or a market perception that we do not maintain high- quality customer support, could adversely affect our reputation and our ability to sell our Talis One system. We may also be subject to warranty claims or breach of contract for damages related to errors, defects or reliability issues in our products. Further, our products are designed to be used at the customer' s location by untrained personnel. We cannot provide assurance that our products will be approved for use by untrained personnel or that our customers will always use our products in the manner in which we intend. Any intentional or unintentional misuse of our products by our customers could lead to substantial civil and criminal monetary and non- monetary penalties and could cause us to incur significant legal and investigatory fees. If our products do not perform, or are perceived to not have performed, as expected or favorably in comparison to competitive products, our operating results, reputation, and business will suffer, and we may also be subject to legal claims arising from product limitations, errors, or inaccuracies. Additionally, many of the pathogens for which we are developing tests may mutate over time. Such mutations may negatively affect the accuracy of our tests or even make our tests obsolete if our tests are unable to detect future variants. The failure of our products to perform as expected could significantly impair our operating results and our reputation, including if we become subject to legal claims arising from any defects or errors in our products or test results. Operational, technical and other difficulties adversely affecting test performance may harm our reputation, impact the commercial attractiveness of our products, increase our costs or divert our resources, including management' s time and attention, from other projects and priorities. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations. Our products may be subject to recalls in the future. A recall of products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us. The FDA has the authority to require the recall of commercialized products that are subject to FDA regulation. Manufacturers may, also, under their own initiative, recall a product or service if any deficiency is found. For reportable corrections and removals, companies are required to make additional periodic submissions to the FDA after initiating the recall, and often engage with the FDA on their recall strategy prior to initiating the recall. A government- mandated or voluntary recall by us or a distributor could occur as a result of an unacceptable health risk, component failures, malfunctions, manufacturing errors, design or labeling defects, or other

deficiencies and issues. Recalls of any of our commercialized products would divert managerial and financial resources and adversely affect our business, results of operations, financial condition and reputation. A recall of Talis One instruments could be required for any number of problems. Given the number of components, determining the cause of the malfunction may be particularly challenging and costly. In addition, any recall of Talis One instruments would decrease the market for our authorized tests given the decreased availability of such instruments. We may also be subject to liability claims, be required to bear other costs or take other actions that may negatively impact our future sales and our ability to generate profits. Companies are also required to maintain certain records of corrections and removals, even if these do not require reporting to the FDA. We may initiate voluntary recalls involving our commercialized products. The FDA or other agency could take enforcement action for failing to report the recalls when they were conducted. In addition, if we are required to make changes to our products to redress the deficiencies leading to the recall, we may be required to seek marketing authorization for the modified device prior to commercializing it. Any recall announcement by us or a governmental authority, or any changes that we make to our products as a result of such recall, could harm our reputation with customers and negatively affect our business, financial condition, and results of operations. If we initiate a recall, including a correction or removal, for one of our commercialized products, if and when approved, issue a safety alert, or undertake a field action or recall to reduce a health risk, this could lead to increased scrutiny by the FDA, other governmental and regulatory enforcement bodies, and our customers regarding the quality and safety of our products, and to negative publicity, including FDA alerts, press releases, or administrative or judicial actions. Furthermore, the submission of these reports could be used against us by competitors and cause customers to delay purchase decisions or cancel orders, which would harm our reputation. The diagnostic testing industry is subject to rapid change, which could make our current or future products obsolete. Our industry is characterized by rapid changes, including technological and scientific breakthroughs, frequent new product introductions and enhancements and evolving industry standards, all of which could make our current products and the other products we are developing obsolete. Concerns about obsolescence could make it particularly difficult to successfully deploy our Talis One system to a sufficiently broad customer base to enable us to profitably sell our authorized tests in the future. Our future success will depend on our ability to keep pace with the evolving needs of customers on a timely and cost- effective basis and to pursue new market opportunities that develop as a result of scientific and technological advances. We must continuously enhance our Talis One system and develop new tests to keep pace with evolving standards of care. If we do not update our products to reflect new scientific knowledge our products could become obsolete and sales of our current products and any new products we develop could decline or fail to grow as expected. We have eliminated our sales and customer support capabilities which could impact our ability to commercialize our future products, if and when they are approved, and we may not be able to generate any revenue. In 2022, we implemented two reductions in force of approximately 40 % of our employees which has impacted our sales, service and support personnel, and thus our ability to market, sell and support future products, if any. We may not be successful in re- establishing our commercial organization, if and when we have approved products in the future, and we may not be able to generate any revenue. Factors that may inhibit our efforts to commercialize our future products on our own include: • our inability to retain or hire adequate numbers of effective sales and marketing personnel, particularly following a reduction in force; • the inability of sales personnel to obtain access to accounts, institutions and / or physicians or educate adequate numbers of these customers on the benefits of ordering our products; • competitive disadvantages of our products relative to competitor products; and • unforeseen costs and expenses associated with re- establishing an independent sales and marketing organization or scaling up our commercial organization ~~. We may not successfully implement our strategy to provide customers access to our system through alternative non- direct capital sales channels, including our planned equipment leasing program or other sales and marketing practices. Our ability to execute our growth strategy depends upon our ability to drive adoption of the Talis One system. In addition to direct capital sales of our instrument, we intend to implement methods for customers to access to our system through alternatives such as the rental of our instrument or a promotional instrument placement instead of purchase. Our ability to execute on these programs is unproven. We cannot assure that our rental program will gain market acceptance which will cause us to be dependent on capital equipment sales and may hinder or delay adoption of our system~~ . If our future products are not competitive in their intended markets, we may be unable to generate revenues or achieve profitability. Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property. Due to the significant interest and growth in diagnostics, we expect ongoing intense competition. We anticipate facing competition primarily from centralized laboratories and diagnostic companies offering both point- of- care and at- home solutions. Competitors include those offering molecular, antibody and antigen tests. Competitors in the reference lab category include Laboratory Corporation of America Holdings (commonly referred to as LabCorp) and Quest Diagnostics Incorporated, along with many hospital laboratories. Our competitors in the point- of- care and / or at- home category, for molecular and / or antigen tests include Abbott Laboratories, bioMérieux SA, Cepheid (a subsidiary of Danaher Corporation), Thermo Fischer Scientific Inc., Roche Molecular Systems, Inc., and QuidelOrtho. There are also smaller or earlier- stage companies developing tests that may also prove to be significant competitors in the women' s health and / or sexual health markets. Many of our potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, regulatory clearance approval and compliance, and sales and distribution than we do. Mergers and acquisitions involving diagnostics companies may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies or customer networks. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize diagnostic products or services that are more accurate, more convenient to use or more cost- effective than our products or services. Our competitors also may obtain FDA or other regulatory clearance or approval for their products more rapidly than we may obtain clearance or approval or other marketing authorizations for ours, which could result in our competitors establishing a strong market position before we are able to enter a particular market. Further, some of

our competitors' products are sold at prices that are lower than our anticipated pricing, which could cause sales of our products to decline or force us to reduce our prices, which would harm our revenues, operating income or market share. If we are unable to compete successfully, we may be unable to increase or sustain our revenue or achieve profitability. To remain competitive, we must continually research and develop improvements to our products. However, we may not be able to develop and commercialize improvements to our products in a timely manner. Our competitors may develop and commercialize competing or alternative products and improvements faster than we are able to do so, which would negatively affect our ability to increase or sustain our revenue or achieve profitability. We have estimated the sizes of the markets for our current and future products, and these markets may be smaller than we estimate. Our estimates of the annual addressable markets for our women' s health and STI tests under development are based on a number of internal and third- party estimates as well as the assumed rates at which such products will be reimbursed, or the assumed prices at which we can sell our products for markets that have not been established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, including as a result of factors outside our control, thereby reducing the predictive accuracy of these underlying factors. The market and competitive landscape are continuously changing. Any number of factors that are outside of our control could make our estimates invalid. There can be no assurance that demand for our women' s health and STI tests will continue to exist in the future after we commercialize. If the actual number of patients who would benefit from our products under development, the price at which we can sell future products or the annual addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business, financial condition and results of operations. Unfavorable local and global economic conditions could adversely affect our business, financial condition, and results of operations. Our results of operations could be adversely affected by general conditions in both the local and global economy and financial markets, particularly as the United States and other countries balance concerns around debt, inflation, growth and budget allocations in their policy initiatives. There can be no assurance that global economic conditions and financial markets will not worsen and that we will not experience any adverse effects that may be material to our cash flows, results of operations, financial position or our ability to access capital, such as the adverse effects resulting from a prolonged shutdown in government operations both in the United States and internationally. Our business is also affected by local economic environments, including inflation, recession, financial liquidity and currency volatility or devaluation. Political changes, including war or other conflicts, some of which may be disruptive, could interfere with our supply chain, our customers and all of our activities in a particular location. A severe or prolonged global economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our manufacturers and suppliers, possibly resulting in supply disruption. In addition, geopolitical, economic and military conditions around the world may directly affect our business. Any hostilities involving any of the countries in which we or our third- party suppliers operate, including terrorist activities, political instability or violence in the region or the interruption or curtailment of trade or transport between such country and its trading partners could adversely affect our business and results of operations. 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 are highly dependent on our senior management team and key personnel, and ~~if~~ we ~~are unable to retain~~ **may encounter difficulties in managing our operations** , ~~recruit~~ **completing a strategic transaction or keeping current** and ~~train key personnel~~ **timely with our Exchange Act reporting obligations with our reduced staffing and limited resources. Due to our limited resources** , we may not ~~achieve~~ **be able to effectively manage our operations, complete any possible strategic transaction** ~~our~~ - **or** ~~goals. Our future success depends, and will likely continue to depend, on our ability to retain~~ **remain current** ~~, recruit, develop~~ and **timely** ~~motivate key personnel. Although we have employment agreements~~ with our ~~senior management~~ **Exchange Act reporting obligations** , ~~they~~ **which** may ~~terminate their employment with us at any time~~ **result in weaknesses in our infrastructure, give rise to operational mistakes, errors in disclosure, loss of additional business opportunities, loss of employees and reduced productivity among remaining employees** . The loss of members of our senior management, research and development, science and engineering, manufacturing and marketing teams could delay **our completion of any possible strategic transaction or** the achievement of our research, product development and commercialization objectives and harm our business. We **also** do not maintain fixed- term employment contracts or key man life insurance with any of our employees ~~. Competition for qualified personnel is intense. The life sciences industry has been challenged by shortages of qualified technical personnel, especially those with experience in infectious disease and / or in vitro diagnostics, resulting in increased competition for new hires and increased employee turnover. In addition, we have a limited number of employees to manage and operate our business and cannot ensure that we will be able to maintain adequate staff to (i) develop our products, (ii) run our operations or (iii) accomplish our objectives. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to attract, develop, retain and motivate qualified personnel could materially harm our operating results and growth prospects. If we fail to achieve the expected financial and operational benefits of our recent reductions in force, our business and financial results may be harmed. In 2022, in connection with our refocus on the women' s health and STI markets, we implemented two reductions in force, of approximately 40 % of our employees, designed to align our remaining resources to focus on (i) developing women' s health and STI tests on the Talis One system, (ii) our internal manufacturing expertise to support the commercial launch of the Talis One system and (iii) reducing costs and preserving cash to extend our runway to commercialize our women' s health and STI tests. We believe these changes will preserve capital and help ensure that we are appropriately resourced to advance our pipeline of women' s health and STI tests on the Talis One system. We may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the reductions in force. These reductions in force may result in unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended number of employees, decreased morale among our remaining employees, and the~~

