Risk Factors Comparison 2024-04-01 to 2023-03-31 Form: 10-K

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We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. In evaluating our company, you should consider carefully the summary risks and uncertainties described below together with the other information included in this Annual Report on Form 10- K, including **the risks and uncertainties described in more detail in " Risk Factors " in Part I, Item 1A and** our consolidated financial statements and related notes included in Part II, Item 8," Financial Statements and Supplementary Data" in this Annual Report on Form 10- K. The occurrence of any of the following risks may materially and adversely affect our business, financial condition, results of operations and future prospects ~~.~~ **;** • our ability to continue as a going concern; • our ability to regain and maintain compliance with Nasdaq listing requirements **; • our expectation that we will incur losses in the future and be unable to utilize limited net operating losses against future profitability, if any; • compliance with the terms of our debt instruments; • our future capital needs and our ability to raise additional funds; • impact of litigation, including our ability to adequately resolve current legal claims** ; • our status as an early- stage commercial company; • ~~our expectation to incur losses in the future and our ability to utilize limited net operating losses against future profitability, if any; •~~ the market acceptance of our technology; • our ability to timely and successfully develop and commercialize our existing products and future product candidates; • the length and variability of our anticipated sales and adoption cycle; • our ability to gain the support of hospitals and key thought leaders and publish the results of our clinical studies in peer- reviewed journals; • our ability to successfully manage our growth; • ~~our future capital needs~~ **fluctuations in demand for,** and **prices of, raw materials and other supplies; •** our ability to ~~raise additional funds~~ **recruit, train and retain key personnel** ; • the performance of our diagnostics; • our ability to compete in the highly competitive diagnostics market; • **manufacturing and other product risks, including unforeseen interruptions in the manufacturing of our products and backlogs in order fulfillment; • our dependence on third parties; • the impact of cybersecurity risks, including ransomware, phishing, and data breaches on our information technology systems; •** our ability to obtain marketing clearance from the U. S. Food and Drug Administration or regulatory clearance or certifications for new product candidates in other jurisdictions. including IVDR in the European Union; • federal, state, and foreign regulatory requirements, including diagnostic product reimbursements and FDA regulation of our products and product candidates; • our ability to protect and enforce our intellectual property rights, including our trade secret- protected proprietary rights in our technology; • **an active** ~~our ability to recruit, train~~ **trading** ~~and retain key personnel~~ **market for our common stock** ; • **volatility** ~~our dependence on third parties; • manufacturing and other product risks, including unforeseen interruptions in the manufacturing~~ of our **stock price which may be** ~~products and backlogs in order fulfillment; • the impact~~ **impacted by** ~~of cybersecurity risks, including ransomware, phishing, and data breaches on our information technology systems; • the impact of~~ short sellers and day traders ~~on our share price~~ ; **and** • ~~the impact of litigation, including~~ our ability to **maintain** ~~adequately resolve current legal claims; and~~ **an effective system of internal control over financial reporting** ~~• our ability to convert T2SARS- CoV- 2 customers to our other test panels~~ . PART I. Item 1. BUSINESS Overview We are an in vitro diagnostics company and leader in the rapid detection of sepsis- causing pathogens and antibiotic resistance genes ~~. We are dedicated to improving patient care and reducing the cost of care by helping clinicians effectively treat patients faster than ever before. We have developed innovative products that offer a rapid, sensitive and simple alternative to existing diagnostic methodologies. We are developing a broad set of applications aimed at improving patient outcomes, reducing the cost of healthcare, and lowering mortality rates by helping medical professionals make earlier targeted treatment decisions~~ . Our technology enables rapid detection of pathogens, biomarkers and other abnormalities in a variety of unpurified patient sample types, including whole blood, plasma, serum, saliva, sputum and urine, and can detect cellular targets at limits of detection as low as one colony forming unit per milliliter, or CFU / mL. We are currently targeting **what we believe to be** a range of critically underserved healthcare conditions, focusing initially on those for which ~~a~~ rapid ~~diagnosis will serve~~ **detection may enable faster targeted antimicrobial treatment, improve patient outcomes,** ~~an~~ **and reduce** ~~important dual role — saving lives and reducing costs~~ **cost** . Our current ~~development efforts primarily target~~ **focus includes three areas –** sepsis **, bioterrorism,** and Lyme disease ~~, –~~ which **we believe collectively** represent **a multi- billion dollar market opportunity** ~~areas of significant unmet medical need in which existing therapies could be more effective with improved diagnostics~~ . Our primary commercial products ~~based on revenue~~ for the year ended December 31, ~~2022~~ **2023** include the T2Dx ® Instrument, the **T2Bacteria ® Panel, the** T2Candida ® Panel, the ~~T2Bacteria ® Panel, the~~ T2Resistance ® Panel, and the **T2Biothreat** ~~T2SARS- CoV- 2~~ ™ Panel. **Our sepsis products – including the T2Dx Instrument, the T2Bacteria Panel, and the T2Candida Panel – are FDA- cleared products able to detect sepsis- causing pathogens directly from blood. Where traditional diagnostics like blood cultures and post- culture diagnostics may take days to produce results, our products are designed to detect these pathogens in three to five hours. We believe our products provide a significant and sustainable competitive advantage compared to other products in our markets.** History **We were incorporated under the laws of the State of Delaware in 2006.** In September 2014, we received marketing authorization from the United States Food and Drug Administration, or FDA, for our first two products, the T2Dx Instrument and the T2Candida Panel, or T2Candida **. T2Candida** , which ~~have~~ **runs on the T2Dx Instrument, has** the ability to rapidly identify the five most clinically relevant species of Candida, a fungal pathogen known to cause sepsis, directly from ~~whole~~ blood specimens. The T2Dx Instrument and T2Candida ~~Panel~~ were CE marked in the European Union, or **the** EU, in July 2014. In May 2018, we received market clearance from the FDA for the T2Bacteria ~~®~~ Panel, or T2Bacteria, which runs on the T2Dx Instrument and has the ability to rapidly identify ~~five~~ **six** of the most common and deadly sepsis- causing bacteria directly

from ~~whole~~ blood specimens. ~~The~~ T2Bacteria ~~Panel~~ was CE marked in the EU in June 2017. In February 2019, our T2Resistance ~~®~~ Panel, or T2Resistance, was granted FDA Breakthrough Device designation and **,** in November 2019, ~~it~~ was CE marked in the EU. In December 2021, we initiated a U. S. clinical trial for ~~the~~ T2Resistance ~~Panel~~ **. The clinical trial is expected to be completed in 2024, and we believe the data from this trial may enable submission of a marketing application to the FDA in 2024** . In September 2019, the Biomedical Advanced Research and Development Authority, or BARDA **, an office of the U. S. Department of Health and Human Services, or HHS** , awarded us a milestone- based contract ~~, with an initial value of $ 6 million, and a potential value of up to $ 62 million,~~ for the development of a next-generation diagnostic instrument, a comprehensive sepsis panel ~~,~~ and a multi- target biothreat panel. In September 2020, BARDA exercised the first contract option valued at $ 10. 5 million. In April 2021, BARDA agreed to modify the contract to accelerate product development by advancing future deliverables ~~,~~ and adding a U. S. T2Resistance Panel into Option 1 of the ~~BARDA~~ contract. In September 2021, BARDA exercised Option 2A valued at approximately $ 6. 4 million to further advance the new product development initiatives. In **December 2021, we initiated the U. S. clinical trials for T2Resistance and the T2Biothreat Panel, or T2Biothreat. In** March 2022, BARDA exercised Option 2B valued at approximately $ 4. 4 million. In ~~December 2021, we initiated the U. S. clinical trials for the T2Resistance and T2Biothreat Panels. In~~ May 2022, BARDA exercised Option 3 valued at approximately $ 3. 7 million to complete the U. S. clinical trials for ~~the~~ T2Resistance ~~® Panel~~ and T2Biothreat ~~Panel~~ and subsequently submit applications to the FDA for U. S. regulatory clearance for those product candidates. In December 2022 the T2Biothreat clinical evaluation was completed. In **May 2023, we submitted a 510 (k) premarket notification to the FDA for T2Biothreat and in September 2023, we received 510 (k) clearance from the FDA to market T2Biothreat. The BARDA contract expired in September 2023. In** June 2020, we launched **a COVID- 19 molecular diagnostic test,** the T2SARS- CoV- 2 Panel, ~~our~~ **or** ~~COVID~~ **T2SARS - CoV- 2** ~~19 molecular diagnostic test~~ , after validation of the test pursuant to the FDA' s policy permitting COVID- 19 tests to be marketed prior to receipt of an Emergency Use Authorization, or EUA, subject to certain prerequisites. In August 2020, the FDA granted an EUA to ~~the~~ T2SARS- CoV- 2 ~~Panel~~ for the qualitative direct detection of nucleic acid from SARS- CoV- 2 in upper respiratory specimens ~~(such as nasal, mid-turbinate, nasopharyngeal, and oropharyngeal swab specimens)~~ and bronchoalveolar lavage specimens from individuals suspected of COVID- 19 by their healthcare provider. We **marketed and sold** ~~expect to continue to experience a decline in COVID- 19 product sales tied to our~~ T2SARS- CoV- 2 ~~Panel,~~ **between 2020** and **2023, with peak sales occurring during 2021. In 2023, we experienced decreased demand for** the ~~focus~~ **product as the incidence** of **COVID** ~~our go- to~~ **19 infections decreased significantly and, as a result, we have stopped marketing, selling and manufacturing T2SARS - CoV- 2. In July 2022** ~~market strategy continues to be increasing sales of our sepsis test panels~~ , **we received Breakthrough Device designation** ~~expanding the installed base of our T2Dx Instruments, and solidifying commercial plans~~ for ~~our~~ **the** T2Lyme Panel **, or T2Lyme, a direct- from- blood molecular diagnostic test designed to run on the T2Dx Instrument and detect Borrelia burgdorferi, the bacteria that cause Lyme disease. T2Lyme is intended to test individuals with signs and symptoms of Lyme disease and aid in the diagnosis of early Lyme disease. In November 2022, the HHS and the Steven & Alexandra Cohen Foundation, or Cohen Foundation, selected T2 Biosystems as a Phase 1 winner in the LymeX Diagnostics Prize, a LymeX Innovation Accelerator prize competition intended to accelerate the development of Lyme disease diagnostics. As a Phase 1 winner, we received $ 100, 000 and an invitation to participate in a second phase. In July 2023, we received Breakthrough Device Designation for our Candida auris (C. auris) test, a direct- from- blood molecular diagnostic test designed to run on the T2Dx Instrument and detect C. auris. C. auris is a multidrug- resistant fungal pathogen recognized as a serious global health threat with a mortality rate of up to 60 %, and is difficult to identify with standard laboratory methods, which can lead to inappropriate treatment. We plan to expand the test menu on the T2Dx Instrument by seeking 510 (k) clearance from the FDA to add C. auris detection to the FDA- cleared T2Candida Panel. In October 2023, we submitted a 510 (k) premarket notification to the FDA to expand the number of pathogens detected on the FDA- cleared T2Bacteria Panel to include the detection of Acinetobacter baumannii (A. baumannii). A. baumannii is a cause of bloodstream infections especially in critically ill patients, which can range from a benign transient bacteremia to septic shock. In December 2023, we submitted a 510 (k) premarket notification to the FDA to expand the use of the T2Candida Panel to include pediatric testing. Candida species are a major contributor to morbidity and mortality in hospitalized children** . Clinical Need Sepsis is the body' s overwhelming and **potentially** life-threatening response to infection that can lead to tissue damage, organ failure, and death. ~~It is~~ **Globally, sepsis causes the death of an estimated 11 million people each year, accounting for** one **in five** ~~of the leading causes of death~~ **deaths globally** ~~in the United States~~ , ~~claiming~~ **and** more **deaths** ~~lives annually~~ than **all** ~~the top three~~ cancers combined **. Sepsis** ~~: lung, colorectal and breast cancer, and it~~ is ~~the most expensive~~ **a leading cause of death in U. S.** ~~hospital~~ **hospitals , claiming at least 350, 000 American lives each year from patients who develop sepsis and die during their hospitalization or are discharged to hospice according to the CDC. Sepsis** ~~- treated - related condition~~ **costs in U** . ~~Most commonly afflicting immunocompromised, critical care, and elderly patients~~ **S. hospitalizations total nearly $ 38 billion annually according to the US Agency for Healthcare Research & Quality in 2020. Finally** , sepsis is a **leading cause** ~~severe inflammatory response to a bacterial or fungal infection with a mortality rate~~ of ~~approximately~~ 30 **- day hospital readmissions. Nearly 20** % ~~. Based on a 2020 study from the Department of Health and Human Services, or HHS, it was estimated that the annual cost~~ of sepsis **survivors are re-** ~~to the U. S. healthcare system was $ 62 billion. The rate of Medicare beneficiaries~~ hospitalized ~~with~~ **within** ~~sepsis has increased by~~ **30 days after discharge, and nearly** 40 % ~~from 2012 to 2018, the HHS study found~~ **of sepsis survivors are re- hospitalized within 90 days after discharge** . The **rapid detection of** ~~United States Centers for Disease Control and Prevention, or CDC, estimates that~~ sepsis ~~- causes more than 350, 000 American deaths per year. The most common cause of sepsis is bacterial, Gram positive and Gram negative pathogens, while Candida species are the most common cause of fungal sepsis. Early detection and identification of sepsis~~ causing pathogens is critical **as each hour** ~~for effective treatment and positive~~