~~risk that we may not achieve the anticipated benefits of these reductions in force. In addition, while positions have been eliminated certain functions necessary to our operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. These reductions in work force could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. If we are unable to realize the anticipated benefits from these reductions in force, or if we experience significant adverse consequences from these reductions in force, our business, financial condition, and results of operations may be materially adversely affected~~ . If we were sued for product liability or professional liability, we could face substantial liabilities that exceed our resources. The marketing, sale, and use of our products could lead to the filing of product liability claims were someone to allege that our products identified inaccurate or incomplete information regarding their infections, or otherwise failed to perform as designed. We may also be subject to liability for errors in, a misunderstanding of, or inappropriate reliance upon the information we provide in the ordinary course of our business activities. A product liability or professional liability claim could result in substantial damages and be costly and time- consuming for us to defend. We maintain product liability and professional liability insurance, but this insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could damage our reputation, which could impact our results of operations. We depend on our information technology and telecommunications systems, and those of our third- party service providers, contractors and consultants, and any failure of these systems could harm our business. We depend on our information technology and telecommunications systems and those of our third- party service providers, contractors and consultants for significant elements of our operations. We have installed and are expanding a number of enterprise software systems that affect a broad range of business processes and functional areas, including, for example, systems handling human resources, financial controls and reporting, contract management, and other infrastructure operations. These information technology and telecommunications systems support a variety of functions. In addition, our third- party service providers depend upon technology and telecommunications systems provided by outside vendors. Despite the implementation of preventative and detective security controls, such information technology and telecommunications systems are vulnerable to damage or interruption from a variety of sources, including telecommunications or network failures or interruptions, system malfunction, natural disasters, malicious human acts, terrorism and war. Failures or significant downtime of our information technology or telecommunications systems, or those used by our third- party service providers, contractors or consultants could prevent us from conducting our comprehensive genomic analyses, preparing and providing reports and data to clinicians, handling customer inquiries, conducting research and development activities, and managing the administrative aspects of our business. If the information technology systems of our third- party service providers and other contractors and consultants become subject to disruptions, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to help prevent future events of this nature from occurring. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business, financial condition and results of operations. If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences. In the ordinary course of our business, we and our third- party service providers will collect, store, use, transmit, disclose, or otherwise process proprietary, confidential, and sensitive data, including personal data (which includes intellectual property and trade secrets). In addition, upon commercialization, we will offer online customer- facing portals accessible through public web portals, through which our customers may process protected health information (PHI). It is critical that we process PHI and other sensitive data in a secure manner to maintain the confidentiality, availability and integrity of such confidential information. We manage and maintain our applications and data utilizing a combination of on- site systems, managed data center systems, and cloud- based data center systems. These applications and related data encompass a wide variety of business- critical information including research and development information, commercial information, and business and financial information. We rely upon third-party service providers and technologies to operate critical business systems to process confidential information and personal data in a variety of contexts, including, without limitation, third- party providers of cloud- based infrastructure, encryption and authentication technology, employee email and other functions. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive data with or from third parties. Cyberattacks, malicious internet- based activity, and online and offline fraud and other similar activities that threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. These threats are prevalent and continue to increase, are becoming increasingly difficult to detect and come from a variety of sources, including traditional computer " hackers, " threat actors," hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation- states, and nation- state- supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber- attacks, that could materially disrupt our systems and operations and the supply chain. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social- engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks (such as

credential stuffing), personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Ransomware attacks, including those perpetrated by organized criminal threat actors, nation- states, and nation- state- supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third- party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third- party information technology systems that support us and our services. Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. 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. Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to data or could disrupt our ability (and that of third parties upon whom we rely) to provide our services. If such an event were to occur, it could result in a material disruption of our product development programs and our business operations. These threats pose a risk to the security of our systems, the confidentiality and the availability and integrity of our data, and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business. We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry- standard or reasonable security measures to protect our information technology systems and data. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We have previously been, and may in the future become, the target of cyber- attacks by third parties seeking unauthorized access to our or our customers' data or to disrupt our operations or ability to provide our services. For example, we have been subject to phishing incidents, and we may experience additional incidents in the future. We may be unable to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary expenditures; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause delays in the development of our product candidates, cause customers to stop using our products or services, deter new customers from using our products or services, and negatively impact our ability to grow and operate our business. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient of protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. Our risks are likely to increase as we continue to expand our business, grow our customer base, and process, store, and transmit increasingly large amounts of proprietary and sensitive data. We or the third parties upon whom we depend may be adversely affected by power outages, earthquakes, fires, health pandemics or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Our facilities are located in areas ~~,~~ which have experienced severe earthquakes and fires and are at risk for rolling or prolonged power outages. If these earthquakes, fires, other natural disasters, power outages, health pandemics or epidemics, terrorism and similar unforeseen events beyond our control, including for example the ongoing COVID- 19 pandemic, prevented us from using all or a significant portion of our facilities, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time and / or could result in the loss of commercial inventory or inventory and supplies required for our clinical trials. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third- party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business. International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside the United States. Because we intend to market our products outside the United States, if cleared, authorized or approved, our business will be subject to risks associated with

doing business outside the United States, including an increase in our expenses and diversion of our management' s attention from the development of future products. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including: • failure by us or our distributors to obtain regulatory clearance, authorization or approval for the use of our products in various countries; • multiple, conflicting and changing laws and regulations such as privacy, security, and data use regulations, tax laws, export and import restrictions, economic sanctions and embargoes, employment laws, anti- corruption laws, regulatory requirements, reimbursement or payor regimes and other governmental approvals, permits and licenses; • additional potentially relevant third- party patent rights; • complexities and difficulties in obtaining intellectual property protection and maintaining, defending and enforcing our intellectual property; • economic weakness, including inflation, or political and economic instability in particular foreign economies and markets, including wars, terrorism and political unrest, outbreak of disease, natural disasters, boycotts, curtailment of trade and other business restrictions; • difficulties in staffing and managing foreign operations; • employment risks related to hiring employees outside the United States; • logistics and regulations associated with shipping samples, including infrastructure conditions and transportation delays; • limits in our ability to penetrate international markets if we are not able to sell our products locally; • financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations; • regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' activities that may fall within the purview of the U. S. Foreign Corrupt Practices Act (FCPA), its books and records provisions, or its anti- bribery provisions, or laws similar to the FCPA in other jurisdictions in which we may now or in the future operate, such as the United Kingdom' s Bribery Act of 2010 (U. K. Bribery Act); and • onerous anti- bribery requirements of several member states in the EU, the United Kingdom, and other countries that are constantly changing and require disclosure of information to which U. S. legal privilege may not extend. Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations. We may not have adequate insurance coverage. We may not have adequate insurance coverage. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large 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. Performance issues, service interruptions or price increases by our shipping carriers and warehousing providers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis. Expedited, reliable shipping and delivery services and secure warehousing are essential to our operations. When we commercialize our products, we intend to rely heavily on providers of transport services for reliable and secure point- to- point transport of our diagnostic tests to our customers and for tracking of these shipments and require warehousing for our diagnostic tests, sample collection kits and supplies. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our diagnostic tests and increased cost and expense to our business. In addition, we have and may continue to experience higher costs for transportation and warehousing and significant inflation that could adversely affect our operating margins and results of operations, if these costs continue to rise after we commercialize our products. Similarly, strikes, severe weather, natural disasters, civil unrest and disturbances or other service interruptions affecting delivery or warehousing services we use would adversely affect our ability to process orders for our diagnostic tests on a timely basis. We have entered into licenses, collaborations and strategic alliances, and may enter into additional arrangements like these in the future, and we may not realize the anticipated benefits of such arrangements. The development and potential commercialization of products will require substantial additional capital to fund expenses. We may form or seek further strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to any products that we may develop and commercialize, including in territories outside the United States. These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management' s time and attention in order to manage a collaboration or develop acquired technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write- downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into acquisition or in- license agreements or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, or if there are materially adverse impacts on our or the counterparty' s operations which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement. Additionally, we sometimes collaborate with academic institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution' s rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third- party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer. Even if we are successful in attaining a license, we may abandon development of a program utilizing licensed technology

which may adversely affect our business relationships with our licensors or disrupt our business and financial position. Further, rights to certain of the components and technology incorporated into our products are, and in the future, may be held by others and we may be unable to in- license any rights to components, methods of use, processes or other third- party intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which would harm our business. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, or if we lose access to components or technologies controlled by others, we may be required to expend significant time and resources to develop or license replacement technology. Any such redevelopment or any delays in entering into new collaborations or strategic partnership agreements related to our technologies could delay the development and commercialization of our products in certain geographies, which could harm our business prospects, financial condition, and results of operations. See the risk factor titled " We depend on intellectual property licensed from third parties and we are currently party to several in- license agreements under which we acquired rights to use, develop, manufacture and / or commercialize certain of our system components. If we breach our obligations under these agreements or if any of these agreements is terminated, or otherwise experience disruptions to our business relationships with our licensors, we may be required to pay damages, lose our rights to such intellectual property and technology, or both, which would harm our business. " for additional risks related to these licenses, collaborations and strategic alliances. We may acquire other businesses or engage in other strategic transaction discussions with third parties, each of which could require significant management attention, disrupt our business, dilute stockholder value and adversely affect our results of operations. We may in the future make additional acquisitions or investments in companies, diagnostic tests or technologies that we believe either fit within our business model and can address the needs of our customers and potential customers or will otherwise provide strategic benefits to us. In the future, we may not be able to acquire and integrate other companies, diagnostic tests or technologies in a successful manner. We may not be able to find suitable acquisition candidates, and we may not be able to complete such acquisitions on favorable terms, if at all. In addition, the pursuit of potential acquisitions may divert the attention of management and cause us to incur additional expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. If we do complete acquisitions, we may not ultimately strengthen our competitive position or achieve our goals, including increases in revenue, and any acquisitions we complete could be viewed negatively by our customers, investors and industry analysts. Additionally, we may engage with third parties, including potential acquirers, in discussions regarding strategic transactions. The time required to engage with any such third parties could require significant attention from management, disrupt the ordinary functioning of our business and adversely affect our operating results. Future acquisitions may reduce our cash available for operations and other uses and could result in amortization expense related to identifiable assets acquired. We may have to pay cash, incur debt or issue equity securities to pay for any such acquisition, each of which could adversely affect our financial condition or the value of our common stock. The sale or issuance of equity to finance any such acquisitions would result in dilution to our stockholders. The incurrence of indebtedness to finance any such acquisition would result in fixed obligations and could also include covenants or other restrictions that could impede our ability to manage our operations. In addition, our future results of operations may be adversely affected by the dilutive effect of an acquisition, performance earn- outs or contingent bonuses associated with an acquisition. Furthermore, acquisitions may require large, onetime charges and can result in increased debt or contingent liabilities, adverse tax consequences, additional stock- based compensation expenses and the recording and subsequent amortization of amounts related to certain purchased intangible assets, any of which items could negatively affect our future results of operations. We may also incur goodwill impairment charges in the future if we do not realize the expected value of any such acquisitions. Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write- offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results. We **must obtain** ~~intend to seek to market~~ **marketing authorizations for** our products for point- of- care clinical diagnostic use ~~and will be required to obtain marketing authorizations~~ before they can be marketed. Any such regulatory process would be expensive, time- consuming and uncertain both in timing and in outcome. If we fail to obtain or maintain necessary marketing authorizations, or if such authorizations for future products are delayed or not issued, it will negatively affect our business, financial condition and results of operations. **Our** ~~While we focused initially on the development of the stand- alone Talis One COVID- 19 test, our strategy is to expand our product line to encompass products that are intended to be used as point- of- care diagnostics for a variety of infectious diseases particularly in the women' s health and STI health markets. Such~~ products will be subject to regulation by the FDA as medical devices, including requirements for regulatory clearance or approval of such products before they can be marketed. Accordingly, ~~we will be required to obtain~~ marketing authorization **is required** in order to sell our future products in a manner consistent with FDA laws and regulations. Such processes are expensive, time- consuming and uncertain; our efforts may never result in any marketing authorization; and failure ~~by us~~ to obtain or comply with such marketing authorizations could have ~~an~~ **a material** adverse effect on **the ability to commercialize** ~~our business, financial condition or~~ **our products** ~~operating results~~. The FDA or other regulators can delay, limit, or deny clearance, approval, or other form of marketing authorization of a device for many reasons, including: • our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our Talis One system and any tests we propose for use with it, are substantially equivalent to a legally marketed predicate device or safe or effective for their proposed intended uses, or meet other standards required to obtain relevant marketing authorizations; • the disagreement of the FDA with the design or implementation of any clinical trials or the interpretation of data from preclinical studies or clinical trials; • serious and unexpected adverse device effects experienced by participants in our clinical trials; • the data from preclinical studies or clinical trials may be insufficient to support clearance or approval, where required; • our inability to demonstrate that the clinical and

other benefits of the device outweigh the risks; • the manufacturing process or facilities we use may not meet applicable requirements; and • the potential for market authorization policies, regulations or laws of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval. The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces these regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we will be found compliant in connection with any future regulatory inspections. Moreover, the FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by any such agency, which may include any of the following sanctions: • adverse publicity, warning letters, untitled letters, it has come to our attention letters, fines, injunctions, consent decrees and civil penalties; • repair, replacement, refunds, recall or seizure; • operating restrictions, partial suspension or total shutdown of production; • denial of our requests for regulatory clearance or PMA approval or other marketing authorization of new products, new intended uses or modifications to existing products; • withdrawal of marketing authorization that have already been granted; or • criminal prosecution. If any of these events were to occur, it would negatively affect our business, financial condition and results of operations. In addition, a CLIA- waived designation by the FDA is required for our products to be used at the point- of- care, and outside of the clinical laboratory setting. Laboratory tests regulated under CLIA are categorized by the FDA as waived, moderate complexity or high complexity based on set criteria. Tests that are waived by regulation, or cleared, approved, or otherwise authorized by the FDA for home use or a point- of- care test, are deemed waived following marketing authorization. Otherwise, a manufacturer of a test categorized as moderate complexity may request categorization of the test as waived through a CLIA Waiver by Application submission to the FDA. The manufacturer must provide evidence to the FDA that a test meets the CLIA statutory criteria for waiver, including, among other things, that the test employs methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible. When a test is categorized as waived, it may be performed by laboratories with a Certificate of Waiver, which is issued by the Centers for Medicare & Medicaid Services (CMS), the federal agency responsible for the oversight of clinical laboratories, which includes issuing waiver certificates. If we fail to obtain, or experience significant delays in obtaining, a waiver approval by the FDA for our tests, our tests will only be able to be performed by CLIA certified and state licensed laboratories, which may limit our commercial success and have an adverse effect on our business, financial condition or operations. We may never obtain authorization to market our tests in any foreign country for any of our products and, even if we do, we may never be able to commercialize them in any other jurisdiction, which would limit our ability to realize their full market potential. In order to eventually market any of our products in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction- by- jurisdiction basis regarding quality, safety, performance and efficacy. In addition, clinical trials or clinical investigations conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory clearance, authorization or approval in one country does not guarantee regulatory clearance, authorization or approval in any other country. For example, the performance characteristics of our products may need to be validated separately in specific ethnic and genetic populations. Marketing authorization processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory clearance, authorization or approval could result in difficulties and costs for us and our collaborators and require additional preclinical studies, clinical trials or clinical investigations which could be costly and time- consuming. Regulatory requirements and ethical approval obligations can vary widely from country to country and could delay or prevent the introduction of our products in those countries. The foreign regulatory clearance, authorization or approval process involves all of the risks and uncertainties associated with FDA clearance, authorization or approval. We have no experience in obtaining regulatory clearance, authorization or approval in international markets. If we or our collaborators fail to comply with regulatory requirements in international markets or to obtain and maintain required regulatory clearances, authorizations or approvals in international markets, or if those approvals are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized. ~~Our~~ **The** commercial success **of the Talis One system** could be compromised if our customers do not receive coverage and adequate reimbursement for our products, if and when approved. The potential end- users of our women' s health and STI tests include hospitals, physician practices, urgent care centers, public health and retail clinics that need rapid and high- quality testing to best serve their patients. If these end- users do not receive adequate reimbursement for the cost of our products from their patients' healthcare insurers or payors, the use of our products could be negatively impacted. Furthermore, the net sales of our products could also be adversely affected by changes in reimbursement policies of government or private healthcare payors. Due to the overall escalating cost of medical products and services, especially in light of the COVID- 19 outbreak and its straining of healthcare systems across the globe, there is increased pressure on the healthcare industry, both foreign and domestic, to reduce the cost of products and services. Given the efforts to control and reduce healthcare costs in the United States, available levels of reimbursement may change for our products. Third- party reimbursement and coverage may not be available or adequate in either the United States or international markets, current reimbursement amounts may be decreased in the future and future legislation, and regulation or reimbursement policies of third- party payors, may reduce the demand for our products or our ability to sell our products on a profitable basis. In the United States, we expect that our customers will use standard industry billing codes, known as CPT codes, to bill for our tests. If these codes were to change, there is a risk of an error being made in the claim adjudication process. Such errors can occur with claims submission, third- party transmission or in the processing of the claim by the payor. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment received, either of which may materially impact the demand for our testing products. If we introduce new testing products, we may need to apply for new codes to describe our tests, which may not be approved or if approved, may not have adequate reimbursement rates, any of

which could result in reduced demand for our tests or additional pricing pressures. Hospitals, physicians and other healthcare providers who purchase diagnostic products in the United States generally rely on third- party payors, such as private health insurance plans, Medicare and Medicaid, to reimburse all or part of the cost of the product. Therefore, our market success is highly dependent upon government and commercial third- party payors providing coverage and adequate reimbursement for our test. While we believe our women' s health and STI tests will qualify for coverage that is currently available for other women' s health and STI tests on the market, coverage criteria and reimbursement rates for diagnostic tests are subject to adjustment by payors, and current reimbursement rates could be reduced, or coverage criteria restricted in the future, which could adversely affect the market for our tests. In addition, the availability of other forms of testing in the future, such as at- home tests, could impact the reimbursement rate and market acceptance for our women' s health and STI tests. We also cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business in the future, or the effect any future legislation or regulation will have on us. Although we cannot predict the full effect of recent legislative changes, such changes individually or in the aggregate may result in decreased profits to us and / or lower reimbursement by payors for our tests, which may adversely affect our business, financial condition and results of operations. In addition, the coverage and reimbursement market is ever changing and we are not in control of how our competitors' coverage and pricing strategies are established. Some of our competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower- priced, less complex tests that payors and physicians could view as functionally equivalent to our products, which could force us to lower the list price of our tests and impact our operating margins and our ability to achieve and maintain profitability. In addition, technological innovations that result in the creation of enhanced diagnostic tools that are more effective than ours may enable other hospitals, physicians or medical providers to provide specialized diagnostic tests similar to ours in a more patient- friendly, efficient or cost- effective manner than is currently possible. If we cannot compete successfully against current or future competitors, we may be unable to increase or create market acceptance and sales of our products, which could prevent us from increasing or sustaining our revenue or achieving or sustaining profitability ~~. Modifications to our products may require new 510 (k) clearances, PMA approvals, or other marketing authorizations, or may require us to cease marketing or recall the modified products until clearances, approvals, or other marketing authorizations are obtained. Modifications to any products for which we receive clearance, approval, or other marketing authorization may require new regulatory approvals, clearances, or marketing authorizations, including 510 (k) clearances or PMA approvals, or require us to recall or cease marketing the modified systems until these clearances, approvals, or other marketing authorizations are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. For a product subject to 510 (k) clearance, a manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510 (k) clearance is necessary. However, the FDA can review a manufacturer' s decision and may disagree. The FDA may also on its own initiative determine that a new clearance, approval, or marketing authorization is required. If the FDA disagrees and requires new clearances, approvals, or other marketing authorizations for the modifications, we may be required to recall and to stop marketing the modified products, which could require us to seek new marketing authorizations and harm our operating results. In these circumstances, we may be subject to significant enforcement actions. Moreover, even if we seek new clearances, approvals, or other marketing authorizations for our modifications, we may not obtain clearance, approval, or other marketing authorizations in a timely manner, if at all. Obtaining clearances and approvals can be a time consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth~~ . Clinical trials will be required to support future product submissions to the FDA. The clinical trials that may be required for our products are expensive and time-consuming, their outcome is uncertain, and if our clinical trials do not meet the stated endpoints in their evaluations, or if we experience significant delays in any of these tests or trials, our ability to commercialize our products and our financial position will be impaired. Clinical development is a long, expensive and uncertain process with several clinical trials involved, any of which is subject to significant delays. Due to known or unknown circumstances beyond our control, it may take us several years to complete our testing, and failure can occur at any stage of testing. Delays associated with products for which we are directly conducting preclinical or clinical trials may cause us to incur additional operating expenses. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials. The results of preclinical studies and clinical trials of our products conducted to date and ongoing or future studies and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials. Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example: • we may be required to submit an Investigational Device Exemption (IDE) application to the FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical trials; • regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials; • regulators and / or an Institutional Review Board (IRB), or other reviewing bodies may not authorize us or our investigators to commence a clinical

trial, or to conduct or continue a clinical trial at a prospective or specific trial site; • we may not reach 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; • clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; • the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate; • our third- party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • we might have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks; • we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and / or regulatory authorities for re- examination; • regulators, IRBs, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements; • the cost of clinical trials may be greater than we anticipate; • clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial; • we may be unable to recruit a sufficient number of clinical trial sites; • regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third- party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; • market authorization policies, regulations or laws of the FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for market authorization; and • our current or future products may have undesirable side effects or other unexpected characteristics. In addition, disruptions caused by the COVID- 19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. Clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. Conducting successful clinical studies will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow- up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites and ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post- treatment procedures or follow- up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice (GCP) requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non- U. S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care. Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required, and we may not adequately develop such protocols to support clearance and approval. Further, the FDA may require us to submit data on a greater number of patients than we originally anticipated and / or for a longer follow- up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, the FDA may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects. Even if we receive marketing authorization for a planned product, we and our suppliers will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements. Any product for which we obtain clearance, approval, or other marketing authorization, and the manufacturing processes, post- market surveillance, post- approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight, requirements, and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, unless exempt, we and our suppliers are required to comply with the FDA' s QSR and other regulations enforced outside the United States which cover the manufacture of our products and the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of medical devices. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions: • untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; • unanticipated expenditures to address or defend such actions; • customer notifications for repair, replacement, refunds; • recall,

detention or seizure of our products; • operating restrictions or partial suspension or total shutdown of production; • refusing or delaying our requests for 510 (k) clearance or PMA approval of new products or modified products; • operating restrictions; • withdrawal of 510 (k) clearances or PMA approvals that have already been granted; and • refusal to grant export approval for our products; or criminal prosecution. If any of these actions were to occur, it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all. In addition, we are required to conduct costly post- market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as the QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects. Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory clearance or approval is withdrawn, it would have a material adverse effect on our business, financial condition and results of operations. Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us. We are subject to the FDA' s medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance or approval of future products. The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA' s authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government- mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future. Depending on the corrective action we take to redress a product' s deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines. Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results. Changes in funding or disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain 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, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, 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. Disruptions at the FDA and other agencies may also slow the time necessary for new product applications to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including for 35 days beginning on December 22, 2018, the U. S. government shut down several times and certain regulatory agencies, including the FDA, had to furlough critical employees and stop critical activities. Separately, in response to the COVID- 19 pandemic, in March 2020, the FDA announced its intention to postpone most