~~patient outcomes. Today, sepsis- causing pathogens are typically detected through a series~~ of ~~blood cultures, post- blood culture species identification and antimicrobial susceptibility testing. These methods have substantial limitations including the risk of false negative test results, a delay~~ **delayed** ~~in administration of~~ targeted antimicrobial treatment **increases mortality risk by up to 8 %. Today** , **the standard of care for patients at risk of sepsis relies on broad empiric protocols to administer antimicrobial (i. e., antibiotic** and **antifungal) therapy, despite the fact that data shows** ~~the~~ **those protocols are only optimal** ~~incurrence of unnecessary hospital expense. According to a study published~~ in ~~the Journal~~ **approximately 50 %** of ~~Clinical Microbiology in 2010,~~ **cases. The current standard of care continues to rely on a positive blood culture to identify the presence of a blood stream infection and** ~~targeted~~ -- **target** therapy for patients ~~with bloodstream infections~~ **suspected of sepsis. However, studies show blood cultures** can ~~be delayed up~~ **take 1- 5 days** to **achieve** ~~72 hours due to~~ the ~~wait time~~ **growth necessary** for **species identification and may. require multiple** blood ~~culture~~ **cultures to minimize false negative** results ~~. In another study published in Clinical Infectious Diseases in 2012, the delayed administration of appropriate antifungal therapy was associated with higher mortality among patients with septic shock attributed to Candida infection. In addition, the Survey of Physicians' Perspectives and Knowledge About Diagnostic Tests for Bloodstream Infections in 2015 reported that negative blood culture results are only trusted by 36 % of those physicians~~ . Without the ability to rapidly identify pathogens, physicians typically start treatment of at- risk patients with broad- spectrum ~~antibiotics~~ **antimicrobials** and switch therapies every 12 to 24 hours if a patient is not responding. These **antimicrobials** ~~drugs, which~~ can be costly, are often ineffective and unnecessary **,** and have contributed to the spread of antimicrobial resistance. The ~~speed to getting the patient on the right targeted therapy is critical. According to a study published by Critical Care Medicine in 2006, in sepsis patients with documented hypotension,~~ administration of ~~effective~~ **inappropriate** antimicrobial ~~therapy within the first hour of detection was associated with a survival rate of 79. 9 % and, over the ensuing six hours, each hour of delay in initiation of treatment was associated with an average decrease in survival of 7. 6 %. Candida is the fourth leading hospital- acquired bloodstream infection, afflicting more than 135, 000 patients per year in the United States, and the most lethal form of common bloodstream infections that cause sepsis, with an average mortality rate of approximately 40 %. This high mortality rate is largely due to a delay in providing targeted therapy to the patient due to the elapsed time from Candida infection to positive diagnosis. According to a study published in Antimicrobial Agents and Chemotherapy, the Candida mortality rate can be reduced from 40 % to 11 % with the initiation of targeted therapy within 12 hours of presentation of symptoms. Additionally, a typical patient with a Candida infection averages 40 days in the hospital, including nine days in intensive care, resulting in an average cost per hospital stay of more than $ 130, 000 per patient. In a study published in the American Journal of Respiratory and Critical Care Medicine, providing targeted antifungal therapy within 24 hours of the presentation of symptoms decreased the length of hospital stay by approximately ten days and decreased the average cost of care by approximately $ 30, 000 per patient. In addition, due to the high mortality rate associated with Candida infections, physicians often will place patients on antifungal drugs while they await blood culture diagnostic results which generally take at least five days to generate a negative test result. Antifungal drugs are toxic and may result in side effects and can cost over $ 50 per day. The speed to result of T2Candida, coupled with higher sensitivity as compared to blood culture, may help reduce the overuse of ineffective, or even unnecessary, antimicrobial therapy which may reduce side effects for patients, lower hospital costs and potentially counteract the growing resistance to antifungal therapy. The administration of inappropriate~~ therapy is a driving force behind the spread of antimicrobial- resistant pathogens, which the **Centers for Disease Control and Prevention, or** CDC **, has** called " one of our most serious health threats. " ~~Currently~~ **In 2021** , ~~high risk~~ **the results of a meta- analysis were published in a peer- reviewed medical journal, Expert Review of Medical Devices, analyzing fourteen controlled studies and comparing the use of our sepsis products to the use of blood culture- based diagnostics. The use of our products resulted in species identification 77 hours earlier than blood culture- based diagnostics, enabled** patients **testing positive** ~~are typically initially treated~~ with ~~broad spectrum antibiotic~~ **T2' s products to receive targeted antimicrobial** therapy **42 hours earlier** ~~that~~ **than** ~~cover approximately 60 % of~~ **blood culture- based diagnostics, enabled** patients **testing negative** with **T2' s products** ~~infections. Of the remaining 40 % of patients, approximately 30 % of the patients typically have a bacterial infection and 10 % typically have Candida infections. T2Candida and T2Bacteria are designed~~ to **be de- escalated from empirical antimicrobial** ~~identify pathogens either resistant to, or not covered by, broad spectrum antibiotic~~ therapy **seven hours earlier than those using blood culture- based diagnostics, and allowed a reduction of stay in the ICU and hospital of 5. 0 and 4. 8 days, respectively, compared to the use of blood culture- based diagnostics** . Products- Commercially Available Our T2Dx Instrument, which is FDA- cleared ~~for use with our T2Candida and T2Bacteria panels~~ and CE marked ~~in the EU for use with our T2Candida, T2Bacteria and T2Resistance Panels~~ , is a fully automated, easy- to- use, bench- top instrument that is capable of running a broad range of diagnostic tests from patient samples, eliminating the need for manual workflow steps, such as pipetting, that can introduce risks of cross- contamination. To operate the system, a tube containing the patient' s **blood** sample is placed onto a disposable test cartridge, which is pre- loaded with all necessary reagents and consumables. The cartridge is then inserted into the T2Dx Instrument, which automatically processes the sample and then delivers a diagnostic test result **in three to five hours** . Test results are displayed on screen and can be printed or connected directly to the hospital or laboratory information system. The T2Dx Instrument eliminates the need for sample purification and analyte extraction often required by other diagnostic technologies, which increases sensitivity and specificity, enables a broad menu of tests to be run on a single platform, and greatly reduces the complexity of the consumables. The T2Dx Instrument ~~incorporates~~ **is designed to have** a simple user interface and ~~is designed~~ to efficiently process up to seven specimens simultaneously. The commercially available test panels **are** designed to run on the T2Dx Instrument ~~are~~ **include T2Bacteria,** T2Candida, **T2Resistance, and T2Biothreat.** T2Bacteria ~~, T2Resistance, and T2SARS- CoV- 2 panels, which are focused on identifying life- threatening pathogens associated with sepsis and COVID- 19. Our T2Candida Panel~~ , which is FDA- cleared ~~in the U. S.~~ and CE marked ~~in the EU~~ , is a direct- from- blood **molecular diagnostic** test **panel** that ~~identifies~~ **detects bacterial pathogens found in blood stream infections including:**

Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, and Escherichia coli. T2Bacteria received FDA clearance in 2018 after the clinical trial demonstrated overall sensitivity of 90 % and overall specificity of 98 %. In October 2023, we submitted a 510 (k) premarket notification to the FDA to expand the number of pathogens detected on the FDA- cleared T2Bacteria Panel to include the detection of Acinetobacter baumannii and we received FDA 510 (k) clearance in February 2024. These six bacterial pathogens account for approximately 75 % of bacterial blood stream infections. These pathogens are often referred to as the ESKAPE pathogens, which are responsible for the majority of nosocomial infections and are often capable of " escaping " the biocidal action of antimicrobial agents, exhibiting multidrug resistance and virulence. A systematic review of the clinical and economic impact of antibiotic resistance reveals that the ESKAPE pathogens are associated with the highest risk of mortality, thereby resulting in increased health care costs. In the T2Bacteria clinical trial, the mean time for the T2Bacteria Panel to result was 6. 46 hours, while the result for blood culture was substantially longer with a mean time to result of 123. 8 ± 9 hrs. for a negative result and 51. 0 ± 43. 0 hrs. for a positive result, and the mean time to species identification was 83. 7 ± 47. 6 hours. A study published in the Microbiology Open found that T2Bacteria decreased the time to species identification on average by 55 hours faster than blood culture. The rapid detection and identification of the pathogens by T2Bacteria in positive specimens also allowed for the early antimicrobial stewardship interventions with faster initiation of an effective targeted antibiotic therapy in some of the patients, which was captured in another study presented by Paggi R, et al. July 2021 with 29. 2 % of patients with T2Bacteria positive results switched to an appropriate therapy. In a 2019 study published in Open Forum Infectious Diseases, the data showed that patients diagnosed using T2Bacteria had shorter hospital stays, on average, as compared with patients diagnosed using blood culture alone. In August 2019, Centers for Medicare & Medicaid Services, or CMS, granted approval for a New Technology Add- on Payment, or NTAP, for T2Bacteria, effective October 1, 2019, which was extended until September 30, 2022. In its 2020 inpatient prospective payments system final rule, CMS explained: " the T2Bacteria Panel represents a substantial clinical improvement over existing technologies because it reduces the proportion of patients on inappropriate therapy, thus reducing the rate of subsequent diagnostic or therapeutic intervention as well as length of stay and mortality rates caused by sepsis causing bacterial infections. " We believe T2Bacteria can enable clinicians to achieve faster targeted antibiotic therapy, improve patient outcomes, and reduce costs. We further believe that the adoption of the T2Dx Instrument and T2Bacteria can enable clinicians to make earlier and more informed decisions by providing positive test results to direct therapy and negative test results to reduce the use of antibiotics. T2Candida, which is FDA- cleared and CE marked, is a direct- from- blood molecular diagnostic test panel that detects the most lethal form of common blood stream infections that cause sepsis, candidemia, which has an average mortality rate of approximately 40 %. T2Candida ~~identifies~~ **detects** five species of Candida, directly from certain human whole blood specimens, including Candida albicans, Candida tropicalis, Candida krusei, Candida glabrata, and Candida parapsilosis. **T2Candida received FDA clearance in 2014 after the clinical trial demonstrated overall sensitivity of 91 % and overall specificity of 99 %.** These **five Candida** species account for **approximately** 90 % of Candida blood stream infections. According to a 2005 report published in Antimicrobial Agents and Chemotherapy, the high mortality rate associated with Candida infection can be reduced to 11 % with the initiation of targeted therapy within 12 hours of presentation of symptoms. Currently, a typical patient with a Candida infection averages 40 days in the hospital, including nine days in intensive care, resulting in an average cost per hospital stay of over $ 130, 000 per patient. In a study published in the American Journal of Respiratory and Critical Care Medicine in 2009, providing targeted antifungal therapy within 24 hours of the presentation of symptoms decreased the length of hospital stay by approximately ten days and decreased the average cost of care by approximately $ 30, 000 per patient. In addition, many hospitals initiate antifungal drugs, such as caspofungin or micafungin, while waiting for blood culture- based diagnostic results. We estimate this practice costs approximately $ 500 per patient and is currently in use for over 40 % of high- risk patients on average and for all high- risk patients in some hospitals. A negative result from T2Candida can provide timely data allowing physicians to avoid unnecessary antifungal treatment and potentially reduce the treatment cost further. In 2014 we received FDA marketing authorization for ~~the~~ T2Candida ~~Panel~~ in the U. S. and in July 2014 ~~the~~ T2Candida ~~Panel~~ was CE marked in the EU. In ~~our pivotal clinical trial for T2Candida, we demonstrated that it delivered results in as few as three hours, with an average time to result during the trial of 4. 2 hours, compared to the average time to result of one to six or more days typically required for blood- culture- based diagnostics. We believe the speed of T2Candida will enable physicians to potentially make treatment decisions and administer targeted treatment to patients in 4 to 6 hours versus 24 to 144 hours for blood culture. In the pivotal clinical trial, the T2Candida Panel also demonstrated overall sensitivity of 91. 1 % and overall specificity of 99. 4 %. Furthermore, in~~ April 2015, Future Microbiology published the results of an economic study regarding the use of T2Candida conducted by IMS Health, a healthcare economics agency. In **the** ~~that economic~~ study, IMS demonstrated that an average hospital admitting 5, 100 patients at risk for Candida infections could save approximately $ 5. 8 million annually due to decreased hospital stays for patients, reduction in use of antifungal drugs and other associated savings. The economic study further showed T2Candida potentially reduced the costs of care by $ 26, 887 per Candida patient and that rapid detection of Candida reduced patient deaths by 60. 6 %. Results from a data analysis of T2Candida for the detection and monitoring of Candida infection and sepsis were published comparing aggregated results from the use of T2Candida to blood culture- based diagnostics for the detection of invasive candidiasis and candidemia. The analysis included samples acquired from more than 1, 900 patients. Out of 55 prospective patient cases that were tested with T2Candida and blood culture and determined to be positive or likely to be positive for a Candida infection, T2Candida detected 96. 4 % of the patients (53 cases) compared to ~~detection of~~ **blood culture which detected only** 60 % of the patients (33 cases) **. Candidiasis disproportionally affects critically ill children, and we believe a pediatric testing claim for our FDA- cleared T2Candida will allow clinicians to improve outcomes and reduce cost by achieving faster targeted antifungal treatment for their pediatric patients.**