inspections of foreign and domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on- site inspections of domestic manufacturing facilities subject to a risk- based prioritization system. The FDA intends to use this risk- based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to remote interactive evaluations to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID- 19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. We expect to rely on third parties in conducting future clinical studies of diagnostic products that may be required by the FDA or other regulatory authorities, and those third parties may not perform satisfactorily. We do not have the ability to independently conduct clinical trials that may be required to obtain FDA and other regulatory clearance or approval for future diagnostic products. Accordingly, we expect that we would rely on third parties, such as, laboratories, clinical investigators, CROs, consultants, and collaborators to conduct such studies if needed. Our reliance on these third parties for clinical and other development activities would reduce our control over these activities but will not relieve us of our responsibilities. We will remain responsible for ensuring that each of our clinical studies is conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA requires us to comply with standards, commonly referred to as GCPs, for conducting, recording and reporting the results of clinical studies to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of patients in clinical studies are protected. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to current GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, including on account of the outbreak of infectious disease, such as the COVID- 19 pandemic, or otherwise, we may be affected by increased costs, program delays or both, any resulting data may be unreliable or unusable for regulatory purposes, and we may be subject to enforcement action. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences. We process personal data and other sensitive data (including health data we collect about trial participants in connection with clinical trials); proprietary and confidential business data; trade secrets; intellectual property; and sensitive third- party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf. Data privacy and information security have become significant issues in the United States, countries in Europe, and in other countries in which we operate. The legal and regulatory framework for privacy and security issues is rapidly evolving, and is expected to increase our compliance costs and exposure to liability. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws, and other similar laws (e. g., wiretapping laws). These privacy laws include, without limitation, the following laws and regulations: Section 5 of the Federal Trade Commission Act, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and the California Privacy Rights Act of 2020 (CPRA). HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. The CPRA imposes obligations on businesses to which it applies that include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CPRA allows for statutory fines for noncompliance (up to $ 7, 500 per violation) and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CPRA exempts some data processed in the context of clinical trials, the CPRA may increase compliance costs and potential liability with respect to other personal data we may maintain about California residents. In addition, the CPRA extends to personal information of business representatives and employees and established a new regulatory agency to implement and enforce the law. Other states, like Colorado, Connecticut, Utah, and Virginia, have passed comprehensive data privacy laws which differ from the CPRA and all of which went into effect in 2023. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts and may increase legal risk and compliance costs for us and the third parties upon whom we rely. Additionally, under various privacy laws and other obligations, we may be required to obtain certain consents to process personal data. Our inability or failure to do so could result in adverse consequences. If we are or become subject to these laws and / or new or amended data privacy laws, the risk of enforcement actions against us could increase because we may be subject to obligations under applicable regulatory frameworks and the number of individuals or entities that could initiate actions against us may increase (including individuals via a private right of action), in addition to further complicating our compliance efforts. In addition, privacy advocates and industry groups have proposed, and may propose in the future, standards with which we are legally or contractually bound to comply. Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union' s General Data Protection Regulation (EU GDPR) and the equivalent law in the United Kingdom (UK GDPR) impose strict requirements for processing the personal data

of individuals, including sensitive data that we may process such as health data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4 % of annual global revenue, whichever is greater. Similar processing penalties and fines exist under the UK GDPR and the uncertainty of data protection laws in the UK following Brexit has increased the complexity of our compliance efforts. Further, individuals may initiate litigation related to our processing of their personal data. In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Most jurisdictions have adopted similarly stringent data protection laws which include data localization and cross- border data transfer limitations. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK' s standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have prevented companies from transferring personal data out of Europe for allegedly violating the GDPR' s cross- border data transfer limitations. Other jurisdictions require all processing of sensitive personal information be done inside the borders of that jurisdiction. We may also be bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CPRA, require our customers to impose specific contractual restrictions on their service providers. We may publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self- regulatory principles, regarding data privacy and security. If these policies, materials or statements 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 are quickly changing, becoming increasingly stringent and creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or in direct conflict among jurisdictions. 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 services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change our business model. Our business model materially depends on our ability to process personal data, so we are particularly exposed to the risks associated with the rapidly changing legal landscape. For example, we may be at heightened risk of regulatory scrutiny, and any changes in the regulatory framework could require us to fundamentally change our business model. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third- party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to operate our business and proceedings against us by governmental entities or others. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the third- party providers (such as contract research organizations) who share this information with us, may contractually limit our ability to use and disclose the information. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class- related claims); additional reporting requirements and / or oversight; bans on processing personal data; and orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including our clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our product candidates; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations. All of our employees, principal investigators, consultants, and commercial partners may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants, and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non- United States regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and our code of conduct and the other precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks

or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these 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 result in the imposition of significant fines or other sanctions, which could have a significant impact on our business. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these actions or investigations. We may be subject to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws. We and our collaborators and strategic partners may be subject to broadly applicable healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we develop, market, sell, and distribute our products. These health care laws and regulations include, for example: • the federal Anti- Kickback Statute (AKS), which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or services for which payment may be made under a federal health care program such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal AKS or specific intent to violate it in order to have committed a violation; • the federal civil and criminal false claims laws, such as the civil False Claims Act (FCA), which can be enforced by private citizens through civil qui tam actions, and civil monetary penalty laws, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment or approval by the federal government, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal AKS constitutes a false or fraudulent claim for purposes of the civil FCA; • HIPAA, which established additional federal civil and criminal liability for, among other things, knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services. Similar to the federal AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the federal Physician Payments Sunshine Act requirements under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), which require certain manufacturers of drugs, devices, biologics and medical supplies to report to the CMS, information related to payments and other transfers of value made to or at the request of covered recipients, such as physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and certain ownership and investment interests held by physicians and their immediate family members; and • state 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. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, including our planned reagent rental program or other sales and marketing practices, could be subject to challenge under one or more of such laws. Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including, among others, significant administrative, civil and criminal penalties, damages, fines, disgorgement, imprisonment, integrity oversight and reporting obligations, and exclusion from participation in government funded healthcare programs such as Medicare and Medicaid. Additionally, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could significantly harm our business, financial condition, and results of operations. In addition, if any of the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant civil, criminal and administrative sanctions, including exclusion from government funded healthcare programs. Legislative or regulatory reforms may make it more difficult and costly for us to obtain marketing authorization for any future products and to manufacture, market and distribute our products after marketing authorization is obtained. From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the marketing authorization, manufacture and marketing of regulated products or the reimbursement thereof. In addition, the FDA may change its policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay marketing authorization of our future products under development or impact our ability to modify any then- marketed products on a timely basis. Any new regulations or revisions or reinterpretations of existing laws and regulations may impose additional costs or lengthen review times of planned or future products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. For example, over the last several years, the FDA has proposed reforms to its 510 (k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510 (k) clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the pre- market notification pathway under Section 510 (k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510 (k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510 (k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. The FDA also announced that it intended to finalize guidance to establish a pre- market review pathway for " manufacturers of certain well- understood device types " as an alternative to the

510 (k) clearance pathway and that such pre- market review pathway would allow manufacturers to rely on objective safety and performance criteria recognized by the FDA to demonstrate substantial equivalence, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. In May 2019, the FDA solicited public feedback on its plans to develop proposals to drive manufacturers utilizing the 510 (k) pathway toward the use of newer predicates, including whether the FDA should publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. The FDA requested public feedback on whether it should consider certain actions that might require new authority, such as whether to sunset certain older devices that were used as predicates under the 510 (k) clearance pathway. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510 (k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business. More recently, in September 2019, the FDA finalized the aforementioned guidance to describe an optional " safety and performance based " pre- market review pathway for manufacturers of " certain, well- understood device types " to demonstrate substantial equivalence under the 510 (k) clearance pathway, by demonstrating that such device meets objective safety and performance criteria established by the FDA, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA intends to maintain a list device types appropriate for the " safety and performance based pathway " and develop product- specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510 (k) clearances or otherwise create competition that may negatively affect our business. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping. The FDA' s and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay regulatory clearance or approval of our products. 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. Any change in the laws or regulations that govern the clearance and approval, or other marketing authorization, relating to our current, planned and future products could make it more difficult and costly to obtain marketing authorization for new products or to produce, market and distribute existing products. Significant delays in or the failure to receive marketing authorization for any new products would have an adverse effect on our ability to expand our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing authorization that we may have obtained and we may not achieve or sustain profitability. The misuse or off- label use of our products may harm our reputation in the marketplace, result in false test results that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business. We are not permitted to market our products for off- label uses. For example, the EUA for our Talis One COVID- 19 Test System, prior to its revocation, was for the in vitro qualitative detection of RNA from the SARS- CoV- 2 virus in nasal swab specimens from individuals suspected of COVID- 19 by a healthcare provider. We were not permitted to market our Talis One COVID- 19 Test System for use in screening of asymptomatic populations, for use in pooling samples for testing, or for use with different specimen samples (other than nasal swab specimens). Such uses would have been considered " off- label. " We have trained and will train our marketing and direct sales force to not promote our products for uses outside of any FDA- authorized indications for use. We cannot, however, prevent a physician from using our products off- label, when in the physician' s independent professional medical judgment, he or she deems it appropriate. There may be increased risk of inaccurate results if physicians attempt to use our tests off- label. Furthermore, such off- label uses could harm our reputation in the marketplace among physicians and patients. If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off- label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties, or withdrawal of any EUA or other marketing authorization we obtain. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority if they consider our business activities to constitute promotion of an off- label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations. A significant portion of the funding for the development of our Talis One system came from U. S. federal government grants, and if the cognizant federal agencies were to eliminate, reduce or delay funding from our agreements, this could have a significant, negative impact on our revenues and cash flows, and we may be forced to suspend or terminate our development programs or obtain alternative sources of funding. We have received grant funding from the U. S. federal government, including through a grant from the NIH, National Institute of Allergy and Infectious Diseases, a sub- award from the Biomedical Advanced Research and Development Authority Combating Antibiotic- Resistant Bacteria Biopharmaceutical Accelerator (CARB- X) program, a sub- award from the

NIH RADx program, and an NIH RADx grant. We anticipate that a portion of the funding for the development of our technologies will come from these agreements, which provide for grant funds ultimately from the government. In addition, activities covered under the awards may ultimately cost more than is covered by the grants and sub- awards or require a longer performance periods to complete than are remaining on our agreements; if we are unable to secure additional funding or allow for additional time for completion, we would have to incur additional costs to complete the activities or terminate the activities before completion. Moreover, the continuation of our agreements depends in large part on our ability to meet development milestones previously agreed to and on our compliance with certain operating procedures and protocols. These agreements may be suspended or terminated should we fail to achieve key milestones or fail to comply with the operating procedures and processes approved by the government and its audit agencies. There can be no assurance that we will be able to achieve these milestones or continue to comply with these procedures and protocols. For example, although we extended the time to perform certain milestones under the NIH Contract, we also had to reduce the potential milestone payments, and we were unable to satisfy all of the remaining milestones before the NIH Contract expired. In addition, changes in government budgets and agendas may result in a decreased and deprioritized emphasis on supporting the development of our programs. While the NIH has provided funding for many activities associated with combating COVID- 19, the availability and focus for any NIH funding will likely be finite and may require us to compete with other technologies, both similar and disparate. If our agreements are terminated or suspended, if there is any reduction or delay in funding under our agreements, or if the government or higher- tier grantees determine not to exercise some or all of the options provided for under the agreements, our revenues and cash flows would be significantly and negatively impacted and we may be forced to seek alternative sources of funding, which may not be available on non- dilutive terms, terms favorable to us or at all. If alternative sources of funding are not available, we may be forced to suspend or terminate certain of our related development activities. Furthermore, should we be unable to deploy personnel or derive a benefit from fixed study costs or generate data from clinical sites and studies reimbursed through the agreements, our cash flows would be negatively impacted or we may have to initiate furloughs and layoffs which would likely prove disruptive to our management and operations. This in turn would impair our ability to recommence and complete studies if and when the COVID- 19 crisis subsides and we are able to restart many suspended or delayed activities. Unfavorable provisions in government contracts, including in our grant and sub- award agreements, may harm our business, financial condition and operating results. U. S. government contracts and grants typically contain unfavorable provisions and are subject to audit and modification by the government at its sole discretion, which will subject us to additional risks. For example, under our grant and sub- award agreements, the U. S. government and higher- tier grantees, in certain circumstances, have the power to unilaterally: • suspend or prevent us for a set period of time from receiving new government contracts or grants or extending our existing agreements based on violations or suspected violations of laws or regulations; • claim and exercise nonexclusive, nontransferable rights to products manufactured and intellectual property and data developed and generated under the agreements and may, under certain circumstances, license such inventions to third parties without our consent; • impose U. S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such contracts and grants; • cancel, terminate or suspend our agreements based on violations or suspected violations of laws or regulations; • terminate our agreements in whole or in part for convenience for any reason or no reason, including if funds become unavailable; • reduce the scope and value of our agreements; • decline to exercise an option to continue the agreements; • direct the course of the development of the programs in a manner not chosen by us; • require us to perform the option periods provided for under the agreements even if doing so may cause us to forego or delay the pursuit of other program opportunities with greater commercial potential; • take actions that result in longer development timelines than expected; and • change certain terms and conditions in our agreements. Generally, government contracts and grants, including our grant and sub- award agreements, contain provisions permitting unilateral termination or modification, in whole or in part. Termination- for- convenience provisions generally enable us to recover only our costs incurred or committed, plus a portion of the agreed fee (if a fee has been negotiated) and settlement expenses on the work completed prior to termination. Except for the amount of services received by the government, termination- for- default provisions do not permit recovery of fees and may subject us to damages, including reprocurement expenses. In addition, in the event of termination or upon expiration of our agreements, the U. S. government or higher- tier grantees may dispute wind- down and termination costs and may question prior expenses under the agreements and deny payment of those expenses. Should we choose to challenge those denials, such a challenge could subject us to substantial additional expenses that we may or may not recover. Further, if our agreements are terminated for convenience, or if we default by failing to perform in accordance with the schedule and terms, a significant negative impact on our cash flows and operations could result. In addition, government contracts and grants normally contain additional requirements that may increase our costs of doing business and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example: • public disclosures of certain contract information, which may enable competitors to gain insights into our research program; • mandatory internal control systems and policies; and • mandatory socioeconomic compliance requirements, including labor standards, prioritization of subcontracts to small businesses and others, non- discrimination and affirmative action programs and environmental compliance requirements. If we fail to maintain compliance with these requirements, we may be subject to potential liability and to the termination of our agreements. Furthermore, we have entered into and will continue to enter into agreements and subcontracts with third parties, including suppliers, consultants and other third- party contractors, in order to satisfy our contractual obligations under our agreements. Negotiating and entering into such arrangements can be time- consuming and we may not be able to reach agreement with such third parties. Any such agreement must also be compliant with the terms of our grant and sub- award agreements. Any delay or inability to enter into such arrangements or entering into such arrangements in a manner that is non- compliant with the terms, may result in violations of our agreements. In addition, under the agreements, the government and higher- tier grantees will regularly review our development efforts and clinical activities. Under certain circumstances, they may advise us to delay certain activities and invest