According to the Journal of Fungi, a peer- reviewed scientific journal that provides an advanced forum for studies related to pathogenic fungi, Candida species are a major contributor to morbidity and mortality in hospitalized children. Additionally, children with **invasive candidiasis present a significant burden to the U. S. healthcare system, with a mean increased hospital length of stay of 21 days and approximately $ 92, 000 in excess hospital costs. Clinical use in Europe and research studies in the United States indicate the strong potential utility for T2Candida in pediatric patients. A Journal of Clinical Microbiology (2022) study conducted at the Bambino Gesù hospital in Rome, Italy found that pediatric patients suspected of fungal bloodstream infections that were tested with T2Candida received species identification results 121. 8 hours faster compared to** blood culture **. The study also found a higher detection rate with T2Candida as six additional probable or possible fungal bloodstream infections in pediatric patients were detected by T2Candida and missed by blood culture. In addition, a prospective observational study published in Clinical Infectious Diseases (2022) evaluated the performance of four pre- blood culture tests for detecting the presence of invasive candidiasis in pediatric patients and found that T2Candida had the highest sensitivity and specificity of all four assays among five hundred patients enrolled. T2Candida was the only test recommended for individual use as a tool for the diagnosis of invasive candidiasis in at- risk children and adolescents** . We believe T2Candida can enable clinicians to ~~administer the most effective~~ **achieve faster targeted antifungal** therapy, ~~faster, significantly improving~~ **improve** patient outcomes **,** and **reduce** ~~reducing hospital~~ costs. We further believe that the adoption of the T2Dx Instrument and T2Candida can decrease the high mortality rate of Candida infections because these products can enable clinicians to make earlier and more informed decisions by providing positive test results to direct therapy and negative test results to reduce the use of antifungal drugs. **T2Resistance** ~~Our T2Bacteria Panel~~ , which is ~~FDA- cleared in the U. S. and~~ CE marked ~~in the EU~~ , is a direct- from- blood **molecular diagnostic** test ~~that detects certain bacterial pathogens associated with sepsis that are frequently not covered by first- line antibiotics, often referred to as the " ESKAPE pathogens. " The T2Bacteria Panel is designed for the detection of most of the ESKAPE pathogens from human whole blood specimens: Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Pseudomonas aeruginosa, Escherichia coli, and the CE marked T2Bacteria Panel in addition identifies a sixth species, Acinetobacter baumannii, with a positive percent agreement ranging from 81. 3 % to 100 % and the negative percent agreement ranging from 95. 0 % to 100. 0 %. The ESKAPE pathogens are responsible for the majority of nosocomial infections and are often capable of " escaping " the biocidal action of antimicrobial agents, exhibiting multidrug resistance and virulence. These pathogens cause over 2 million illnesses and 23, 000 deaths per year. In the pivotal clinical trial the T2Bacteria Panel also demonstrated overall sensitivity of 90 % and overall specificity of 98 %. A systematic review of the clinical and economic impact of antibiotic resistance reveals that the ESKAPE pathogens are associated with the highest risk of mortality, thereby resulting in increased health care costs. In the T2Bacteria clinical trial, the mean time for the T2Bacteria Panel to result was 6. 46 hours, while the result for blood culture was substantially longer with a mean time to result of 123. 8 ± 9 hrs. for a negative result and 51. 0 ± 43. 0 hrs. for a positive result, and the mean time to species identification was 83. 7 ± 47. 6 hours. A study published in the Microbiology Open found that the T2Bacteria Panel decreased the time to species identification on average by 55 hours faster than blood culture. The rapid detection and identification of the pathogens by the T2Bacteria Panel in positive specimens also allowed for the early antimicrobial stewardship interventions with faster initiation of an effective targeted antibiotic therapy, in some of the patients which was captured in another study presented by Paggi R, et al. July 2021 with 29. 2 % of patients with T2Bacteria positive results switched to an appropriate therapy. Seitz T et al presented on the Evaluation of the clinical impact of the T2MR for the Diagnosis of Blood Stream Infections, where the data showed that the use of T2Bacteria led to a shorter length of stay for T2Bacteria of 10 days as compared with the 13 days for blood culture. The T2Bacteria Panel can ensure prompt diagnosis, assist clinicians in making clinical decisions about patient management such as the escalation or de- escalation of therapy faster, with improvement in patient care and outcomes, by potentially shortening the time of exposure to ineffective antibiotics, which may reduce the chances of developing anti- microbial resistance. Our sepsis panels~~ **panel** ~~are to be used in conjunction with whole blood cultures, and detecting the ESKAPE pathogens directly from whole blood in 3- 5 hours, potentially enables therapy targeted to these organisms, which are often resistant to common empiric therapies. Detecting these commonly resistant organisms in 3- 5 hours pre- culture is more critical than rapidly detecting those organisms which typically respond to common empiric therapies. In August 2019, CMS granted approval for a New Technology Add- on Payment, or NTAP, for the T2Bacteria Panel, effective October 1, 2019, which was extended through the 2022 fiscal year. In its 2020 inpatient prospective payments system final rule, CMS explained: " the T2Bacteria Panel represents a substantial clinical improvement over existing technologies because it reduces the proportion of patients on inappropriate therapy, thus reducing the rate of subsequent diagnostic or therapeutic intervention as well as length of stay and mortality rates caused by sepsis causing bacterial infections. " Effective fiscal year 2023, T2 Bacteria is no longer eligible for NTAP reimbursement. We believe T2Bacteria can enable clinicians to achieve targeted antimicrobial therapy, faster, significantly improving patient outcomes and reducing hospital costs. We further believe that the adoption of the T2Dx Instrument and T2Bacteria can enable clinicians to make earlier and more informed decisions by providing positive test results to direct therapy and negative test results to reduce the use of antimicrobial drugs. Our T2Resistance Panel, which is CE marked in the EU, is a direct- from- blood test~~ that simultaneously detects thirteen antibiotic resistance genes from both gram- positive and gram- negative pathogens. T2Resistance is designed to identify the most clinically important carbapenem resistance genes KPC, OXA- 48, NDM, VIM, and IMP. Carbapenem resistance has been listed on the CDC Urgent Threat list for antibiotic resistance **according to the latest CDC " AR Threats Report "** . ~~The~~ T2Resistance ~~Panel~~ also detects a major source of extended spectrum beta lactamases, or ESBLs, CTXM- 14 and CTXM- 15; AmpC beta- lactamase genes (CMY, DHA); vanA vanB resistance genes, which are responsible for vancomycin resistant gram- positive enterococcus; and the detection of the methicillin resistance genes mecC and mecA, which cause methicillin resistant Staphylococcus aureus. Clinical performance data demonstrated that the T2Resistance Panel identified carbapenemase resistance genes with an average time of 5. 3 hours. Antibiotic resistance ~~is~~ **was** recognized by the

~~WHO~~ **World Health Organization in 2017** as " one of the biggest threats to global health, food security, and development today ~~.~~" ~~The~~ **and in 2022 released the Global Antimicrobial Resistance and Use Surveillance System (GLASS) report.** T2Resistance ~~Panel~~ received FDA Breakthrough Device designation in February 2019 and CE marked in the EU in November 2019 and is available for purchase in the United States as a Research- Use- Only,or RUO **,** product,meaning that it is in the laboratory research phase of development and is being shipped or delivered for an investigation that is not subject to FDA regulations governing investigational device studies.In December 2021 we initiated a U.S.clinical trial for the T2Resistance Panel.The clinical trial is expected to be completed in ~~2023~~ **2024** ,and we believe the data from this trial may enable submission of a marketing application to the FDA in ~~2023~~ **2024** . ~~Our T2SARS- CoV- 2 Panel,which is commercially available in the United States~~ We believe ~~the~~ T2Resistance ~~Panel~~ can help to prevent the spread of multidrug- resistant organisms and improve patient outcomes by enabling rapid identification of the genes associated with antibiotic resistance – enabling correct targeted therapy and the reduction of unnecessary antibiotic use, which is a primary cause of antibiotic resistance. ~~Most importantly,~~ **We further believe that** ~~these~~ -- **the** ~~tests have~~ **adoption of** the ~~potential to~~ **T2Dx Instrument and T2Resistance can** enable more patients to get on appropriate targeted therapy faster, ~~and~~ thereby ~~reduce~~ **reducing** mortality and **lowering** hospitalization costs. The T2Resistance Panel received FDA Breakthrough Device..... development. Products- in Development Our T2Biothreat ~~Panel~~ is a direct- from- blood **molecular diagnostic** test panel that ~~is designed to run~~ **runs** on the T2Dx Instrument and ~~to~~ simultaneously ~~detect~~ **detects** six biothreat pathogens **, including the organisms that cause 1) anthrax (Bacillus anthracis); 2) tularemia (Francisella tularensis); 3) glanders (Burkholderia mallei); 4) melioidosis (Burkholderia pseudomallei); 5) plague (Yersinia pestis); and 6) typhus (Rickettsia prowazekii). These pathogens have been** identified as threats by the **CDC** ~~U. S. Government, including Bacillus anthracis, Burkholderia mallei, Burkholderia pseudomallei, Francisella tularensis, Richettsia prowazekii~~ and ~~Yersinia pestis~~ **identified as material biological threats under section 319- 2 (c) (2) (A) (ii) of the Public Health Service Act** . ~~The~~ **If not treated promptly, these pathogens can have mortality rates of 40- 90 %.** ~~T2Biotreat~~ **T2Biothreat** ~~Panel~~ is indicated as an aid in the diagnosis of anthrax, tularemia, melioidosis, glanders, typhus fever and plague. In December 2021, **we** ~~the Company~~ initiated a U. S. clinical evaluation for ~~the~~ T2Biothreat ~~Panel~~ that ~~includes~~ **included** positive samples being prepared and analyzed at a high- containment Biosafety Level 3 laboratory and negative samples being analyzed at a clinical site. ~~The~~ **Our** clinical evaluation **of T2Biothreat demonstrated positive percent agreement, or sensitivity, of 100 % for all targets except Francisella tularensis, which** was ~~completed in~~ **94. 3 %, and negative percent agreement, or specificity, for all six targets of 100 %. On May 8,** ~~2022~~ **2023** . ~~and~~ we **submitted a 510 (k) premarket notification to the FDA for T2Biothreat. On September 19, 2023, we received 510 (k) clearance from the FDA for T2Biothreat. The six biothreat pathogens detected by the T2Biothreat are identified as biological threats by the U. S. Administration for Strategic Preparedness and Response, or ASPR. ASPR engages partners through Public Health Emergency Medical Countermeasures Enterprise activities to share information and coordinate plans and actions to ensure the nation has and can use medical countermeasures to protect Americans during disasters and emergencies resulting from known and unknown chemical, biological, radiological, or nuclear threats and emerging infectious diseases. We** believe ~~the data~~ **T2Biothreat can help to protect Americans** from ~~this evaluation will~~ **the consequences of deliberate or naturally occurring outbreaks of these biothreat pathogens by enabling clinicians to achieve faster targeted antibiotic therapy, improve patient outcomes, and reducing mortality. We further believe that the adoption of the T2Dx Instrument and T2Biothreat can** enable **clinicians** ~~submission of a marketing application~~ to **make earlier and more informed decisions by providing positive test results to direct therapy and negative test results to reduce** the **use** ~~FDA in the first half~~ of ~~2023~~ **antibiotics** . ~~Our~~ **Products In Development** T2Lyme ~~Panel~~ is a direct- from- blood **molecular diagnostic** test ~~panel~~ designed to run on the T2Dx Instrument ~~to identify~~ **and detect Borellia burgdorferi,** the bacteria that ~~cause~~ **causes** Lyme disease. We believe ~~the~~ T2Lyme ~~Panel~~ may benefit from similar advantages provided by our technology, including the potential for high sensitivity, high specificity, ease of use and **more** rapid time to result. T2Lyme is designed to provide accurate and timely diagnosis of **early** Lyme disease ~~causing pathogens~~ **, enabling faster targeted treatment** , with the goal of preventing the evolution of the disease to its later stages with associated neurological and musculoskeletal diseases. According to the CDC, Lyme disease affects approximately 30, 000 people in the U. S. each year, but the CDC also estimates that the actual number is closer to 476, 000 due to under- reporting because of poor diagnostic methods. Approximately 3. 4 million tests are run for Lyme disease each year, including serology testing, PCR techniques and blood culture, which has low sensitivity and takes approximately two to three weeks to provide results. Inadequate identification of Lyme disease may lead to antibiotic resistance, significant costs, and transmission of the disease through healthcare procedures such as blood transfusion. The misdiagnosis of Lyme disease has been reported to have an annual cost of more than $ 10, 000 per patient in the United States, representing over $ 3 billion per year. We believe that our technology can address the significant unmet need associated with Lyme disease, a tick- borne illness that can cause prolonged neurological disease and musculoskeletal disease. For patients with Lyme disease, early diagnosis and appropriate treatment significantly reduces both the likelihood of developing neurological and musculoskeletal disorders, as well as the significant costs associated with treating these complications. Multiple diagnostic methods are used to test for Lyme disease today, which are labor- intensive, can take weeks to process, and are subject to high false negative rates due to their inability to detect the disease, making each method unreliable in the diagnosis of the condition. Because of these limitations, patients are frequently misdiagnosed or are delayed in the diagnosis of this disease. In November 2022, the T2Lyme Panel was selected as a Phase 1 winner of the LymeX Diagnostics Prize, a LymeX Innovation Accelerator prize competition, ~~also known as LymeX,~~ a partnership between the **HHS** ~~U. S Department of Health~~ and ~~Human Services and the Steven & Alexandra~~ Cohen Foundation, the largest public- private partnership for Lyme disease, that includes up to $ 10 million in funding to accelerate the development of Lyme disease diagnostics. The T2Lyme Panel received FDA Breakthrough Device designation in July 2022 as an aid in the diagnosis for the detection of early Lyme disease caused by Borrelia burgdorferi, ~~Borrelia afzelii, and Borrelia garinii,~~ directly from human whole blood. We are currently exploring commercial

opportunities with partners and initially plan to ~~commence~~ launch T2Lyme as a ~~U~~ Laboratory Developed Test, or LDT . ~~S. clinical trial to support submission a marketing application to the FDA~~ T2Cauris Panel Our T2Cauris ™ Panel is a direct- from- blood molecular diagnostic test designed to ~~provide direct~~ run on the T2Dx Instrument and ~~detection~~ --- detect ~~of the emerging superbug~~ Candida auris ~~in patient skin, patient blood, and hospital environmental samples and is now available for RUO. The CDC evaluated the T2Cauris ™ Panel swab test on patient skin samples and published their findings in Mycoses~~ . We currently intend to complete product development ~~of the T2Cauris Panel~~ and seek FDA 510 (k) clearance to include the detection of Candida auris on ~~our~~ T2Candida, which is already FDA- cleared and CE marked ~~T2Candida Panel~~ . T2Cauris received FDA Breakthrough Device designation in July 2023 . Candida auris , or C. auris, is a multi- drug resistant pathogen recognized by the CDC as a serious global health threat ~~because it can be~~ . C. auris has a mortality rate of up to 60 % and some strains of C. auris are resistant to all three ~~major~~ available classes of antifungal ~~drugs and~~ therapies. According to the CDC, C. auris is difficult to identify ~~. The CDC has also reported that more than one- in- three patients~~ with ~~Candida auris infections have died~~ standard laboratory methods, including blood culture, which can lead to inappropriate treatment . Unlike most other species of Candida, ~~Candida~~ C. auris can spread quickly in a hospital ~~making~~ and rapid detection may assist in ~~identification and hospital environment surveillance a critical component of~~ containing these outbreaks. ~~Existing laboratory methods that detect Candida~~ The CDC has called on public health professionals to help lower the burden of fungal disease by continuing to raise awareness of the life- saving benefits of early diagnosis and proper treatment. Reported cases of C. auris ~~, including blood culture, suffer from prolonged detection times and low accuracy, which exacerbates the challenge in the fight to contain the superbug. Recently, reported cases~~ have surged internationally, and the CDC has reported a significant increase in infected patients in the United States since the CDC issued an alert on C. auris in 2016 . According to the European Centre for Disease Prevention and Control, hospital outbreaks have occurred in the United Kingdom and Spain. Because ~~Candida~~ C. auris can be resistant to most antifungal treatment options and can spread so quickly, these hospital outbreaks have been difficult to contain ~~by even~~ . We previously collaborated with the ~~most enhanced control measures~~ CDC regarding C. auris detection using our technology . The goals of the CDC collaboration were to use the T2Dx Instrument to (i) validate the detection of ~~Candida~~ C. auris from patient skin samples and hospital environmental samples, (ii) validate a process for surveillance of ~~Candida~~ C. auris in healthcare facilities from skin and environmental samples, and (iii) assist state and local public health labs in combating the outbreak. ~~In~~ The CDC evaluated the T2Cauris swab test on patient skin samples and published their findings in Mycoses. Additionally, in a study presented at ASM Microbe 2018 regarding the detection of ~~Candida~~ C. auris, it was found that our technology provided accurate diagnostic results from patient skin samples. ~~Comprehensive Sepsis Panel Our comprehensive sepsis panel is~~ Following our collaboration with the CDC, we have completed feasibility and early development of a diagnostic test to detect the C. auris pathogen ~~direct~~ directly - from- blood and we plan to seek FDA 510 (k) clearance to add this test ~~panel that is designed~~ to T2Candida ~~run on our next generation instrument~~ . We believe adding C. auris ~~The new test panel is designed to detect~~ detection ~~greater than~~ to our existing T2Candida Panel will increase the value proposition of T2Candida by covering approximately 95 % of all ~~bloodstream~~ sepsis- causing Candida pathogens commonly found in blood stream infections ~~caused by bacterial and~~ . The current FDA- cleared T2Candida Panel simultaneously detects five Candida species, including Candida albicans, Candida tropicalis, Candida parapsilosis, Candida krusei, and ~~antibiotic resistant markers identified~~ Candida glabrata. Rapid detection of these pathogens, as well ~~threats by the CDC, in a single test and to provide a time to result of approximately 3 hours. We believe this test panel, if successfully developed and authorized by the FDA, could be positioned~~ as ~~the primary test for~~ Candida auris, is essential to getting infected patients ~~at risk of sepsis, and substantially change the blood culture based laboratory workflow. Next Generation Instrument Our next- generation instrument, which is being developed in conjunction with our comprehensive sepsis panel, is designed to be fully automated,~~ on ~~- demand~~ appropriate antifungal therapy , improving patient outcomes, ~~and random access. This design is similar to our current T2Dx Instrument but incorporates faster turnaround times and is designed to detect an~~ and reducing cost ~~increased number of pathogens and resistance genes from a single, whole blood sample~~ . Strategy Our objective is to establish our products as the standard of care for clinical diagnostics. To achieve this objective, our strategy is to focus on the following three corporate objectives: • Accelerating our Sales. Our sales strategy consists of two primary objectives: 1) increasing our sepsis test panel revenue by driving ~~broad~~ broader utilization among new and existing customers, and 2) expanding our T2Dx Instrument installed base globally by selling or placing new instruments. ~~In 2022, we entered into contracts for 51 T2Dx Instruments, including 27 instruments in the U. S. and 24 outside the U. S. Our installed base of T2Dx Instruments at the end of 2022 was 181, including 106 in the U. S. and 75 internationally. We generated sepsis and related revenue of $ 8. 4 million representing an increase of 17 % compared to the prior year. We continue to expand our international distribution network which allows our products to be marketed and sold in more countries. Hospitals around the world face similar challenges when caring for patients suspected of sepsis and we are leaning into this opportunity. In 2022, we entered into exclusive distribution agreements with distributors in South Africa, and countries in Scandinavian and Baltic regions.~~ • Enhancing our Operations. Our operations strategy consists ~~To sustain growth and drive adoption and utilization~~ of ~~our~~ four ~~products over the long~~ primary objectives: 1) reducing inventory, 2) reduce scrap, 3) improve on - time delivery ~~term we continue to implement changes to our operations that enable a more efficient business model. During the second quarter of 2022~~ , ~~we reduced our overall cost structure, including reductions in headcount, which now stands at 150 employees,~~ and 4) complete Oracle ERP system cutover ~~operating expenses. As part of the headcount reductions, we also revised our hiring plans and eliminated several open roles, including the position of Chief Operations Officer. During 2022, we also made process improvements to the T2Bacteria and T2Candida Panels to reduce manufacturing costs and gain manufacturing efficiencies. We believe these improvements will contribute to improved product gross margins, which we expect to begin positively impacting our financial statements in 2023~~ . We believe that we will continue to meet our current manufacturing needs with our operations at our Lexington and Wilmington,

Massachusetts facilities. • Advancing our Pipeline. **Our** ~~We are continuing to prioritize the programs under our milestone- based~~ product **pipeline strategy** ~~development contract awarded by BARDA, which~~ is **focused** ~~valued at up to $ 62 million. The four products that we are advancing under the BARDA contract are the T2Resistance Panel, the T2Biothreat Panel, the comprehensive sepsis panel, and the next- generation instrument. We are currently operating in Option 3 of our BARDA contract, having successfully met all development milestones under the Base Phase, Option 1, Option 2A, and Option 2B. In March of 2023 we executed a no- cost extension with BARDA, under Option 3, to allow time for the completion of the T2Resistance U. S. clinical trial. In December 2021, we initiated the U. S. clinical trials for the T2Resistance Panel and the T2Biothreat Panel. The clinical trials are designed to evaluate the performance of the T2Resistance and T2Biothreat panels and support submission of marketing applications to the FDA. The T2Resistance Panel, which runs~~ on ~~our~~ **expanding the test menu on the** T2Dx Instrument ~~, is a direct- from- blood~~ **and consists of three primary objectives: 1) developing new tests or** test panel ~~panel~~ **panels** ~~that simultaneously detects thirteen antibiotic resistance genes from both Gram- positive and Gram- negative bacterial pathogens~~, ~~which are known to cause antibiotic- resistant infections that may lead to sepsis. It provides accurate results in 3- 5 hours without the need to wait days for a positive blood culture. The T2Resistance Panel, which is currently marketed and sold in the EU under a CE- mark, was granted Breakthrough Device designation from the FDA, which offers manufacturers an opportunity to interact with the FDA' s experts through several different program options to efficiently address topics as they arise during the premarket review phase, and may help manufacturers receive feedback from the FDA in a timely way. All submissions for devices designated as Breakthrough Devices will receive priority review, meaning that the review of the submission is placed at the top of the appropriate review queue and receives additional review resources at FDA, as needed. The clinical trial for the T2Resistance Panel, includes up to 1, 500 patients across 10 U. S. hospitals, is estimated to cost T2 Biosystems $~~ 2 **) completing** ~~. 5 million and is expected to be completed in 2023, and we believe the data from this trial may enable filing a submission to the FDA in 2023. The T2Biothreat Panel, which also runs on our T2Dx Instrument, is a direct- from- blood test panel that is designed to provide results in 3- 5 hours, and to simultaneously detect six biothreat pathogens identified as threats by the CDC. The~~ clinical evaluation ~~was completed in 2022~~, and **3) obtaining regulatory clearance (e. g., ~~we believe the data from this evaluation will enable filing a submission to the~~** FDA **510 (k)** ~~in early 2023. The comprehensive sepsis panel is a direct- from- blood test panel that is designed to run on our next generation instrument. This test panel is designed to detect greater than 95 % of all bloodstream infections caused by bacterial and Candida species~~, **CE mark** ~~and antibiotic resistant markers identified as threats by the CDC~~, **etc** ~~in a single test and to provide a time to result of approximately 3 hours~~. **)** ~~We believe this test panel, if successfully developed and authorized by the FDA, could be positioned as the primary test for patients at risk of sepsis, and substantially change the blood culture based laboratory workflow. The next- generation instrument, which is being developed in conjunction with our comprehensive sepsis panel, is designed to be fully- automated, on- demand, and random access. This design is similar to our current T2Dx Instrument but incorporates faster turnaround times and is designed to detect an increased number of pathogens and resistance genes from a single, whole blood sample~~. Sales, Marketing and Distribution ~~We are working to drive awareness and adoption of our products with a direct sales force that targets hospitals that treat critical care patients. At the end of 2022, our commercial organization consisted of 38 people, including sales, marketing, medical affairs, service and support.~~ Our sales team **and our distribution partners** ~~employs~~ - **employ** a strategic approach focusing on **the** clinical value ~~of our products highlighting clinical data, clinical performance~~ of our products, improved patient outcomes and ~~the~~ economic value for hospitals, including providing these hospitals with a customized budget-impact analysis. They also demonstrate the ease- of- use of our products and highlight the advantages of our products over existing **culture- based** diagnostics and empiric therapy practices. ~~Today~~ **In the U. S.** , **we** ~~our team markets~~ - **market** and ~~sells~~ - **sell** the T2Dx Instrument, T2Bacteria **Panel** , **and** T2Candida **Panel** ~~and T2SARS- CoV- 2~~ products directly to hospitals ~~in~~ **. We have received FDA 510 (k) clearance for** ~~the~~ **these** ~~United States~~ **products, and we expect to receive FDA 510 (k) clearance for additional products currently in our pipeline. At the end of 2023, our direct commercial organization consisted of 27 people, including sales, marketing, medical affairs, service, and support** . If **hospitals** ~~these institutions~~ optimize the full extent of our technology, we expect a positive network effect in the hospital community, **helping to** ~~accelerating~~ **accelerate** adoption of T2Bacteria and T2Candida. We believe key aspects of healthcare reform, including a sensitivity to the growing problem of antimicrobial resistance, the focus on cost containment, risk- sharing, and outcomes- based treatment and reimbursement, are aligned with the value proposition of our sepsis products, **helping to** ~~contributing~~ **contribute** positively to their adoption. **Internationally** ~~Outside of the United States~~, we **market and sell the T2Dx Instrument, T2Bacteria, T2Candida, and T2Resistance products through territory exclusive distribution partners. We** have received marketing ~~authorizations~~ - **authorization,** or certifications ~~in the EU~~ **, covering Europe** , Australia, and certain countries in the Middle East **, Latin America, Asia Pacific,** and Africa, and expect to seek regulatory authorizations or certifications in additional international markets. We ~~market our products primarily through distribution partners who utilize a similar model as our sales approach in the United States. We~~ have affixed a CE mark on **the** ~~our products as follows: T2Candida and~~ T2Dx Instrument ~~in July 2014~~ **and the T2Candida** , T2Bacteria ~~in September 2017,~~ and T2Resistance **panels** ~~in November 2019~~. As of the end of ~~2022~~ **2023** , we had distributors throughout the EU, and in a growing number of countries in Asia Pacific, Latin America **,** and the Middle East. These distributors typically have strong, existing relationships with key opinion leaders, have relationships with important hospitals in their respective countries, and have experience ~~in~~ **marketing and selling** infectious ~~diseases~~ - **disease** and / or microbiology **products** ~~. We continue to develop partner relationships in other key international markets and plan to further expand our distribution channels in other key markets around the world~~. We have employed a small regionally- focused commercial team of business managers and field service personnel primarily to support the efforts of our **international** distributors **, and we plan to further expand our distribution channels in other key international markets. We are marketing, and intend to sell, T2Biothreat directly to U. S. government agencies tasked with defending the United States from bioterrorism threats. Customers Our total revenues are concentrated among a small number of large**

customers. For fiscal year 2023, two customers represented 29 % of our total revenue, and for fiscal year 2022 our BARDA contract represented 50 % of our total revenue. For a discussion of risks related to customer concentration, see " Risk Factors- We have relied on a few large customers for a significant portion of our business, and the loss of any of these customers has in the past and could in the future materially and adversely impact our results of operations and financial condition. " and Note 2, Significant Accounting Policies, to the Consolidated Financial Statements included in Part II, Item 8, Financial Statements and Supplementary Data, of this Annual Report on Form 10- K . Medical and Clinical Affairs ~~We continue to educate physicians, key decision makers and thought leaders through publishing scientific data in peer- reviewed journals, presenting at major industry conferences and conducting and supporting clinical studies. Our clinical and medical affairs teams are raising awareness by amplifying clinical value messaging for our products. The team is actively engaged with Key Opinion Leaders to generate and share real world data via scientific journal publications, at medical conferences, and at industry trade shows. During 2022, our products were mentioned in over 52 publications, posters, and presentations.~~ We believe the key decision- makers at hospitals are infectious disease and critical care physicians, laboratory directors, hospital pharmacy, ~~Chief~~ **chief** ~~Medical~~ **medical** ~~Officers~~ **officers** , and hospital administrators **. Accordingly, we continue to educate these key decision makers through in- person meetings, publishing scientific data in peer- reviewed journals, presenting at major industry conferences, and conducting and supporting clinical studies. Our clinical and medical affairs team is raising awareness by amplifying clinical value messaging for our products. The team is actively engaged with key opinion leaders to generate and share real world data via scientific journal publications, at medical conferences, and at industry trade shows. During 2023, our products were mentioned in over 35 publications, posters, and presentations** . In response to the severity and complexity of managing bloodstream infections, a growing number of hospitals have instituted sepsis committees or antimicrobial stewardship committees to control hospital practices related to infections, including the use of antibiotic and antifungal therapy. These committees typically include key decision- makers, and we believe they can provide a central forum to present the benefits of our products. In addition, we plan to continue to publish scientific data in peer- reviewed journals, present at major medical and scientific conferences and conduct and support clinical trials to provide additional data relative to the performance of **T2Bacteria,** T2Candida **,** and ~~T2Bacteria~~ **T2Resistance** to these **key** decision- makers. Manufacturing We manufacture our proprietary T2Dx Instrument **,** and our sepsis test panels **and reagents** at our manufacturing facilities in Lexington ~~, MA~~ and Wilmington, ~~MA~~ **Massachusetts** . We perform all manufacturing and packaging of final components in accordance with applicable guidelines for medical device manufacturing. Our particles are supplied by a sole source supplier, Cytiva (a Danaher company), formerly GE Healthcare. We believe we can secure arrangements with other suppliers on commercially reasonable terms for the products and parts we outsource. We have implemented a quality management system designed to comply with FDA regulations and International Standards Organization, or ISO, standards governing medical device products. These regulations govern the design, manufacture, testing, release, installation and service of diagnostic products as well as raw material receipt and control. We have received ISO 13485: 2016 certification from the National Standards Authority of Ireland. Our key outsourcing partners are also ISO- certified. We plan to continue to manufacture components that we determine are proprietary or require special processes to produce, while outsourcing the supply of more commodity- like components. We expect to establish additional outsourcing partnerships as we manufacture more products. We believe our facilities in Lexington and Wilmington, Massachusetts are adequate to meet our current manufacturing needs and that additional manufacturing space is readily available for future expansion. **During 2023, we experienced process and raw material challenges that impacted our ability to timely deliver our sepsis test panels to our global customers. We took a variety of actions to address these challenges, including the hiring of a new Vice President of Operations, advanced procurement of raw materials, process improvements, and investments in equipment. As of the end of December 2023, we had resolved the backorders for T2Bacteria and T2Candida, and as of the end of January 2024, we had resolved the backorder for T2Resistance.** Raw Materials We purchase many different types of raw materials, including plastics, magnets, metals, electronic and mechanical sub- assemblies and various biological and chemical products. We seek to ensure continuity of raw material supply by securing multiple options for sourcing and also review relevant sources for compliance with conflict minerals requirements. Some of our components are custom- made by only a handful of external suppliers. In certain instances, we have a sole source supply for key product components of the T2Dx Instruments and certain components for our test kits. We have entered into supply agreements with most of our suppliers to help ensure component availability and flexible purchasing terms with respect to the purchase of such components. We have reviewed our suppliers and quantities of key materials and believe we have sufficient stocks and alternate sources of critical materials should our supply chains become disrupted, although raw materials and plastics for the manufacturing of reagents and consumables are in high demand, and interruptions in supply are difficult to predict. We are also experiencing cost increases from many of our suppliers, primarily as a result of increased inflation. The areas of cost increases include raw materials, components, and value- add supplier labor. We believe that we can continue to take actions to limit the impact of cost increases on such devices, including bulk purchases and entering into long term supply agreements. See " Risk Factors- Risks Related to Our Business and Strategies- We utilize third- party, single- source suppliers for some components and materials used in our products and product candidates, and the loss of any of these suppliers could have an adverse impact on our business. " for additional information. Intellectual Property We strive to protect and enhance the proprietary technologies that we believe are important to our business ~~,~~ and seek to obtain and maintain patents for any patentable aspects of our product and product candidates, including their methods of use and any other inventions that are important to the development of our business. We own or exclusively license over ~~35~~ **40** issued U. S. patents and ~~over 15 pending~~ U. S. patent applications ~~, including provisional and non- provisional filings~~ . We also own or license over 50 pending or granted counterpart applications worldwide. We possess substantial know- how and trade secrets which protect various aspects of our business and products. The patent families comprising our patent portfolio are primarily focused on protection of a range of general and specific attributes of our proprietary assay architecture and assay