additional time and resources before proceeding. If we follow such advice, overall program delays and costs associated with additional resources for which we had not planned may result. Also, the costs associated with following such advice may or may not be reimbursed under our agreement. Finally, we may decide not to follow the advice provided and instead pursue activities that we believe are in the best interests of our programs and our business, even if those would not be reimbursed under our agreement. As a result of the unfavorable provisions in our agreements, we must undertake significant compliance activities. The diversion of resources from our development and commercial programs to these compliance activities, as well as the exercise by the U. S. government or higher- tier grantees of any rights under these provisions, could materially harm our business. Laws and regulations affecting government contracts and grants, including our grants and sub- award agreements, make it more costly and difficult for us to successfully conduct our business. Failure to comply with these laws and regulations could result in significant civil and criminal penalties and adversely affect our business. We must comply with numerous laws, regulations, and agency- specific policies and procedures relating to the administration and performance of our grant and sub-award agreements. Among the most significant are: • the Federal Acquisition Regulation (FAR) and agency- specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts; • the business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the AKS, the Procurement Integrity Act, the FCA and the FCPA; and • laws, regulations and executive orders restricting the exportation of certain products and technical data. In addition, as a U. S. government contractor, we are required to comply with applicable laws, regulations and standards relating to our accounting practices, including unique accounting requirements regarding allowable and unallowable costs, and are subject to periodic audits and reviews. As part of any such audit or review, the U. S. government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, estimating, compensation and management information systems. Based on the results of its audits, the U. S. government may adjust our agreement- related costs and fees, including allocated indirect costs. This adjustment could impact the amount of revenues reported on a historic basis and could impact our cash flows under the contract prospectively. In addition, in the event the U. S. government determines that certain costs and fees were unallowable or determines that the allocated indirect cost rate was higher than the actual indirect cost rate, it would be entitled to recoup any overpayment from us as a result. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our agreements, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U. S. government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us, which could cause our stock price to decline. Further, as a U. S. government contractor, we are subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities as compared to private sector commercial companies. In addition, the qui tam provisions of the civil FCA authorize a private person to file civil actions on behalf of the federal and state governments and retain a share of any recovery, which can include treble damages and civil penalties. If we or our third- party manufacturing partners 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 and our suppliers and manufacturers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations, and the manufacturer of our products, involve the production and use of hazardous and flammable materials and waste, including chemicals and biological and radioactive materials. 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, 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, hazardous or radioactive materials. Our manufacturers are subject to federal, state and local laws and regulations in the U. S. governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations. Healthcare policy changes may have a material adverse effect on our business, financial condition and results of operations. The ACA, enacted in March 2010, made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which the ACA may significantly impact our business, the ACA includes: provisions regarding coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures; initiatives to revise Medicare payment methodologies; and initiatives to promote quality indicators in payment methodologies. There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, the legislation enacted on December 22, 2017, informally known as the Tax Cuts and Jobs Act (TCJA) repealed the tax- based shared responsibility payment imposed by the ACA, on certain individuals who fail to maintain qualifying health

coverage for all or part of a year, which is commonly referred to as the " individual mandate. " Additionally, 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. Further, 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, which began on February 15, 2021 and remained open through August 15, 2021. 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. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the" donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any additional healthcare reform measure of the Biden administration will impact the ACA or our business. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers and suppliers of 2 % per fiscal year, starting in 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1 % in 2022 to up to 4 % in the final fiscal year of this sequester. Furthermore, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, there has been numerous governmental reform activity in response to the COVID- 19 pandemic. It is possible that additional governmental action is taken to address the COVID- 19 pandemic, which may impact our business. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. The expansion of government' s role in the U. S. healthcare industry as a result of the ACA' s implementation, and changes to the reimbursement amounts paid by Medicare and other payors for our tests and our planned future tests, may reduce our profits, if any, and have a materially adverse effect on our business, financial condition, results of operations and cash flows. We cannot predict the impact changes to these laws or the implementation of, or changes to, any other laws applicable to us in the future may have on our business, financial condition and results of operations. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused U. S. federal net operating losses (NOLs) for taxable years beginning before January 1, 2018, may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under the TCJA, as modified by the CARES Act, U. S. federal NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such U. S. federal NOLs in taxable years beginning after December 31, 2020, is limited to 80 % of taxable income. It is uncertain if and to what extent various states will conform to the TCJA or the CARES Act. As of December 31, ~~2022~~ **2023**, we had $ 30. 9 million of U. S. federal NOLs that were generated in 2017 and prior periods that will expire at various dates through 2037, and $ ~~202~~ **258**. 2 million of U. S. federal NOLs that can be carried forward indefinitely under current law. As of December 31, ~~2022~~ **2023**, we also had aggregate U. S. federal research and development (R & D) credits of approximately $ ~~9~~ **11**. ~~6~~ **4 million and U. S. state research and development (R & D) credits of approximately $ 8. 7** million. Our NOL carryforwards and R & D credits are subject to review and possible adjustment by the U. S. and state tax authorities. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (Code), and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a three- year period, the corporation' s ability to use its pre- change NOL carryforwards, R & D credits and certain other tax attributes to offset its post- change income or taxes may be limited. This could limit the amount of NOLs, R & D credit carryforwards or other applicable tax attributes that we can utilize annually to offset future taxable income or tax liabilities. Subsequent ownership changes and changes to the U. S. tax rules in respect of the utilization of NOLs, R & D credits and other applicable tax attributes carried forward may further affect the limitation in future years. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently imposed limits on the usability of California state NOL carryforwards to offset taxable income in tax years beginning after 2019 and before 2023. As a result, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows. Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the TCJA enacted many significant changes to the U. S. tax laws, and the CARES Act modified certain provisions of the TCJA. Future guidance from the Internal Revenue Service and other tax authorities with respect to the TCJA may affect us, and certain aspects of the TCJA could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to the TCJA or any other federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets, could result in significant one- time charges, and

could increase our future U. S. tax expense. Risks related to our intellectual property We may be, in the future, subject to claims against us alleging that we are infringing, misappropriating or otherwise violating the intellectual property rights of third parties, the outcome of which could have a material adverse effect on our business. Our commercial success depends in part upon our ability to develop, manufacture, market and sell our products and use our technology without infringing, misappropriating or otherwise violating the patents, trademarks or other intellectual property or proprietary rights of third parties. We cannot assure you that technologies we may develop will not infringe existing or future patents owned by third parties. Litigation relating to infringement, misappropriation or other violations of intellectual property rights in biotechnology industry is common, unpredictable and generally expensive and time consuming, including patent infringement lawsuits, trade secret lawsuits, interferences, oppositions, and inter- partes review, post- grant review and ex parte reexamination proceedings before the United States Patent and Trademark Office (USPTO), and corresponding post- grant proceedings in international patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property- dependent industries, including the biotechnology industry, have employed intellectual property litigation as a means to gain an advantage over their competitors. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. We recently settled a trademark suit as described under the heading" Legal Proceedings" above. In the future, we may also be subject to other third- party claims and adversarial proceedings or litigation regarding infringement, misappropriation or other violation by us of patent, trademark or other intellectual property rights of third parties. We cannot provide any assurances that third- party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties. If any such claim or proceeding is brought against us, our collaborators or our third- party service providers, our development, manufacturing, marketing, sales and other commercialization activities could be similarly adversely affected. 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. A court of competent jurisdiction could hold that third- party patents asserted against us are valid, enforceable, and infringed, which could materially and adversely affect our ability to develop, manufacture, market, sell and commercialize any of our products. To successfully challenge the validity of any such U. S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U. S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U. S. patent. If we are found to infringe any third- party' s patents or other intellectual property rights, and we are unsuccessful in demonstrating that such patents or other intellectual property are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing, marketing, selling and commercializing our products. However, we may not be able to obtain any required license on commercially reasonable terms or at all, and if we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms, our ability to commercialize our products may be impaired or delayed, which could in turn significantly harm our business. Even if we were able to obtain a license, it could be non- exclusive, which would give our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing, royalty and other payments. We also could be forced, including by court order, to cease developing, manufacturing, marketing, selling and commercializing the infringing product or technology. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects. There may be third- party patents of which we are currently unaware with claims to machines, manufactures, compositions, formulations, methods of manufacture, or methods of use or treatment that cover our products. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to the technologies we may develop, could be found to be infringed by our technology. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our products may infringe. In addition, third parties, our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may obtain patents in the future that may prevent, limit or otherwise interfere with our ability to make, use and sell our products, and may claim that use of our technologies or the manufacture, use, or sale of our products infringes upon these patents. 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. In addition, if the breadth or strength of protection provided by the patents and patent applications we own or in- license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future technology. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers or business collaborators, cause product shipment delays or prohibit us from manufacturing, marketing, selling or otherwise commercializing our products and technology. We may receive, and expect to receive, communications from various industry participants alleging our infringement of their patents, trade secrets or other intellectual property rights and / or offering licenses to such intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities

analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or commercialization activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Uncertainties resulting from patent and other intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace, our ability to raise additional funds, and could otherwise have a material adverse effect on our business, financial condition, results of operations, and prospects. We may be, in the future, involved in lawsuits to defend or enforce our patents and proprietary rights. Such disputes could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of our technology, products, prohibit our use of proprietary technology or sale of products, or put our patents and other proprietary rights at risk. Competitors and other third parties may infringe, misappropriate, mischaracterize or otherwise violate our patents and intellectual property rights or the patents and intellectual property rights of our licensors. The enforcement of such claims can be expensive and time- consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Further, there can be no assurance that the pending patent application in question will result in an issued patent for enforcement. In an infringement proceeding, a court may decide that a patent owned or in- licensed by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our owned and in- licensed patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our owned or in- licensed patents at risk of being invalidated, interpreted narrowly or amended to no longer cover our technology or products. If we were to initiate legal proceedings against any other third party to enforce a patent covering our technology, the defendant could assert that our patent is invalid or unenforceable. If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering our technologies, the defendant could counterclaim we infringe their patents or that the patent covering our technology is invalid or unenforceable, or both. In patent litigation in the United States and Europe, defendants alleging invalidity or unenforceability are common. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness, lack of written description or non- enablement. Third parties might allege unenforceability of our patents because during prosecution of the patent an individual connected with such prosecution withheld relevant information, or made a misleading statement affecting the interpretation of the relevant scope of the claims. There is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. Third parties may also raise challenges to the validity of our patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post- grant review, inter- partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technology or products and that we do not have the right to stop the other party from using the invention at issue. The outcome of proceedings involving assertions of invalidity and unenforceability, including during patent litigation, is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution, but that an adverse third party may identify and submit in support of such assertions of invalidity. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent' s claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party' s use of our patented technology falls under the safe harbor to patent infringement under 35 U. S. C. § 271 (e) (1). Such a loss of patent protection could have a material adverse effect on our business. Our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights. Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to, or the correct inventorship of, our patents or patent applications or those of our licensors. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur negative publicity, reputational harm, significant expenses and could distract our personnel from their normal responsibilities, and the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or commercialization activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Uncertainties resulting from patent and other intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace, our ability to raise additional funds, and could otherwise have a material adverse effect on our business, financial condition, results of operations, and prospects. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. If we are not able to obtain, maintain, defend or enforce patent and other intellectual property protection for products, or if the scope of the patent and other intellectual property protection obtained is

not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. Our success depends in part on our ability to obtain, maintain, defend and enforce patents and other forms of intellectual property rights, including in- licenses of intellectual property rights of others, for our products, as well as our ability to preserve our trade secrets, to prevent third parties from infringing, misappropriating, mischaracterizing or otherwise violating our intellectual property and proprietary rights. Our ability to protect our products from unauthorized use by third parties depends on the extent to which valid and enforceable patents cover them or they are effectively protected as trade secrets. While we have a number of issued patents in the United States and foreign countries, several aspects of our patent portfolio are in much earlier stages of prosecution in the United States and foreign countries. Moreover, we do not own or license any issued patents related to certain aspects of our products and technology, including certain structures and components used in our instruments and established molecular biology techniques. The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. There can be no assurance that our patent rights will not be invalidated or held to be unenforceable, will adequately protect our technology, products or provide any competitive advantage, or that any of our pending or future patent applications will issue as valid and enforceable patents. Our ability to obtain and maintain patent protection for our products is uncertain due to a number of factors, including that: • we or our licensors may not have been the first to invent the technology covered by our pending patent applications or issued patents; • we or our licensors may not be the first to file all patent applications covering our methods or products, as patent applications in the United States and most other countries are confidential for a period of time after filing; • our products and related methods may not be patentable; • our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability; • there may be prior art of which we or the examiner may not be aware that may affect the patentability of our invention claims, or, if issued, affect the validity ~~of~~ **or** enforceability of a patent claim; • any or all of our pending patent applications may not result in issued patents; • others may independently develop identical, similar or alternative technologies; • others may design around our patent claims to produce competitive technologies or methods or products that fall outside of the scope of our patents; • we may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection; • parties with access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, may disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection; • we may not seek or obtain patent protection in countries that may eventually provide us a significant business opportunity; • any patents issued to us may not provide a basis for commercially viable products or methods, may not provide any competitive advantages or may be successfully challenged by third parties; • the patents of others could harm our business; • a third party may challenge our patents and, if challenged, a court may hold that one or more of our patents are invalid in whole or in part; • a third party may challenge our patents in various patent offices and, if challenged, we may be compelled to limit the scope of our allowed or granted claims or lose the allowed or granted claims altogether; • our competitors could conduct research and development activities in countries where we will not have enforceable patent rights and then use the information learned from such activities to develop competitive methods or products for sale in our major commercial markets; and • the growing scientific and patent literature relating to molecular testing, including our own patents and publications, may make it increasingly difficult or impossible to patent new products and methods in the future. Even if we have or obtain patents covering our products or methods, we may still be barred from making, using and selling such products or methods because of the patent rights of others. Others may have filed, and in the future may file, patent applications covering compositions, products or methods that are similar or identical to ours, which could materially affect our ability to successfully develop our technology or to successfully commercialize any approved products alone or with collaborators. Patent applications in the U. S. and elsewhere are generally published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our methods and products could have been filed by others without our knowledge. Additionally, pending claims in patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our system technologies or related products. These patent applications may have priority over patent applications filed by us. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to third- party pre- issuance submissions of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post- grant and inter- partes review, or interference proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our products and technology and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. Moreover, we, or our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post- grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products and technology, or limit the duration of the patent protection of our products and technology. Such proceedings also may result in substantial cost and require significant time from our employees and management, even if the eventual outcome is favorable to us. Furthermore, we cannot guarantee that any patents will be issued from any of our pending or future patent applications. Criteria determining patentable subject matter and enforcement thereof may be impacted from future judicial and legislative changes or developments in the United States and abroad. Additionally, the

standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in diagnostic patents. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. While we will endeavor to protect our technology with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time- consuming, expensive and sometimes unpredictable. In addition, third parties may be able to develop technology that is similar to, or better than, ours in a way that is not covered by the claims of our patents, or may have blocking patents that could prevent us from marketing our products or practicing our own patented technology. Moreover, patents have a limited lifespan. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years from the filing date of the earliest U. S. or international (PCT) application, to which priority is claimed (excluding provisional applications), thus the life of a patent, and the protection it affords, is limited. In addition, although upon issuance in the United States a patent' s life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Without patent protection for current or future methods and related products, we may face competing technology. Given the amount of time required for the development and testing, and regulatory review where necessary, patents protecting such technology might expire before or shortly after such technology is commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing technology similar or identical to that we or our collaborators may develop. Moreover, certain of our patents and patent applications are, and others may in the future be, co- owned with third parties. If we are unable to obtain an exclusive license to any such third- party co- owners' interest in such patents or patent applications, such co- owners may be able to use or license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co- owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects. We depend on intellectual property licensed from third parties and we are currently party to several in- license agreements under which we acquired rights to use, develop, manufacture and / or commercialize certain of our system components. If we breach our obligations under these agreements or if any of these agreements is terminated, or otherwise experience disruptions to our business relationships with our licensors, we may be **required to pay damages, lose our rights to such intellectual property and technology, or both, which would harm our business.** We are dependent on patents, know- how, and proprietary technology, both our own and licensed from others. We are a party to a number of intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. For example, we have licensed technology related to frangible seals and reagent plugs in our Talis One cartridges, under an agreement with thinXXS. Our existing license agreements impose (under certain circumstances), and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, including due to the impact of the COVID- 19 pandemic on our business operations or our use of the intellectual property licensed to us in an unauthorized manner, or we are subject to a bankruptcy, we may be required to pay damages and the licensor may have the right to terminate the license. Any termination of these licenses could result in the loss of significant rights and could harm our ability to develop, manufacture and / or commercialize our system or product candidates. In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. Our business also would suffer if any current or future licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor' s rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability. The growth of our business may depend, in part, on our ability to acquire or in- license additional proprietary rights, including to advance the development or commercialization of our products. In that event, we may be required to expend considerable time and resources to license such technology. From time to time, in order to avoid infringing third- party patents, we may be required to license technology from additional third parties to further develop or commercialize our products. We may be unable to acquire or in- license any relevant third- party intellectual property rights, including any such intellectual property rights required to manufacture, use or sell our products, that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, and as a result we may be unable to develop or commercialize the affected product candidates, and we may have to abandon development of the relevant products, which would harm our business. We may need to cease use of the compositions or methods covered by such third- party intellectual property rights, and may need to seek to develop

alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non- exclusive, which may allow our competitors' access to the same technologies licensed to us. The licensing and acquisition of third- party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our products. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional products that we may seek to acquire. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement. If disputes over intellectual property that we have licensed 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. 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 this intellectual property, our ability to commercialize our products could suffer. We depend, in part, on our licensors to file, prosecute, maintain, defend, and enforce patents and patent applications that are material to our business. Patents relating to certain components of our Talis One cartridge are controlled by a third party. Such third party has rights to file, prosecute, maintain, and defend the patents we have licensed from such licensor. If our licensors or any future licensees having rights to file, prosecute, maintain, and defend patent rights that are critical to our products fail to conduct these activities, including due to the impact of the COVID- 19 pandemic on our licensors' business operations, our ability to develop and commercialize our products may be adversely affected and we may not be able to prevent competitors from making, using, or selling competing products. We cannot be certain that such activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and, even if we are permitted to pursue such enforcement or defense, we cannot ensure the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need in our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents, or defense of claims asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after our assuming control. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which might adversely affect our ability to develop and market our products. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third- party patent or may incorrectly predict whether a third- party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. 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. For example, we have identified certain third- party patents that may be asserted against us with respect to our technology. These patents may expire prior to commercial launch of our products. We believe that the relevant claims of these third- party patents are likely invalid or unenforceable, and we may choose to challenge those patents, though the outcome of any challenge that we may initiate in the future is uncertain. We may also decide in the future to seek a license to those third- party patents, but we might not be able to do so on reasonable terms. 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. Further, we may not be aware of all third- party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third- party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third- party intellectual property upon our freedom to operate, is highly uncertain. Because patent applications in the United States and most other countries are confidential for typically a period of 18 months after filing, or may not be published at all, we cannot be certain that we were the first to file any patent application related to our product candidates. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, for U. S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For U. S. applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law in view of the passage of the Leahy-

Smith America Invents Act (AIA), which brought into effect significant changes to the U. S. patent laws, including new procedures for challenging pending patent applications and issued patents. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Obtaining and maintaining a patent portfolio entails significant expense, including periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications. These expenditures can be at numerous stages of prosecuting patent applications and over the lifetime of maintaining and enforcing issued patents. We may or may not choose to pursue or maintain protection for particular intellectual property in our portfolio. If we choose to forgo patent protection or to allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. Furthermore, we employ reputable law firms and other professionals to help us comply with the various procedural, documentary, fee payment and other similar provisions we are subject to and, in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with a jurisdiction' s applicable rules. There are situations, however, in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business. Legal action that may be required to enforce our patent rights can be expensive and may involve the diversion of significant management time. There can be no assurance that we will have sufficient financial or other resources to file and pursue infringement claims, which typically last for years before they are concluded. In addition, these legal actions could be unsuccessful and result in the limitation of scope or invalidation of our patents, a finding that they are unenforceable or a requirement that we enter into a licensing agreement with or pay monies to a third party for use of technology covered by our patents. We may or may not choose to pursue litigation or other actions against those that have infringed on our patents, or have used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to successfully protect or enforce our intellectual property rights, our competitive position could suffer, which could harm our results of operations. Some of our intellectual property has been discovered through government funded programs and thus may be subject to federal regulations such as " march- in " rights, certain reporting requirements and a preference for U. S.- based companies, and compliance with such regulations may limit our exclusive rights and our ability to contract with non- U. S. manufacturers. Our intellectual property rights may be subject to a reservation of rights by one or more third parties. For example, certain intellectual property rights related to structures, such as the rotor or test chambers, within Talis One test cartridges were generated, at least in part, through the use of U. S. government funding and are therefore subject to certain federal regulations. As a result, the U. S. government may have certain rights to intellectual property embodied in the cartridges of our current or future products pursuant to the Bayh- Dole Act of 1980 (Bayh- Dole Act). These U. S. government rights include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government has what are referred to as " march- in " rights to, under certain limited circumstances, require the licensor to grant exclusive, partially exclusive or non- exclusive licenses to any of these inventions to a third party if it determines that (1) adequate steps have not been taken to commercialize the invention and achieve practical application of the government- funded technology, (2) government action is necessary to meet public health or safety needs, (3) government action is necessary to meet requirements for public use under federal regulations or (4) we fail to meet requirements of federal regulations. The U. S. government also has the right to take title to these inventions if we or our licensors fail to disclose the invention to the government or fail to file an application to register the intellectual property within specified time limits. These rights may permit the government to disclose our confidential information to third parties. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. To the extent any of our future owned or licensed intellectual property is also generated through the use of U. S. government funding, the provisions of the Bayh- Dole Act may similarly apply. Any exercise by the government of such rights could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. Changes to US and international patent laws on a jurisdiction by jurisdiction basis is highly uncertain and 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 and international jurisdictions could increase the uncertainties and costs, and may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. There are numerous recent changes to the patent laws and proposed changes to the rules of the USPTO which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the AIA, enacted on September 16, 2011, resulted in significant changes to the U. S. patent system. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned from a " first- to- invent " to a " first- to- file " system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. Under a " first- to- file " system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the USPTO after March 16, 2013, but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. 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 (typically 18 months), after filing or until issuance, we cannot be certain that we or our licensors were the first to either (1) file any patent application related to our product candidates and other proprietary technologies we may develop or (2)

invent any of the inventions claimed in our or our licensor' s patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. The AIA provided opportunities for third parties to challenge any issued patent in the USPTO. Those provisions apply to all of our U. S. patents, regardless of when issued. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U. S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. These provisions could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. Depending on decisions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing U. S. patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the 2013 case Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U. S. Supreme Court held that certain claims to naturally- occurring substances are not patentable. Although we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by Congress, the federal courts or the USPTO may impact the value of our patents. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, but the complexity and uncertainty of European patent laws has also increased in recent years. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business. In addition, changes in, or different interpretations of, patent laws in the United States and other countries may permit others to use our discoveries or to develop and commercialize our technology without providing any compensation to us, or may limit the scope of patent protection that we are able to obtain. The laws of some countries do not protect intellectual property rights to the same extent as U. S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights. If the patent applications we hold or have in-licensed with respect to our current and future technology fail to issue, if the validity, breadth or strength of protection of our patent rights is threatened, or if such patent rights fail to provide meaningful exclusivity for our methods and related products that we or our collaborators may develop, it could dissuade companies from collaborating with us, encourage competitors to develop competing technology and threaten our or our collaborators' ability to commercialize future products or services. Any such outcome could have a material adverse effect on our business. We will not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection. Filing, prosecuting, enforcing and defending patents in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States, assuming that rights are obtained in the United States. In-licensing patents covering our technology in all countries throughout the world may similarly be prohibitively expensive, if such opportunities are available at all. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection, or from selling or importing our technology in and into the United States or other jurisdictions. We generally apply for patents in those countries where we intend to make, have made, use, offer for sale or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we may not seek protection in all countries where we will commercialize our products and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. Competitors may use our technology in jurisdictions where we do not pursue and obtain patent protection to develop their own tests and products and may export otherwise infringing tests and products to territories where we have patent protection, but where our ability to enforce our patent rights is not as strong as in the United States. These tests and products may compete with technologies that we or our collaborators may develop, and our patents or other intellectual property rights may not be effective or sufficient to prevent such competition. The laws of some other countries do not protect intellectual property rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U. S. law does. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time- consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals or biotechnologies. As a result, many companies have encountered significant difficulties in protecting and defending intellectual property rights in certain jurisdictions outside the United States. Such issues may make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many other countries, including countries in the EU, have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents and could limit our potential revenue opportunities. Accordingly, our and our licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Furthermore, proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, subject our patents to the risk of being invalidated or interpreted narrowly, subject our patent applications to the risk of not issuing or provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded to us, if any, may not be commercially meaningful, while the damages and other remedies we may be ordered to pay such third parties may be significant. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patent protection for certain aspects of our technology, we also consider trade secrets, including technical and commercial information, including but not limited to confidential and unpatented formulas, processes, know- how, customer and supplier lists, methods of distribution, and advertising strategies, important to the maintenance of our competitive position. We protect trade secrets and confidential and unpatented information, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their invention rights to us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes or that the assignment agreements that have been entered into are self- executing. Despite these efforts, any of these parties may breach the agreements, intentionally or inadvertently, and disclose our proprietary information, including our trade secrets, or claim ownership in intellectual property that we believe is owned by us. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts in the U. S. and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. Moreover, our competitors or other third parties may independently develop knowledge, methods and know- how equivalent to our trade secrets or seek to reverse engineer our technology for which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third parties, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. We are also subject both in the U. S. and outside the U. S. to various regulatory schemes regarding requests for the information we provide to regulatory authorities, which may include, in whole or in part, trade secrets or confidential commercial information. While we are likely to be notified in advance of any disclosure of such information and would likely object to such disclosure, there can be no assurance that our challenge to the request would be successful. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects. We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed trade secrets or other confidential information of their current or former employers or claims asserting inventorship or ownership of what we regard as our own intellectual property. Many of our employees, consultants, and advisors are currently or were previously employed at universities or other healthcare, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors 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 these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual' s current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. We may be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co- inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co- ownership of potential joint inventions. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on 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. In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self- executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they

may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects. If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our trademarks or trade names may be challenged, opposed, infringed, circumvented, invalidated, cancelled, declared generic, determined to be not entitled to registration, or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. For example, our application to register the trademark TALIS in the United States was the subject of an opposition before the USPTO and related litigation which was resolved with a settlement agreement imposing certain restrictions on our use and registration of our trademarks. Any trademark litigation could be expensive. In addition, we could be found liable for significant monetary damages, including treble damages, disgorgement of profits and attorneys' fees, if we are found to have willfully infringed a trademark. We may not be able to protect our exclusive right to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential collaborators or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our use of " open source " software could subject our proprietary software to general release, adversely affect our ability to sell our products, and subject us to possible litigation. A portion of our products incorporate so- called " open source " software and we may incorporate open source software into other products or technologies in the future. Such open source software is generally licensed by its authors or other third parties under open source licenses. Some open source licenses contain requirements that we disclose source code for modifications we make to the open source software and that we license such modifications to third parties at no cost. In some circumstances, distribution of our software in connection with open source software could require that we disclose and license some or all of our proprietary code in that software as well as distribute our products that use particular open source software at no cost to the user. We monitor our use of open source software in an effort to avoid uses in a manner that would require us to disclose or grant licenses under our proprietary source code, however, there can be no assurance that such efforts will be successful. Open source license terms are often ambiguous and such use could inadvertently occur. There is little legal precedent governing the interpretation of many of the terms of certain of these licenses, and the potential impact of these terms on our business may result in unanticipated obligations regarding our products and technologies. Companies that incorporate open source software into their products have, in the past, faced claims seeking enforcement of open source license provisions and claims asserting ownership of open source software incorporated into their product. If an author or other third party that distributes such open source software were to allege that we had not complied with the conditions of an open source license, we could incur significant legal costs defending ourselves against such allegations. In the event such claims were successful, we could be subject to significant damages or be enjoined from the distribution of our products. In addition, if we combine our proprietary software with open source software in certain ways, under some open source licenses we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products that are similar to or better than ours and otherwise have a material adverse effect on our business. Intellectual property rights do not necessarily address all potential threats. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make products or provide services that are similar to ours but that are not protected by our intellectual property; • we or our licensors might not have been the first to make the inventions covered by our patents; • we or our licensors might not have been the first to file patent applications covering certain of our or their inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents; • issued patents for which we have rights may be held invalid or unenforceable, including as a result of legal challenges by our competitors; • our competitors might conduct activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products in our commercial markets; • we may not develop additional proprietary technologies that are patentable; • if enforced, a court may not hold that our patents are valid, enforceable and infringed; • we cannot predict the scope of protection of any patent issuing based on our patent applications, including 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; • the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties; • we may need to initiate litigation or administrative proceedings to enforce and / or defend our patent rights which will be costly whether we win or lose; • we may fail to adequately protect and police our trademarks and trade secrets; • the patents of others may harm our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications; and • we or our licensors may choose not to file a patent in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property. Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects. Risks related to our financial condition and capital requirements We have incurred significant losses since our inception, and we anticipate that

we will continue to incur losses for the foreseeable future, which could harm our future business prospects. We have historically incurred substantial net losses, including net losses of $ ~~113~~ **62** . 0 million and $ ~~192~~ **113** . 0 million for the twelve months ended December 31, **2023 and** 2022 ~~and 2021~~ , respectively. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~478~~ **540** . 0 million. We expect our losses to continue as we continue to devote a substantial portion of our resources to efforts to develop women' s health and STI test tests, for the commercial launch of the Talis One system, and thereafter to increase the adoption of our products, improve these products, scale our manufacturing capabilities and research, develop and commercialize new products. We have devoted a substantial portion of our resources to the development and commercialization of the Talis One system, a molecular diagnostic system, including clinical and regulatory initiatives to obtain regulatory clearance. These losses have had, and will continue to have, an adverse effect on our working capital, total assets, and stockholders' equity. Because of the numerous risks and uncertainties associated with our research, development and commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations, and cash flows. We will likely need to raise additional capital to fund our existing operations, further develop our diagnostic system, commercialize products, if and when approved, and expand our operations. We may seek to sell common or preferred equity or convertible debt securities, enter into a credit facility or another form of third- party funding, or seek other debt financing. We may also need to raise capital sooner or in larger amounts than currently anticipated for numerous reasons, including as a result of failure to obtain regulatory approvals for our tests, or other risks described in this Annual Report. In addition, we intend to pursue a reagent rental model where the customer does not purchase our Talis One instrument, which will require substantial additional working capital. We may also consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities, or for other reasons, including to: • increase our sales and marketing efforts to facilitate market adoption of our products and address competitive developments; • fund development and marketing efforts of any future products; • further expand our operations outside the United States; • acquire, license or invest in technologies, including information technologies; • acquire or invest in complementary businesses or assets; and • finance capital expenditures and selling, general and administrative expenses. Our present and future funding requirements will depend on many factors, including: • our rate of progress in, and cost of research and development activities associated with, products in research and early development; • our ability to secure and maintain domestic and international regulatory approval for our products; • our ability to successfully launch our products; • our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our products; • the effect of competing technological and market developments; and • the potential cost of and delays in research and development as a result of any regulatory oversight applicable to our products. The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, our stockholders' ownership interests will be diluted. Any equity securities we issue could also provide for rights, preferences, or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, those debt securities would have rights, preferences, and privileges senior to those of holders of our common stock. If we raise funds through borrowings pursuant to a credit agreement, the incurrence of such indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt and acquire or license intellectual property rights, and other operating restrictions that could adversely impact our ability to conduct our business. If we raise funds through collaborations and alliances and licensing arrangements, we might be required to relinquish significant rights to our system or technologies or to grant licenses on terms that are unfavorable to us. Additional equity or debt financing might not be available on reasonable terms, if at all. If we cannot secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more research and development programs or sales and marketing initiatives. In addition, we may have to work with a partner on one or more of our development programs, which could lower the economic value of those programs to us. Lastly, if we are unable to obtain the requisite amount of financing needed to fund our planned operations, it could have a material adverse effect on our business and ability to continue operating as a going concern. Risks related to ownership of our common stock The market price of our common stock has been and may continue to be volatile or may decline regardless of our operating performance and you could lose all or part of your investment. The market price of our common stock may be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control, including, but not limited to: • actual or anticipated fluctuations in our financial condition or results of operations; • variance in our financial performance from expectations of securities analysts; • changes in the pricing of our products; • changes in our projected operating and financial results; • changes in laws or regulations applicable to our products; • changes to the proportion of our customers directly purchasing the Talis One system as compared to utilizing our planned reagent rental model; • announcements by us or our competitors of significant business developments, acquisitions, or new offerings; • changes in the structure of healthcare payment systems; • significant data breaches of our company, providers, vendors or pharmacies; • our involvement in litigation; • future sales of our common stock by us or our stockholders; • changes in senior management or key personnel; • negative publicity, such as whistleblower complaints or unsupported allegations made by short sellers, about us or our products; • the trading volume of our common stock; • changes in investor perceptions of us or our industry; • changes in the anticipated future size and growth rate of our market; • general economic, political, regulatory, industry, and market conditions; and • natural disasters or major catastrophic events. These and other factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In recent years, stock markets in general, and the market for life science technology companies in particular (including companies in the genomics, biotechnology, diagnostics and related sectors), have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations ~~. From~~