instrumentation for our **T2Bacteria,** T2Candida, ~~T2Bacteria,~~ T2Resistance, **T2Biothreat, T2Lyme, and** T2Cauris **Panels** ~~products,~~ and our ~~T2Lyme~~ product candidates, as well as protection of certain aspects of the conduct of the assays and detection of analytes. The **Company' s patent portfolio includes** issued patents ~~in our patent families~~ that cover **T2Bacteria,** T2Candida and ~~T2Bacteria are expected to expire between 2023 and 2034, while additional pending applications covering T2Candida and T2Bacteria would be expected, if issued, to expire as late as 2037. The issued patents in our patent families that cover~~ T2Lyme ~~are expected to expire between 2023 and 2034, while additional pending applications covering T2Lyme would be expected, if issued, to expire as late as 2037. In all cases, the expiration dates are subject to any extension that may be available under applicable law~~ . Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important proprietary technology, inventions and know- how related to our business, including our methods, processes and product candidate designs, and our ability to defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on trademarks, copyrights, know- how, continuing technological innovation and in- licensing opportunities to develop, strengthen, and maintain our proprietary position in the fields targeted by our products and product candidates. Protecting these rights is a primary focus in our relationships with other parties, and we seek to protect such rights, in part, by entering into confidentiality and non- disclosure agreements with such third parties and including protections for such proprietary information and intellectual property rights in our other contracts with such third parties, including material transfer agreements, licenses and research agreements. Proprietary Rights and Processes We rely, in some circumstances, on proprietary technology and processes (including trade secrets) to protect our technology. However, these can be difficult to protect. We require all full- time and temporary employees, scientific advisors, contractors and consultants working for us who have access to our confidential information to execute confidentiality agreements in order to safeguard our proprietary technologies, methods, processes, know- how, and trade secrets. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. All of our full- time and temporary employees and independent contractors and consultants are also bound by invention assignment obligations, pursuant to which rights to all inventions and other types of intellectual property conceived by them during the course of their employment are assigned to us. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. To the extent that our employees, consultants, scientific advisors, contractors, or any future collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know- how and inventions. Further, any of our intellectual property and proprietary rights could be challenged, invalidated, circumvented, infringed or misappropriated, or such intellectual property and proprietary rights may not be sufficient to provide competitive advantages. For more information, please see " **Risk Factors-** Risks Related to Intellectual Property. " Trademarks We have trademarks and intend to continue to seek trademark protection. License Agreements In 2006, we entered into an exclusive license agreement with Massachusetts General Hospital, or MGH, pursuant to which MGH granted to us an exclusive, worldwide, sublicensable license under certain patent rights to make, use, import and commercialize products and processes for diagnostic, industrial and research and development purposes. In 2008 and 2011, we amended our agreement with MGH to add patent rights and to modify, among other things, our diligence and payment obligations. We are required to use reasonable commercial efforts to develop and make available to the public products and processes covered by the agreement, and to achieve specified organizational, development and commercialization milestones by specified dates. To date, we have met all of our diligence obligations pursuant to this agreement. We paid MGH an upfront fee and issued to MGH shares of our common stock equal to a low single- digit percentage of our then- outstanding common stock, subject to limited adjustments to prevent dilution in certain circumstances. In addition, we are responsible for reimbursing MGH' s costs associated with prosecution and maintenance of the patent rights licensed to us under the agreement. We will also be required to make payments for achievement of specified regulatory milestones with respect to products and processes covered by the agreement. In addition, we are required to pay an annual license maintenance fee, which is creditable against any royalty payments we are obligated to make to MGH under the agreement. We are required to pay royalties to MGH on net sales of products and processes that are covered by patent rights licensed to us under the agreement at percentages in the low single digits, subject to reductions and offsets in specified circumstances. The products and processes covered by the agreement include T2Bacteria, T2Candida and other particle- based test panels that we may develop in the future. Our royalty obligations, if any, and their duration, will depend on the specific patent rights covering the product or process being sold, and the particular category of product or process, as noted above. With respect to T2Bacteria, T2Candida and other potential particle- based test panels we may develop in the future, our obligation to pay royalties to MGH will expire upon the later of ten years after the first commercial sale of the first product or process in the particular category and the expiration of the patent rights licensed to us under the agreement. We will also be required to pay to MGH a low double- digit percentage of specified gross revenue that we receive from our sublicensees. In addition, we will be required to pay royalties to MGH of less than one percent on net sales of specified products and processes that are not covered by the patent rights licensed to us under the agreement. Our obligation to pay royalties to MGH with respect to such products and processes will expire upon the earlier of 12 years after the first commercial sale of the first such product or process and the termination by MGH of all of the licenses granted to us under the agreement. We have the right to terminate our agreement with MGH for any reason upon 90 days' written notice to MGH. MGH may terminate our agreement in its entirety if we fail to make a payment required under the agreement and do not cure such failure within a specified time period, if we fail to maintain adequate insurance coverage or if we become insolvent. MGH may also terminate our agreement, with respect to a given category of products or processes, on 60 days' notice for our uncured breach with respect to such category of products or processes. Absent earlier termination, our agreement with MGH will remain in force until the later of the expiration or abandonment of the licensed patents and patent applications, and the expiration of our

obligations under the agreement. Supply Agreement with SMC Ltd. We are currently party to a supply agreement with SMC Ltd. for the supply and manufacture of plastic injection molded ~~products~~ **parts that** are used across all T2 Biosystems' ~~product lines~~ **test panels** . The agreement contains other terms and conditions generally consistent with an agreement for the manufacture and supply of materials or products for use in the development and commercialization of **diagnostics** ~~biotechnology products~~ such as our products and product candidates, including with respect to ordering, supply of such product in accordance with specifications, and quality assurance and quality control activities. The supply agreement may be terminated prior to the end of its term upon the occurrence of certain specified events and further provides that upon termination, including upon the expiration of the term, SMC shall continue to manufacture and ship products subject to outstanding purchase orders and we shall be responsible for purchasing finished products, inventory, raw materials and work- in- progress held by SMC to the extent SMC, after the use of commercially reasonable efforts to use such inventory, cannot use such inventory in a financially viable way. BARDA Contract In September 2019, BARDA awarded **us** ~~the Company~~ a milestone- based contract ~~, with an initial value of $ 6. 0 million, and a potential value of up to $ 62. 0 million, if BARDA awards all contract options. BARDA operates within the Office of the Assistant Secretary~~ for ~~Preparedness and Response, or ASPR, at HHS. If BARDA awards and~~ the **development** ~~Company completes all options, the Company' s management believes it will enable a significant expansion~~ of **a next- generation** ~~the Company' s current portfolio of diagnostics~~ - **diagnostic** ~~for~~ **instrument, a comprehensive** sepsis **panel and a multi** - **target biothreat panel** ~~causing pathogen and antibiotic resistance genes~~ . In September 2020, ~~the Company completed the initial award and~~ BARDA exercised the first contract option valued at $ 10. 5 million **. In April 2021, BARDA agreed to modify the contract to accelerate product development by advancing future deliverables and adding a U. S. T2Resistance Panel into Option 1 of the contract** . In September 2021, BARDA exercised Option 2A valued at approximately $ 6. 4 million **to further advance the new product development initiatives. In December 2021, we initiated the U. S. clinical trials for the T2Resistance Panel and T2Biothreat Panel** . In March 2022, BARDA exercised Option 2B valued at approximately $ 4. 4 million. In ~~April 2021, BARDA agreed to accelerate product development by modifying the contract to advance future deliverables into the currently funded Option 1 of the BARDA contract for the next generation instrument, T2Biothreat, T2Resistance and comprehensive sepsis panel. In~~ May 2022, BARDA exercised Option 3 valued at approximately $ 3. 7 million to **complete** ~~further advance~~ the U. S. clinical trials for the T2Resistance ~~®~~ Panel and T2Biothreat Panel and **subsequently** ~~submitting~~ ---- **submit** applications to the FDA for U. S. regulatory clearance for those product candidates. ~~Should~~ **In December 2022, the T2Biothreat clinical evaluation was completed. In May 2023, we submitted a 510 (k) premarket notification to the FDA for the T2Biothreat Panel and in September 2023, we received 510 (k) clearance from the FDA to market the T2Biothreat Panel. The** BARDA **contract expired in September 2023** ~~reduce, cancel or not grant additional milestone projects, our ability to continue our future product development may be impacted.~~ Competition While we believe that we are currently the only diagnostic company with FDA- cleared or CE marked commercial products capable of detecting sepsis- causing pathogens and antibiotic resistance genes directly from ~~whole~~ blood **in three to five hours** , at limits of detection as low as 1 CFU / mL, without the need ~~of~~ **to wait days for a positive blood** ~~culturing~~ **culture** ~~colony growth~~ , we compete with commercial diagnostics companies for the limited resources of our customers. Our principal competition is from a number of companies that offer **blood culture- dependent diagnostic** platforms ~~and applications in our target sepsis markets~~ , most of which are more established commercial organizations with considerable name recognition and significant financial resources. Companies that currently provide traditional blood culture- based diagnostics include Becton Dickinson & Co. and bioMerieux, Inc. In addition, companies offering post- culture species identification using both molecular and non- molecular methods include bioMerieux, Inc. (and its affiliate, BioFire Diagnostics, Inc.), Bruker Corporation, Accelerate Diagnostics, Luminex, Roche, Cepheid and Beckman Coulter, a Danaher company. These post- culture competitors rely on a positive result from blood culture in order to perform their tests, significantly prolonging their results when compared to our technology. Some of the products offered by our competitors require hours of extensive hands- on labor by an operator, while some rely on high concentrations of pathogens present in a positive blood culture, which can require a final concentration of at least 1, 000, 000 CFU / mL. In addition, there may be a number of new market entrants in the process of developing other post- blood culture diagnostic technologies that may be perceived as competitive with our technology. Karius, Inc. offers a lab developed culture independent diagnostic test for the identification of pathogens that has not been cleared by the FDA but may be perceived as competitive with our technology. We believe that we have a number of competitive advantages, including: • our products' ability to detect targets directly **from** ~~in complex and high volume samples, including whole~~ blood, ~~eliminating~~ **without** the need **to wait days** for ~~sample extraction and purification~~ **positive blood culture results** ; • our products' ability to ~~detect a broad range of targets, providing a wide variety of potential applications both within and outside of the in vitro diagnostics market; • our products' ability to~~ provide rapid ~~and~~ **,** highly- sensitive **and highly- specific** diagnostic results, which can provide timely information to **enable clinicians** ~~assist physicians and hospitals~~ to make therapeutic decisions that can improve patient outcomes and reduce healthcare costs; • our **products'** ability to ~~develop easily operable products for end users~~ **detect a broad range of targets, providing a wider variety of potential applications both within and outside of the in vitro diagnostics market** ; • our applications in the field of sepsis that we believe will not require separate reimbursement codes due to the established payment and reimbursement structure in place; ~~and~~ • our applications may provide substantial economic benefits to hospitals that can accrue the savings related to the rapid treatment of sepsis patients ~~. In addition~~ **; and • our ability** to **develop easily operable products** ~~identifying sepsis- causing pathogens, we can also identify the existence of the SARS- CoV- 2 virus. Competition~~ for **end users** ~~molecular testing of the SARS- CoV- 2 virus includes the same large commercial organizations named above, and extends to other large companies like Abbott, Roche, Bio- Rad, PerkinElmer, Hologic, Thermo Fisher and others~~ . Government Regulation Our products and our operations are subject to significant government regulation by the FDA and other federal, state, and local regulatory authorities, as well as comparable authorities in other jurisdictions. Our products are subject to regulation as medical devices under the Federal Food, Drug, and Cosmetic Act,

or FDCA, as implemented and enforced by the FDA. The FDA and other U. S. and foreign governmental agencies regulate, among other things, with respect to medical devices: • design, development and manufacturing; • testing, labeling, content and language of instructions for use and storage; • clinical studies; • product safety; • marketing, sales and distribution; • pre- market clearance, certification, and approval; • record keeping procedures; • advertising and promotion; • recalls and field safety corrective actions; • post- market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; • post- market approval studies; and • product import and export. FDA ~~Pre- market~~ **Premarket** Clearance and Approval Requirements Each medical device we seek to commercially distribute in the United States must first receive 510 (k) clearance, de novo classification, or pre- market approval, or PMA, from the FDA, unless specifically exempted by the FDA. Under the FDCA, medical devices are classified into one of three classes — Class I, Class II or Class III — depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA' s General Controls for medical devices, which include compliance with the applicable portions of the FDA' s Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events, and truthful and non- misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA' s General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post- market surveillance, patient registries and FDA guidance documents. While most Class I devices are exempt from the 510 (k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510 (k) of the FDCA requesting permission to commercially distribute the device **based on the substantial equivalence of the device to a previously cleared device using the same pathway** . The FDA' s permission to commercially distribute a device subject to a 510 (k) premarket notification is generally known as 510 (k) clearance. Devices deemed by the FDA to pose the greatest risk, such as life- sustaining, life- supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510 (k) cleared device are categorized as Class III. These devices require submission and approval of a PMA application. 510 (k) Clearance Process **A** ~~Certain~~ **certain number** of our products have received 510 (k) clearance from the FDA **for various indications for use** . To obtain 510 (k) clearance, we must submit a pre- market notification to the FDA demonstrating that the proposed device is substantially equivalent to a previously ~~,~~ cleared 510 (k) device, a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of pre- market approval applications, or is a device that has been reclassified from Class III to either Class II or I. The FDA' s 510 (k) clearance process usually takes from three to 12 months from the date the application is submitted and accepted by the FDA ~~,~~ but may take significantly longer. The FDA may **have questions on data provided or** require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, FDA collects user fees for certain medical device submissions and annual fees for **registering** medical device establishments. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510 (k) clearance to commercially market the device. If the FDA determines that the device is " not substantially equivalent " to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements ~~,~~ or can request a risk- based classification determination for the device in accordance with the de novo classification process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. After a device receives 510 (k) clearance, any subsequent modification of the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510 (k) clearance or, depending on the modification, could require pre- market approval or de novo classification. The FDA requires each manufacturer to make this determination initially, but the FDA may review any such decision and may disagree with a manufacturer' s determination. If the FDA disagrees with a manufacturer' s determination, the FDA may require the manufacturer to cease marketing and / or recall the modified device until 510 (k) clearance, issuance of a de novo classification or approval of a PMA is obtained. Under these circumstances, the FDA may also subject a manufacturer to significant regulatory fines or other penalties. ~~Over the last several years, the FDA has proposed reforms to its 510 (k) clearance process. For example, in September 2019, the FDA issued revised final guidance describing an optional " safety and performance based " premarket~~ **Premarket** ~~review pathway for manufacturers of " certain, well- understood device types " to demonstrate substantial equivalence under the 510 (k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby 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 has developed and maintains a list of device types appropriate for the " safety and performance based " pathway and continues to develop product- specific guidance documents that identify the performance criteria for each such device type, as well as recommended testing methods, where feasible. Pre- market~~ Approval Process **Most** Class III devices require PMA approval before they can be marketed ~~, although some pre- amendment Class III devices for which FDA has not yet required a PMA are cleared through the 510 (k) process~~ . The PMA process is more demanding than the 510 (k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by **human clinical and non** ~~extensive data, including data from pre~~ - clinical **data** ~~studies and human clinical trials~~ . The PMA must also contain a full description of the device ~~and~~ , its ~~components, a full description of the methods, facilities, and controls used for~~ manufacturing, and proposed labeling. ~~After~~ **FDA review of** a PMA application ~~is submitted and filed by the FDA, the FDA begins an in- depth review of the submitted information, which~~ typically takes between one and three years, but may take significantly longer. ~~During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the~~

panel' s recommendation. In addition, the FDA will conduct a pre- approval inspection of the manufacturing facility to ensure compliance with the QSR **before** , which imposes elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process. The FDA will approve **approving** the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use (s). The FDA may approve a PMA application with post- approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long- term follow- up data from patients in the clinical study that supported approval or requirements to conduct additional clinical studies post- approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval . Certain changes to an approved device , such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as an original PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an **and** advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change **changed device** in demonstrating a reasonable assurance of safety and effectiveness . De novo Classification Process Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. The **FDCA contains** Food and Drug Administration Modernization Act of 1997 established a route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the " Request for Evaluation of Automatic Class III Designation, " or the de novo classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down- classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. **The** Prior to the enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, in July 2012, a medical device could only be eligible for de novo classification if the manufacturer first submitted a 510 (k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the de novo classification pathway by permitting **allows a manufacturers manufacturer** to request de novo classification directly without first submitting a 510 (k) premarket notification to the FDA and receiving a not substantially equivalent determination. **The** Under FDASIA, FDA is required to classify the device within 120 days following receipt of the de novo application. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the de novo request if it identifies a legally marketed predicate device that would be appropriate for a 510 (k) or determines that the device is not low- to- moderate- risk or that general controls would be inadequate to control the risks and / or that special controls cannot be developed. On September 22, 2014, the FDA agreed with the de novo classification request for the T2Dx and T2Candida Panel , and classified these products as Class II medical devices. Clinical Trials Clinical trials are typically required to support a PMA application or de novo reclassification request, and are sometimes required to support a 510 (k) pre- market notification. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA' s investigational device exemption, or IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a " significant risk " to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. If the device under evaluation does not present a significant risk to human health, then the device sponsor is not required to submit an IDE application to the FDA before initiating human clinical trials, but must still comply with abbreviated IDE requirements when conducting such trials. A **Regardless of the degree of risk (** significant risk device is one that presents a potential for **or nonsignificant)** serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval. Regardless of the degree of risk presented by the medical device, clinical studies must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE , and may pose additional requirements for the conduct of the study . If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects . During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are

also subject to FDA' s regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, the sponsor, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Expedited Development and Review Programs Following passage of the 21st Century Cures Act, the FDA implemented the Breakthrough Devices Program, which is a voluntary program offered to manufacturers of certain medical devices and device- led combination products that may provide for more effective treatment or diagnosis of life- threatening or irreversibly debilitating diseases or conditions. The goal of the program is to provide patients and health care providers with more timely access to qualifying devices by expediting their development, assessment and review, while preserving the statutory standards for PMA approval, 510 (k) clearance and de novo classification. The program is available to medical devices that meet certain eligibility criteria, including that the device provides more effective treatment or diagnosis of life- threatening or irreversibly debilitating diseases or conditions, and that the device meets one of the following criteria: (i) the device represents a breakthrough technology, (ii) no approved or cleared alternatives exist, (iii) the device offers significant advantages over existing approved or cleared alternatives, or (iv) the availability of the device is in the best interest of patients. Breakthrough Device designation provides certain benefits to device developers, including more interactive and timely communications with FDA staff, use of post- market data collection, when scientifically appropriate, to facilitate expedited and efficient development and review of the device, opportunities for efficient and flexible clinical study design, and ~~prioritized~~ **expedited** review of premarket submissions **. In February 2019, our T2Resistance Panel was granted FDA Breakthrough Device designation, in July 2022, we received Breakthrough Device Designation for the T2Lyme Panel, and in July 2023, we received Breakthrough Device designation for our Candida auris test** . The Commissioner of the FDA, under delegated authority from the Secretary of HHS may, under certain circumstances in connection with a declared public health emergency, allow for the marketing of a product that does not otherwise comply with FDA regulations by issuing an EUA for such product. Before an EUA may be issued by HHS, the Secretary must declare an emergency based a determination that public health emergency exists that effects or has the significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or CBRN, or a specified disease or condition that may be attributable to such CBRN. On February 4, 2020, the HHS Secretary determined that there is such a public health emergency that involves the virus now known as SARS- CoV- 2, the virus that causes the COVID- 19 infection. Once the determination of the threat or emergency has been made, the Secretary of HHS must then declare that an emergency exists justifying the issuance of EUAs for certain types of products (referred to as EUA declarations). On February 4, 2020, the Secretary of HHS declared – on the basis of his determination of a public health emergency that has the potential to affect national security or the health and security of U. S. citizens living abroad that involves SARS- CoV- 2 – that circumstances exist justifying authorization of in vitro diagnostic devices during the COVID- 19 pandemic, subject to the terms of any EUA that is issued. Once an EUA declaration has been issued, the FDA can issue EUAs for products that fall within the scope of that declaration. To issue an EUA, the FDA Commissioner must conclude that ~~(~~1) the CBRN that is referred to in the EUA declaration can cause serious or life- threatening diseases or conditions; ~~(~~2) based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the disease or condition attributable to the CBRN and that the product' s known and potential benefits outweigh its known and potential risks; and ~~(~~3) there is no adequate, approved, and available alternative to the product. Products subject to an EUA must still comply with the conditions of the EUA, including labeling and marketing requirements. Moreover, the authorization to market products under an EUA is limited to the period of time the EUA declaration is in effect, and the FDA can revoke an EUA in certain circumstances. At certain points during the COVID- 19 pandemic, the FDA ~~has~~ issued policies indicating that it would not object to test developers distributing or offering their validated tests prior to receipt of an EUA, provided the test developers met certain criteria set forth in published enforcement policies. In June 2020, we launched the T2SARS- CoV- 2 Panel, our COVID- 19 molecular diagnostic test, after validation of the test pursuant to the FDA' s policy permitting COVID- 19 tests to be marketed prior to receipt of an EUA, subject to certain prerequisites. In August 2020, the FDA granted an EUA to the T2SARS- CoV- 2 Panel for the qualitative direct detection of nucleic acid from SARS- CoV- 2 in upper respiratory specimens (such as nasal, mid- turbinate, nasopharyngeal, and oropharyngeal swab specimens) and bronchoalveolar lavage specimens from individuals suspected of COVID- 19 by their healthcare provider. ~~Although the US Department for Human and Health Services has announced that it will be allowing the COVID- 19 Public Health Emergency to expire on May 11, 2023, this expiration does not affect the FDA EUA process or the devices that are currently available through the EUA process. At present, there are no plans that have been announced by FDA to discontinue the EUA process, which would affect the company' s ability to distribute the T2SARS- CoV- 2 Panel as well as allow the Company to keep product that has already been sold to remain at those commercial inventories. It is expected that FDA will request those companies, like ours, that have products authorized under the COVID- 19 EUA to have their products cleared under the premarket notification or premarket approval process if they wish to continue to distribute products commercially. It is also expected that FDA will provide at least 180 days to transition from EUA authorization to standard regulatory pathways.~~ Research- ~~use~~ **Use** - ~~only~~ **Only** ~~devices~~ **Devices** Some of our products, including our T2Resistance Panel and T2Cauris Panel are currently available RUO. An RUO device is an in vitro diagnostic device, or IVD, that is in the laboratory research phase of development. IVDs that are marketed for RUO are not intended for use in a clinical investigation or for clinical diagnostic use outside an investigation and must be labeled " For Research Use Only. Not for use in diagnostic procedures. " Products that are intended for RUO and are properly labeled as RUO are exempt from compliance with the FDA' s requirements applicable to medical devices more generally, including the requirements for clearance or approval and compliance with the FDA' s QSR. A product labeled RUO but intended to be used diagnostically may be viewed by the FDA as adulterated and misbranded under the FDCA and is subject to FDA enforcement activities. The FDA may consider the totality of the circumstances surrounding distribution and use of an RUO product,

including how the product is marketed, when determining its intended use. Pervasive and Continuing U. S. Food and Drug Administration Regulation After a medical device is placed on the market, numerous FDA regulatory requirements apply, including, but not limited to the following: • ~~including~~ Medical Device Reporting, which requires manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury, or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. • post- market surveillance QSR requirements, which require manufacturers, including third- party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process; • establishment registration, which requires establishments involved in the production and distribution of medical devices, intended for commercial distribution in the United States, to register with the FDA; • medical device listing, which requires manufacturers to list the devices they have in commercial distribution with the FDA; • clearance or approval of product modifications to cleared devices or devices authorized through the de novo classification process that could significantly affect safety or effectiveness, or that would constitute a major change in intended use of such devices, or approval of certain modifications to PMA- approved devices; • labeling regulations, which prohibit " misbranded " devices from entering the market, as well as prohibit the promotion of investigational products or promotion of " off- label " uses for cleared or approved products; and • post- market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device; • correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health; and • the FDA' s recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations. Manufacturing processes for medical devices are required to comply with the applicable portions of the QSR, which cover the methods **,** ~~and the~~ facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled **FDA** inspections ~~by the FDA~~. Failure to maintain compliance with the QSR requirements could result in the shutdown of, or restrictions on, manufacturing operations and the recall or seizure of marketed products. The discovery of previously unknown problems with marketed medical devices, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off- label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls. The FDA has broad regulatory compliance and enforcement powers. Failure to comply with applicable regulatory requirements may result in enforcement action by the FDA, which may include one or more of the following sanctions: • untitled letters or warning letters; • fines, injunctions and civil penalties; • mandatory recall or seizure of our products; • administrative detention or banning of our products; • operating restrictions, partial suspension or total shutdown of production; • refusing our request for 510 (k) clearance or pre- market approval of new product versions; • revocation of 510 (k) clearance or pre- market approvals previously granted; and • criminal prosecution and penalties. International Regulation Medical devices (including in vitro diagnostic medical devices, or IVD MDs) are subject to extensive foreign government regulations are subject, such as premarket review, marketing authorization or certification, by similar agencies or notified bodies outside the United States, and which vary substantially from country to country. In order to market our products in other countries, we must obtain regulatory approvals or certifications and comply with extensive safety and quality regulations in other countries. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ significantly. International regulators and notified bodies are independent and not bound by the findings of the FDA. Regulation of In Vitro Diagnostic Medical Devices in the European Union The EU has adopted specific directives and regulations regulating the design, manufacture, clinical investigations, conformity assessment, labeling and adverse event reporting for medical devices (including IVD MDs). Until May 25, 2022, IVD MDs were regulated by Directive 98 / 79 / EC, or EU IVDD, which has been repealed and replaced by Regulation (EU) No 2017 / 746, or EU IVDR. The transition period to implement EU IVDR requirements is currently underway now, with extensions applied due to the low number of EU Notified Bodies that are accredited to certify to the new Regulation and the high number of IVD companies that require certification. Changes from the IVDD to IVDR have been impactful. Under IVDR, there are now four (4) regulatory classifications for IVD MDs. Class A IVD MDs, such as our T2Dx Instrument **,** allow **us** ~~the company~~ to self- assess the conformity of its products with IVDR requirements. The remaining Classes B, C and D, which include our T2Candida, T2Bacteria and T2Resistance Panels, require a conformity assessment procedure requires the intervention of a Notified Body who is accredited by an EU Competent Authority to certify products to the EU IVDR. Notified Bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A Notified Body would typically audit and examine a product' s technical documentation per the requirements of EU IVDR. If satisfied that the relevant product conforms to the relevant essential requirements, the Notified Body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. While **we** ~~the company~~ had assessed that the T2Dx Instrument and T2Candida met the requirements of the EU IVDD in late 2014, based upon an EC declaration of conformity dated July 7, 2014 **,** and updated on September 9, 2015 and May 26, 2016, allowing us to affix the CE mark to these products. The Class A T2Dx Instrument was self- certified by **us** ~~the company~~ on August 12, 2022. While the T2Bacteria, T2Candida **, T2Biothreat** and T2Resistance Panels were allowed to continue to be self- declared under EU IVDD, EU IVDR requirements have determined that these products are of a higher classification than Class A, therefore **we** ~~the company~~ must now pursue conformity routes for each product as **we** ~~the company continues~~ **continue** to complete the transition to EU IVDR. This work was delayed by **our** ~~the~~