~~February 12, 2021 through March 15, 2023, the closing price of our common stock has ranged between $ 0. 45 and $ 27. 80 per share~~ . Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company' s securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management' s attention and resources from our business. ~~If we are unable to regain compliance with the listing requirements of the Nasdaq Capital Market, our common stock may be delisted from the Nasdaq Capital Market which could have a material adverse effect on our financial condition and could make it more difficult for you to sell your shares. Our common stock is listed on the Nasdaq Capital Market, and we are therefore subject to its continued listing requirements, including requirements with respect to the market value of publicly held shares, market value of listed shares, minimum bid price per share, and minimum stockholders' equity, among others, and requirements relating to board and committee independence. If we fail to satisfy one or more of the requirements, we may be delisted from the Nasdaq Global Market. On July 27, 2022, we received a notice (Notice) from The Nasdaq Stock Market (Nasdaq), that we are not currently in compliance with the $ 1. 00 minimum bid price requirement for continued listing on the Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5450 (a) (1) (Minimum Bid Price Requirement). The Notice indicated that, consistent with Nasdaq Listing Rule 5810 (c) (3) (A), we had 180 days, or until January 23, 2023, to regain compliance with the Minimum Bid Price Requirement by having the minimum bid price of our common stock meet or exceed $ 1. 00 per share for at least ten consecutive business days. On January 24, 2023, we transferred the listing of our securities to the Nasdaq Capital Market (Capital Market) and received a second notice from Nasdaq granting us an additional 180- day period, or until July 24, 2023, to regain compliance with the Minimum Bid Price Requirement. We have committed to effectuate a reverse stock split by the end of the second compliance period, if necessary, to regain compliance with the Minimum Bid Price Requirement. Neither notice nor the transfer to the Capital Market have an immediate effect on the listing of our common stock, and our common stock will continue to trade on the Capital Market under the symbol " TLIS " at this time. If we do not regain compliance with the Minimum Bid Price Requirement by the end of the second compliance period, our common stock will become subject to delisting. In the event that we receive notice that our common stock is being delisted, the Nasdaq listing rules permit us to appeal a delisting determination to a hearings panel. There can be no assurance, however, that we will be able to regain compliance with the Minimum Bid Price Requirement, and even if we do, there can be no assurance that we will be able to maintain compliance with the continued listing requirements for the Capital Market or that our common stock will not be delisted in the future. In addition, we may be unable to meet other applicable listing requirements of the Capital Market, including maintaining minimum levels of stockholders' equity or market values of our common stock in which case, our common stock could be delisted notwithstanding our ability to demonstrate compliance with the Minimum Bid Price Requirement. Delisting from the Capital Market may adversely affect our ability to raise additional financing through the public or private sale of equity securities, may significantly affect the ability of investors to trade our securities and may negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities.~~ We are involved in securities class action litigation and are at risk of additional similar litigation in the future that could divert management' s attention, may be expensive and adversely affect our business and could subject us to significant liabilities. Our share price is volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We are a party to securities class action litigation described under the heading " Legal Proceedings " below. The defense of these claims may be expensive and divert our management' s attention and resources and any unfavorable outcome could have a material adverse effect on our business and results of operations. Any adverse determination in these claims, or any amounts paid to settle these claims could require that we make significant payments. In addition, we may in the future be the target of other securities class actions or similar litigation. Future sales of our common stock in the public market could cause the market price of our common stock to decline. Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. There were ~~8~~ **718** , **230** ~~402, 626~~ shares of common stock issuable upon the exercise of options outstanding and ~~326~~ **14** , ~~364~~ **484** shares of common stock issuable upon vesting of restricted stock units as of December 31, ~~2022~~ **2023** . We registered all of the shares of common stock issuable upon exercise of such outstanding options or other equity incentives we may grant in the future, for public resale under the Securities Act of 1933, as amended (Securities Act). The shares of common stock will become eligible for sale in the public market to the extent such options are exercised, subject to compliance with applicable securities laws. Further, based on shares outstanding as of December 31, ~~2022~~ **2023** , holders of approximately ~~37~~ **2** , ~~489~~ **499** , ~~210~~ **285** shares **(adjusted for the 1- for- 15 reverse stock split and activity during the twelve months ended December 31, 2023)** , or 66 % of our capital stock have certain registration rights with respect to the resale of such shares. ~~We~~ **In March 2024, we terminated a previously** filed ~~a~~ registration statement on Form S- 3 **as the Company was no longer eligible to** ~~registering~~ --- **register securities on Form S- 3 and obtained a waiver of the registration rights relating to** ~~the~~ **these 2** ~~resale of all of the 37~~ , ~~489~~ **499** , ~~210~~ **285** shares **. This waiver of the** ~~held by such holders, which~~ registration **rights is** ~~statement was declared~~ effective **for a period of thirty (30) days from** ~~on May 24, 2022. We are required to maintain~~ the ~~effectiveness~~ **filing** of this **Form 10- K** ~~registration statement and the holders of such securities are entitled to one underwritten offering per calendar year, in each case, subject to certain conditions, limitations and exceptions~~ . The issuance of shares in connection with any subsequent issuance could depress the market price of our common stock. We are unable to predict the effect that such issuances and / or sales may have on the prevailing market price of our common stock. We are an emerging growth company and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors. We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, as amended (JOBS Act). For so long as we remain an emerging

growth company, we are permitted by Securities and Exchange Commission (SEC) rules and plan to rely on exemptions from certain disclosure requirements that are applicable to other SEC- registered public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes – Oxley Act of 2002, as amended (Sarbanes- Oxley Act), not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different from the information that is available with respect to other public companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. In addition, as an emerging growth company the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies, unless we later irrevocably elect not to avail ourselves of this exemption. We have elected to use this extended transition period under the JOBS Act; however, we may choose to early adopt new or revised accounting pronouncements, if permitted under such pronouncements. Even 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 many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 (b) of the Sarbanes- Oxley Act. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We do not expect to pay any dividends for the foreseeable future. Investors may never obtain a return on their investment. You should not rely on an investment in our common stock to provide dividend income. We have never declared or paid cash dividends on our capital stock, and we do not anticipate that we will pay any dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain all available funds and future earnings to fund the development and expansion of our business. In addition, any future credit facility or financing we obtain may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock. If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our common stock, the price of our common stock could decline. The trading market for our common stock will rely in part on the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or securities analysts. If no or few analysts commence coverage of us, the trading price of our common stock could decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our common stock, the price of our common stock could decline. If one or more of these analysts cease to cover our common stock, we could lose visibility in the market for our common stock, which in turn could cause the price of our common stock to decline. We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices. As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company, which we expect to further increase after we are no longer an emerging growth company. The Sarbanes – Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Stock Market (Nasdaq), and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time- consuming and costly. We cannot predict or estimate the amount of additional costs we will incur as a public company or the specific timing of such costs. We have broad discretion in the use of our cash and cash equivalents and may not use them effectively. We have broad discretion in the application and use of our cash and cash equivalents, including the net proceeds from our initial public offering, and you will not have the opportunity as part of your investment decision to assess whether our cash and cash equivalents were used or are being used effectively. Because of the number and variability of factors that determine the application and use of our cash and cash equivalents, our ultimate use may vary or has varied substantially from our original intended uses. For example, due to significant delays in obtaining an EUA for the Talis One COVID- 19 Test System and to produce the Talis One system at scale, which in turn delayed the commercialization of the Talis One system, we have used a larger proportion of the net proceeds from our initial public offering for research and development expenses and a smaller proportion for commercial activities than our original estimates in our prospectus filed with the SEC on February 12, 2021. Investors will need to rely upon the judgment of our management with respect to the use of our cash and cash equivalents. Our failure to apply our cash and cash equivalents effectively could compromise our ability to pursue our business strategy and we might not be able to yield a significant return, if any, and our business, financial condition, results of operations and prospects could be harmed, and the market price of our common stock could decline. Our principal stockholder owns a very significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. As of March ~~15~~ **19** , ~~2023~~ **2024** , our executive officers, directors and five percent or greater stockholders and their respective affiliates, beneficially own, in the aggregate, approximately ~~80~~ **74** % of our outstanding voting stock. Further, 66 % of our outstanding voting stock is owned by entities affiliated with Baker Bros. Advisors LP (Baker Bros.). In addition, the holders of our Series 1 convertible preferred stock, which, subject to certain limitations, is a voting common stock equivalent, may elect to convert shares of Series 1 convertible preferred stock into shares of Series 2 convertible preferred stock, which is a non- voting common stock equivalent. These shares of Series 2 convertible preferred stock are then convertible into shares of our common stock, subject to certain beneficial ownership limitations. We also have a nominating agreement with Baker Bros. that provides that,

for so long as it continues to own a certain number of shares of our common stock, we have the obligation to support the nomination of, and to cause our ~~board~~ **Board** of ~~directors~~ **Directors** to include in the slate of nominees recommended to our stockholders for election, one or two individuals designated by Baker Bros. As a result, Baker Bros. is able to exercise considerable influence over matters requiring stockholder approval, including the election of directors, amendments of our organizational documents and approval of any merger, sale of substantially all our assets or other significant corporate transactions for the foreseeable future. This concentration of ownership may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you or other stockholders may feel are in your or their best interest as one of our stockholders. As a result of being a public company, we are obligated to develop and maintain proper and effective internal controls over financial reporting, and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock. We are required, pursuant to Section 404 of the Sarbanes – Oxley Act to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. These assessments must include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual and interim financial statements will not be detected or prevented on a timely basis. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company if we are not a non-accelerated filer at such time. We continue the costly and challenging process ~~, starting last year,~~ of compiling the information systems, processes and internal controls documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes – Oxley Act, but we may not be able to complete our evaluation, testing and any required remediation in a timely fashion once initiated. Our compliance with Section 404 of the Sarbanes – Oxley Act requires that we incur substantial accounting expenses and expend significant management efforts. We currently do not have an internal audit group, and we will need to outsource or hire the accounting and financial staff with appropriate public company experience and technical accounting knowledge to compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes – Oxley Act. 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, we could lose investor 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 the SEC or other 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. Our amended and restated certificate of incorporation designates the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against us or our directors, officers, or employees. Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, any state court located within the State of Delaware, or if all such state courts lack jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a breach of a fiduciary duty owed by any current or former director, officer or other employee, to us or our stockholders; (3) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provisions of the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; (4) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; (5) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (6) any action asserting a claim against us, or any of our directors, officers or other employees, that is governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court' s having personal jurisdiction over the indispensable parties named as defendants. The amended and restated certificate of incorporation states that these choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Securities Act, the Securities Exchange Act of 1934 (Exchange Act) or any other claim for which the federal courts have exclusive jurisdiction. This amended and restated certificate of incorporation will further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees and may discourage these types of lawsuits. Furthermore, if a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions. Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock. Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and

restated bylaws: • permit our ~~board~~ **Board** of ~~directors~~ **Directors** to issue shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control); • provide that the authorized number of directors may be changed only by resolution of the ~~board~~ **Board** of ~~directors~~ **Directors** ; • provide that the ~~board~~ **Board** of ~~directors~~ **Directors** or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66 2 / 3 % of the voting power of all of our then outstanding capital stock; • provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum; • divide our ~~board~~ **Board** of ~~directors~~ **Directors** into three classes; • require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent; • provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder' s notice; • do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and • provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the ~~board~~ **Board** of ~~directors~~ **Directors** pursuant to a resolution adopted by a majority of the total number of authorized directors. The amendment of any of these provisions, with the exception of the ability of our ~~board~~ **Board** of ~~directors~~ **Directors** to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66 2 / 3 % of our then- outstanding voting capital stock. In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15 % or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our ~~board~~ **Board** of ~~directors~~ **Directors** or initiate actions that are opposed by our then- current ~~board~~ **Board** of ~~directors~~ **Directors** , including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.