~~company' s~~ Notified Body accreditation to certify to EU IVDR on February 25, 2023. **We** ~~The company~~ will continue to work with our Notified Body to achieve full transition to EU IVDR requirements and certification throughout 2023 with an expected completion in 2024. Class B devices are expected to fully transition to EU IVDR certification by May 26, 2027. Class C devices are expected to fully complete transition May 26, 2026. It is currently assumed that the Panel products will be classified as Class B or Class C for our Notified Body per EU IVDR requirements. Our current certificates for the T2 Panels have been granted under the EU IVDD whose regime is described below. However, as of May 26, 2022, some of the EU IVDR requirements apply in place of the corresponding requirements of the EU IVDD with regard to registration of economic operators and of devices, post- market surveillance and vigilance requirements. Pursuing marketing of IVD MDs in the EU will notably require that our devices be certified under the new regime set forth in the EU IVDR by the time the transition period of the applicable IVD classification under IVDR expires. In Vitro Diagnostic Medical Devices Directive Under the EU IVDD, all IVD MDs placed on the market in the EU must meet the essential requirements laid down in Annex I to the EU IVDD, including the requirement that an IVD MD must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter as it creates a rebuttable presumption that the device satisfies that essential requirement. To demonstrate compliance with the essential requirements laid down in Annex I to the EU IVDD, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. As a general rule, demonstration of conformity of IVD MDs and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. Except for (general) IVD MDs (i. e., all IVD MDs other than those covered by Annex II to the EU IVDD and IVD MDs for self- testing), where the manufacturer can self- assess the conformity of its products with the essential requirements, a conformity assessment procedure requires the intervention of a Notified Body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A Notified Body would typically audit and examine a product' s technical dossiers and the manufacturers' quality system (Notified Body must presume that quality systems which implement the relevant harmonized standards – which is ISO 13485: 2016 for Quality Management Systems – conform to these requirements). If satisfied that the relevant product conforms to the relevant essential requirements, the Notified Body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. Throughout the term of the certificate of conformity, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the Notified Body before it will renew the relevant certificate (s). In Vitro Diagnostic Medical Devices Regulation The EU regulatory landscape related to IVD MDs recently evolved. On April 5, 2017, the EU IVDR, was adopted with the aim of ensuring better protection of public health and patient safety. The EU IVDR establishes a uniform, transparent, predictable and sustainable regulatory framework across the EU for IVD MDs and ensure a high level of safety and health while supporting innovation. Unlike the EU IVDD, the EU IVDR is directly applicable in all EU member states without the need for member states to implement into national law. This aims at increasing harmonization across the EU. The EU IVDR became effective on May 26, 2022. In accordance with the recently amended provisions of the EU IVDR both (i) IVD MDs lawfully placed on the market pursuant to the EU IVDD prior to May 26, 2022 and (ii) IVD MDs lawfully placed on the market after May 26, 2022 in accordance with the transitional provisions of the EU IVDR may generally continue to be made available on the market or put into service provided that the requirements of the transitional provisions are fulfilled. However, even in this case, manufacturers must comply with a number of new or reinforced requirements set forth in the EU IVDR, in particular the obligations described below. The EU IVDR requires that before placing an IVD MD on the market, manufacturers (as well as other economic operators such as authorized representatives and importers) must register by submitting identification information to the electronic system (~~Eudamed~~ **EUDAMED**), unless they have already registered. The information to be submitted by manufacturers (and authorized representatives) also includes the name, address and contact details of the person or persons responsible for regulatory compliance. The new Regulation also requires that before placing a device on the market, manufacturers must assign a unique identifier to the device and provide it along with other core data to the unique device identifier, or UDI, database. These new requirements aim at ensuring better identification and traceability of the devices. Each device – and as applicable, each package – will have a UDI composed of two parts: a device identifier, or UDI- DI, specific to a device, and a production identifier, or UDI- PI, to identify the unit producing the device. Manufacturers are also notably responsible for entering the necessary data on ~~Eudamed~~ **EUDAMED** , which includes the UDI database, and for keeping it up to date. The obligations for registration in ~~Eudamed~~ **EUDAMED** will become applicable at a later date (as ~~Eudamed~~ **EUDAMED** is not yet fully functional). Until ~~Eudamed~~ **EUDAMED** is fully functional, the corresponding provisions of the EU IVDD continue to apply for the purpose of meeting the obligations laid down in the provisions regarding exchange of information, including, and in particular, information regarding registration of devices and economic operators. All manufacturers placing medical devices on the market in the EU must comply with the EU medical device vigilance system which has been reinforced by the EU IVDR. Under this system, serious incidents and Field Safety Corrective Actions, or FSCAs, must be reported to the relevant authorities of the EU member states. These reports will have to be submitted through

~~Eudamed~~ **EUDAMED** – once functional – and aim to ensure that, in addition to reporting to the relevant authorities of the EU member states, other actors such as the economic operators in the supply chain will also be informed. Until ~~Eudamed~~ **EUDAMED** is fully functional, the corresponding provisions of the EU Medical Devices Directive continue to apply. A serious incident is defined as any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use- error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side- effect, which, directly or indirectly, might have led or might lead to the death of a patient or user or of other persons or to a temporary or permanent serious deterioration of a patient' s, user' s or other person' s state of health or a serious public health threat. Manufacturers are required to take FSCAs defined as any corrective action for technical or medical reasons to prevent or reduce a risk of a serious incident associated with the use of a medical device that is made available on the market. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and / or to the end users of the device through Field Safety Notices. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a FSCA implemented or where the incidents are common and well documented, manufacturers may provide periodic summary reports instead of individual serious incident reports. The advertising and promotion of medical devices are subject to some general principles set forth in EU legislation. According to the EU IVDR, only devices that are CE marked may be marketed and advertised in the EU in accordance with their intended purpose. Directive 2006 / 114 / EC concerning misleading and comparative advertising and Directive 2005 / 29 / EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising thereof and contain general rules, for example, requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at a national level. EU member states' laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals. Many EU member states have adopted specific anti- gift statutes that further limit commercial practices for medical devices (including IVD MDs), in particular vis- à- vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national " Sunshine Acts " which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs. In the EU, regulatory authorities have the power to carry out announced and, if necessary, unannounced inspections of companies, as well as suppliers and / or sub- contractors and, where necessary, the facilities of professional users. Failure to comply with regulatory requirements (as applicable) could require time and resources to respond to the regulatory authorities' observations and to implement corrective and preventive actions, as appropriate. Regulatory authorities have broad compliance and enforcement powers and if such issues cannot be resolved to their satisfaction can take a variety of actions, including untitled or warning letters, fines, consent decrees, injunctions, or civil or criminal penalties. The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland. Brexit Since the end of the Brexit transition period on January 1, 2021, Great Britain (England, Scotland and Wales) has not been directly subject to EU laws, however under the terms of the Protocol on Ireland / Northern Ireland, EU laws generally apply to Northern Ireland. On February 27, 2023, the United Kingdom, or UK Government and the European Commission reached a political agreement on the " Windsor Agreement " which is likely to lead to further amendments to the Protocol on Ireland / Northern Ireland in order to address some of the perceived shortcomings in its operation. These proposed changes need to be codified and agreed by the respective parliaments of the UK and EU before taking effect. The EU laws that have been transposed into United Kingdom law through secondary legislation remain applicable in Great Britain. However, under the Retained EU Law (Revocation and Reform) Bill 2022, which is currently before the UK parliament, any retained EU law not expressly preserved and " assimilated " into domestic law or extended by ministerial regulations (to no later than June 23, 2026) will automatically expire and be revoked by December 31, 2023. In addition, new legislation such as the EU IVDR is not applicable in Great Britain. The UK government has passed a new Medicines and Medical Devices Act 2021, which introduces delegated powers in favor of the Secretary of State or an ' appropriate authority' to amend or supplement existing regulations in the area of medicinal products and medical devices, including IVD MDs. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices. The EU- UK Trade and Cooperation Agreement, or TCA, came into effect on January 1, 2021. The TCA does not specifically refer to medical devices or IVD MDs but does provide for cooperation and exchange of information in the area of product safety and compliance, including market surveillance, enforcement activities and measures, standardization related activities, exchanges of officials, and coordinated product recalls (or other similar actions). For medical devices and IVD MDs that are locally manufactured but use components from other countries, the " rules of origin " criteria will need to be reviewed. Since January 1, 2021, the Medicines and Healthcare Products Regulatory Agency, or MHRA, has become the sovereign regulatory authority responsible for Great Britain. New regulations require all medical devices and IVD MDs to be registered with the MHRA, and since January 1, 2022, manufacturers based outside the UK have been required to appoint a UK responsible person that has a registered place of business in the UK to register devices with the MHRA. On June 26, 2022, the MHRA published its response to a 10- week consultation on the post- Brexit regulatory framework for medical devices and IVD MDs. The MHRA seeks to amend the UK Medical Devices Regulations 2002 (which are based on EU legislation, primarily the EU Medical Devices Directive 93 / 42 / EEC and the EU IVDD), in particular to create a new access pathway to support innovation, create an innovative framework for regulating software and artificial intelligence as medical devices, reform IVD MD regulation and foster sustainability through the reuse and remanufacture of medical devices. Regulations implementing the new regime were originally scheduled to come into force in July 2023, but the Government has

recently confirmed that this date has been postponed until July 2024. Devices which have valid a valid certificate issued by EU notified bodies under the EU IVDR or EU IVDD are subject to transitional arrangements. In its consultation response, the MHRA indicated that the future regulations in Great Britain will allow IVD MDs with valid certification to continue being placed on the market in Great Britain under the CE mark until either the certificate expires or for five years after the new regulations take effect, whichever is sooner. Following these transitional periods, it is expected that all IVD MDs will require a UK Conformity Assessment, or UKCA, mark. Manufacturers may choose to use the UKCA mark on a voluntary basis prior to the regulations coming into force. However, from July 2024, products which do not have existing and valid certification under the EU IVDD or EU IVDR and are therefore not subject to the transitional arrangements will be required to carry the UKCA mark if they are to be sold into the market in Great Britain. UKCA marking will not be recognized in the EU. The rules for placing IVD MDs on the market in Northern Ireland, which is part of the UK, differ from those in Great Britain and continues to be based on EU law. Under the terms of the Ireland / Northern Ireland Protocol, Northern Ireland follows EU rules on IVD MDs, including the EU IVDR, and IVD MDs marketed in Northern Ireland require assessment according to the EU regulatory regime. Such assessment may be conducted by an EU Notified Body, in which case a CE mark is required before placing the device on the market in Northern Ireland. Alternatively, if a UK approved body conducts such assessment, a' UKNI' mark is applied and the device may only be placed on the market in Northern Ireland and not the EU. Other Healthcare Laws Our current and future business activities are subject to healthcare regulation and enforcement by ~~the~~ federal **, state and local** ~~government~~ **governments** and the ~~states and~~ foreign governments in which we conduct our business. These laws include, without limitation, state and federal anti- kickback, fraud and abuse, false claims, data privacy and security and transparency laws and regulations regarding payments or other transfers of value made to physicians and other licensed healthcare professionals. The federal Anti- Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing **any** remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual, for an item or service or the purchasing, leasing, ordering, or arranging for or recommending the purchase, lease or order of any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs. ~~Although there~~ **There** are a number of statutory exceptions and regulatory safe harbors ~~protecting some common activities from prosecution~~ **that the OIG has promulgated outlining certain categories of relationships between health care providers and persons or entities that may have a referral relationship that would be deemed not to violate the Anti- Kickback Statute. However** , the exceptions and safe harbors are drawn narrowly ~~. Practices that involve remuneration that may be alleged~~ to **avoid inadvertently immunizing prohibited conduct** ~~be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor~~ . Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti- Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case- by- case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute' s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti- Kickback Statute has been violated. In addition, 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 majority of states also have anti- kickback laws which establish similar prohibitions and, in some cases, may apply to items or services reimbursed by any third- party payor, including commercial insurers. Additionally, the ~~civil~~ **federal** False Claims Act prohibits, among other things, **any person or entity from** knowingly presenting or causing the presentation of a false or fraudulent claim for payment to, or approval by, the U. S. government. **The False Claims Act defines the term " knowingly " broadly, and submitting a claim with reckless disregard to its truth or falsity can constitute the " knowing " submission of a false or fraudulent claim for the purposes of the False Claims Act.** In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud **. Such " whistleblower " or " qui tam " provisions are being used with more frequency to challenge the reimbursement practices of providers and suppliers** . Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government **decides to** ~~intervenes~~ **intervene** and is ultimately successful in obtaining redress in the matter, or if the plaintiff succeeds in obtaining redress without the government' s involvement, then the plaintiff will receive a percentage of the **monetary** recovery. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of life sciences companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. The government has obtained multi- million and multi- billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws. **Many states have enacted similar false claims acts as well.** The ~~Federal~~ **federal** Health Insurance Portability and Accountability Act of 1996, ~~or~~ **as amended (" HIPAA ")** , created new federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third- party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent ~~statement~~ **statements or representations** in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The **federal** ~~civil~~ **Civil** ~~monetary~~ **Monetary** ~~penalties~~ **Penalties** ~~statute~~ **Law** imposes penalties against any person or entity that, among other things, **knowingly** ~~is determined to have presented~~

presents or ~~caused~~ **causes** to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Also, as stated above, many states have similar fraud and abuse laws that may be broader in scope and may apply regardless of payor. Moreover, the Physician Payments Sunshine Act requires certain device manufacturers, among others, to report certain payments or " transfers of value " provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non- physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives) and teaching hospitals, and to report ownership and investment interests held by physicians and their immediate family members during the preceding calendar year. The statute includes in its reporting requirements a broad range of transfers of value including, but not limited to, consulting fees, speaker honoraria, charitable contributions, research payments and grants. Failure to report **any covered payment or transfers of value within the Open Payments system** could subject companies to significant financial penalties. Tracking and reporting the required payments and transfers of value may result in considerable expense and additional resources. Several states currently have similar laws and more states may enact similar legislation, some of which may be broader in scope. For example, certain states require the implementation of compliance programs, compliance with industry ethics codes, implementation of gift bans and spending limits, and / or reporting of gifts, compensation and other remuneration to healthcare professionals. We also may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH, through its implementing regulations, makes certain ~~of~~ HIPAA ~~' s~~ privacy and security standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity' s workforce, that creates, receives, maintains or transmits protected health information for or on behalf of a covered entity for a function or activity regulated by HIPAA. In addition to HIPAA criminal penalties, HITECH created four new tiers of civil and monetary penalties and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws **in certain circumstances** and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and / or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our future operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results. Climate Change and Environmental Laws The medical device industry is increasingly becoming subject of scrutiny, stringent regulation and the demand for green, sustainable products. We are focused on monitoring these increasing requirements for efficient and accurate processes for hazardous substance handling, supplier disclosures, and regulatory reporting in order to comply with numerous global health and environmental regulatory requirements and restrictions. We believe that we are in compliance in all material respects with all foreign, federal, state, and local environmental regulations applicable to our manufacturing facilities. The cost of ongoing compliance with such regulations does not have a material effect on our operations. Coverage and Reimbursement Maintaining and growing sales of our diagnostic tests depend in large part on the availability of adequate coverage and reimbursement from third- party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. These third- party payors are increasingly limiting coverage and reducing reimbursement for medical products and services, including clinical laboratory tests. In addition, the U. S. government, state legislatures and foreign governments have continued implementing cost- containment programs, including price controls and restrictions on coverage and reimbursement. Adoption of price controls and cost- containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Third- party payors may deny coverage if they determine that our products are not cost- effective as determined by the payor, or are deemed by the third- party payor to be experimental or medically unnecessary. Decreases in third- party reimbursement for our products, product candidates, or services in which our products are used, or a decision by a third- party payor to not cover our tests, product candidates, or services in which our products are used could reduce physician utilization of our tests, if approved, and have a material adverse effect on our sales, results of operations and financial condition. Hospitals, clinical laboratories and other healthcare provider customers that may purchase our products and / or product candidates generally bill various third- party payors to cover all or a portion of the costs and fees associated with diagnostic tests, including the cost of the purchase of our products and / or product candidates. The majority of our diagnostic tests are performed in a hospital inpatient setting, where governmental payors, such as Medicare, generally reimburse hospitals with a single bundled payment that is based on the patients' diagnosis under a classification system known as the Medicare severity diagnosis- related groups, or MS- DRGs, classification for all items and services provided to the patient during a single hospitalization, regardless of whether our diagnostic tests are performed during such hospitalization. In addition, new products may be eligible for an add- on payment for a time period up to three years if they meet certain criteria, including, among other things, demonstrating a substantial clinical improvement relative to services or technologies previously available. For fiscal years 2021 and 2022, hospitals paid under the Medicare Hospital Inpatient Prospective Payment System were eligible to receive a new technology add- on payment, or NTAP for T2Bacteria, which is incremental to the MS- DRG reimbursement for qualifying Medicare inpatient cases based on the cost of the case. Effective fiscal year 2023, T2Bacteria is no longer eligible for NTAP. To the extent that our diagnostic tests are

performed in an outpatient setting, certain of our tests ~~, including our T2SARS- CoV- 2 Panel~~ may be eligible for separate payment using existing Current Procedural Terminology, or CPT, codes, under the Clinical Laboratory Fee Schedule. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. EU member states and the UK impose controls on whether products are reimbursable by national or regional health service providers and on the prices at which devices are reimbursed under state- run healthcare schemes. More and more, local, product specific reimbursement law is applied as an overlay to medical device regulation, which has provided an additional layer of clearance requirement. We are unable to predict at this time whether our products and / or product candidates, if approved, will be covered by third- party payors. Nor can we predict at this time the adequacy of payments, whether made separately in an outpatient setting or with a bundled payment amount in an inpatient setting. Our customers' access to adequate coverage and reimbursement for our products and / or product candidates by government and private insurance plans is central to the acceptance of our products. We may be unable to sell our products on a profitable basis if third- party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels. Healthcare Reform In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. By way of example, the ACA created a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court' s decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 , through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. Other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions of Medicare payments to providers, which will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 , through March 31, 2022. In addition, 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, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations or cash flows. On January 1, 2018, CMS implemented certain provisions of the Protecting Access to Medicare Act of 2014, or PAMA, which made substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, laboratories that receive the majority of their Medicare revenue from payments made under the CLFS or the Physician Fee Schedule are required to report to CMS, beginning in 2017 and every three years thereafter (or annually for " advanced diagnostics laboratory tests "), private payer payment rates and volumes for their tests. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. CMS uses the data to calculate a weighted median payment rate for each test, which is used to establish a revised Medicare reimbursement rate. Under PAMA, the revised Medicare reimbursement rates were scheduled to apply to clinical diagnostic laboratory tests furnished on or after January 1, 2018. The revised reimbursement methodology is expected to generally result in relatively lower reimbursement under Medicare for clinical diagnostic lab tests that has been historically available. Any reduction to payment rates resulting from the new methodology is limited to 10 % per test per year in 2018 through 2020, and to 15 % per test per year in 2021 through 2023 and 15 % per test per year in 2024 through 2026. The CARES Act, which was signed into law on March 27, 2020, amended the timeline for reporting private payer payment rates and delayed by one year the payment reductions scheduled for 2021. On December 10, 2021, Congress passed the Protecting Medicare and American Farmers from Sequester Cuts Act, or PMAFSA, which delayed the next data reporting period by an additional year and prevented any reduction in payment amounts from commercial payer rate implementation in 2022. The Consolidated Appropriations Act, 2023, enacted on December 29, 2022, further revised the next data reporting period for certain tests and delayed the phase- in of payment reductions for an additional year, through 2026. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure. For instance, in December 2021, the EU Regulation No 2021 / 2282 on Health Technology Assessment, or HTA, amending Directive 2011 / 24 / EU, was adopted. This regulation which entered into force in January 2022 intends to boost cooperation among EU member states in assessing health technologies, including some medical devices and IVD MDs, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation foresees a three- year transitional period and will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from

HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non- clinical (e. g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. We have committed, and expect to commit, significant resources to developing new technologies and products, improving product performance and reliability and reducing costs. We have assembled an experienced research and development team with the scientific, engineering, software and process talent that we believe is required to successfully grow our business. We are currently focused on several product candidates and enhancements utilizing our proprietary technology. Major components of the research and development expenses were salaries and benefits, research- related facility and overhead costs, laboratory supplies, equipment and contract services. Research and development expenses can be impacted by services performed and expenses incurred under collaboration agreements and other research and development contracts. We continuously seek to improve our proprietary technology. As we make improvements, we anticipate we will make available new and improved generations of our diagnostic instruments and panels. Our technology developmental efforts are focused on applying our proprietary technology to additional potential applications in the in vitro diagnostics area. We believe that technical advantage is important to sustain a competitive advantage, and therefore our research and development efforts are focused on the continued enhancement of our proprietary technology. We are dedicated to ongoing innovation to our technology and expanding our pipeline of product candidates. Our goal is for our technology to become a standard of care by offering a rapid, sensitive and simple diagnostic alternative to existing methodologies for identifying sepsis, with a long- term objective of targeting the broader in vitro diagnostics market. **We recorded research** ~~In September 2019, BARDA awarded the Company a milestone- based contract, with an~~ **and** ~~initial value~~ **contribution revenue** of $ ~~6.~~ 0 ~~million, and a potential value of up to $ 62. 0 million, if BARDA awards all contract options (the " U. S. Government Contract "). BARDA operates within the Office of the ASPR at HHS. If BARDA awards and the Company completes all options, the Company' s management believes it will enable a significant expansion of the Company' s current portfolio of diagnostics for sepsis- causing pathogen and antibiotic resistance genes. In September 2020, BARDA exercised the first contract option valued at $ 10. 5 million. In September 2021, BARDA exercised Option 2A valued at approximately $ 6~~. 4 million ~~. In March 2022, BARDA exercised Option 2B valued at approximately $ 4. 4 million. In May 2022, BARDA exercised Option 3 valued at approximately $ 3. 7 million to further advance the U. S. clinical trials for the T2Resistance Panel~~ and ~~T2Biothreat Panel and file submissions to the FDA for U. S. regulatory clearance for those products. In April 2021, BARDA agreed to accelerate product development by modifying the contract to advance future deliverables into the currently funded Option 1 of the BARDA contract for T2Biothreat, T2Resistance and our next- generation instrument and comprehensive sepsis panel. The modification does not change the overall total potential value of the BARDA contract. The Company recorded research and contribution revenue of~~ $ 11. 0 ~~million and $ 11. 4~~ million for the years ended December 31, **2023 and** 2022 ~~and 2021~~, respectively, under the BARDA contract. Human Capital Resources At T2 Biosystems, employees are integral to **our** ~~the Company' s~~ success. Our key human capital management objectives are to attract, retain and develop talent needed to deliver on our strategy and advance our mission. As of December 31, ~~2022~~ **2023**, we had a total of ~~158~~ **113** employees, including ~~110~~ **79** employees working on- site, and ~~48~~ **34** employees working remotely or in the field. All of these employees were full- time employees. None of our employees are represented by labor unions or covered by collective bargaining agreements. We focus on the following areas in supporting our human capital: Diversity and Inclusion. We recognize and appreciate the importance of creating an environment where all team members feel valued, included and empowered to do their best work and bring great ideas to the table. We recognize that each team member' s unique experiences, perspectives, and viewpoints add value to our ability to develop and deliver innovative diagnostic products and make a meaningful impact on patient care. We **strive to** foster an organizational culture that ensures all employees are treated fairly and with respect, promotes inclusivity, and provides equal opportunities for professional growth and advancement based on merit. Our Code of Business Conduct and Ethics prohibits discrimination on the basis of race, color, religion, national origin, sex (including pregnancy), sexual orientation, age, disability, veteran status or other characteristic protected by law. Health and Safety. Safety is a top priority at T2 Biosystems. We promote safety with a robust health and safety program, which includes employee orientation and training, regular safety meetings, contractor management, risk assessments, hazard identification and mitigation, incident reporting and investigation, and corrective and preventative action development. Training and Development. We invest in training and development initiatives to ensure our employees have the skills and tools necessary to successfully contribute towards advancing progress on our strategic priorities and to prepare them to confidently take on new or expanded roles within the organization. Our on- going efforts are aimed at attracting, engaging, retaining, and developing employees in a thoughtful and meaningful way to support an inclusive culture. Compensation and Benefits. We aim to provide fair, competitive compensation and a comprehensive benefits program that will attract, retain and motivate employees. To align individual performance with our short- and long- term corporate objectives, our compensation programs consist of base pay, short- term incentives and long- term incentives, including restricted stock unit grants. Our benefits program currently includes medical, dental, and vision insurance plans for employees and their families, in addition to life insurance and short and long- term disability plans, paid time off for holidays, vacation, sick and other personal leave, and health and dependent care savings accounts. We also provide our employees with a 401 (k) plan that includes a competitive company match, and employees have access to several other programs, such as our Employee Stock Purchase Program (ESPP). Available Information We make available, free of charge, our annual reports on Form 10- K, quarterly reports on Form 10- Q, current reports on Form 8- K and any amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or the SEC. The address of the SEC' s website is www. sec. gov. We also make these documents and certain public financial information available free of charge on our website, which is www. t2biosystems. com. Our SEC reports and other financial information can be accessed through the investor relations section of our website. The information on, or that can be accessed from, our website is not incorporated by reference into this Annual Report or any other

report we file with or furnish to the SEC. Item 1A. RISK FACTORS Investing in our common stock involves a high degree of risk. You should carefully consider the risk factors described below, as well as the other information in this prospectus, including our financial statements and the related notes and " Management' s Discussion and Analysis of Results of Operations and Financial Condition, " before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. The occurrence of any of these risks may cause the trading price of our common stock to decline and you could lose all or part of your investment. Risks Related to our Business and Strategy We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing. Our cash, cash equivalents, and restricted cash as of December 31, ~~2022~~ **2023** was $ ~~11~~ **16** . ~~9~~ **2** million, which will not be sufficient to fund our current operating plan for at least a year from issuance of ~~these~~ **our** financial statements **included herein** . **The** ~~While we completed an underwritten public offering in February 2023 in which the Company raised approximately $ 12 million in gross proceeds, before underwriting discounts and commissions and offering expenses, absent any reductions in current operating expenses, the~~ Company believes it will require additional financing during the first half of ~~2023~~ **2024** . There can be no assurance that any financing by us can be realized, or if realized, what the terms of any such financing may be, or that any amount that we are able to raise will be adequate. The Term Loan Agreement with CRG Servicing LLC (" CRG ") (See Note 6 of the notes to our consolidated financial statements) has a minimum liquidity covenant which requires us to maintain a minimum cash balance of $ **0.** 5 ~~. 0~~ million. As security for its obligations under the Term Loan Agreement, the Company entered into a security agreement with CRG whereby the Company granted a lien on substantially all of its assets, including intellectual property. We intend to continue to evaluate options to refinance the Term Loan Agreement, which becomes due on December ~~30~~ **31** , ~~2024~~ **2025** . There can be no assurances that we will be able to refinance on terms favorable or at all. ~~The amounts involved in any such transactions, individually or in the aggregate may be material.~~ These conditions, as well as those described below under " Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our common stock, " raise substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that the financial statements **for the year ended December 31, 2023** are issued **. Our ability to fund working capital, make capital expenditures, and service our debt depends on our ability to generate cash from operating activities, which is subject to its future operating success, and obtain financing on reasonable terms, which is subject to factors beyond our control, including general economic, political, and financial market conditions. The capital markets have in the past experienced, are currently experiencing, and may in the future experience, periods of upheaval that could impact the availability and cost of financing and there can be no assurances that such financing will be available to the Company on satisfactory terms, or at all** . Management' s plans to alleviate the conditions that raise substantial doubt include raising additional capital, ~~earning payments pursuant to our contract with BARDA,~~ delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels for us to continue as a going concern for a period of 12 months from the date these financial statements are issued. Management has concluded the likelihood that its plan to successfully obtain sufficient funding from one or more of these sources or adequately reduce expenditures, while reasonably possible, is less than probable. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of issuance of ~~these~~ -- **the** financial statements **for the year ended December 31, 2023** . Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our common stock. ~~If we fail to regain~~ **On March 30, 2023, the Company received notice from The Nasdaq Stock Market LLC (" Nasdaq ") indicating that,** ~~or~~ **for** ~~maintain compliance with~~ the **last thirty consecutive business days, the bid price for the Company' s common stock had closed below the minimum $ 1. 00 per share requirement for** continued listing **on the** ~~requirements of The~~ Nasdaq Capital Market ~~,~~ **under** Nasdaq **Listing Rule 555 (** ~~may take steps to delist our common stock. On June 9, 2022, we received~~ a ~~letter from~~ **) (2) (** the **" Minimum** ~~Nasdaq notifying us that the Nasdaq had granted our request to be transferred to The Nasdaq Capital Market, effective at the open of trading on June 13, 2022, and our request for an exception to the~~ Bid Price Rule **")** ~~was granted until November 1, 2022~~ . On ~~October 11~~ **May 23** , ~~2022~~ **2023** , **Nasdaq notified the Company that its securities were subject to delisting due to non- compliance with the Minimum Bid Price Rule and to maintain a minimum value of listed securities (the " MVLS Rule ") of** at **least $ 35 million. The Company requested a hearing with Nasdaq and, on July 6, 2023, appealed to** the **Nasdaq Hearings Panel for an extension to the time period in which to regain compliance with the MVLS Rule and the Minimum Bid Price Rule. On July 26, 2023, we filed a definitive proxy statement to effect a reverse stock split of our common stock in connection with our** annual meeting **that occurred in September 2023 as required by the Nasdaq Hearings Panel. On August 9, 2023, the Company received written notice from Nasdaq informing the Company that it had regained compliance with the MVLS Rule. On September 15, 2023, at the Company' s annual meeting** of stockholders, ~~our~~ **the Company' s** stockholders approved an amendment to ~~our~~ **the Company' s** restated certificate of incorporation to effect a reverse stock split of ~~our~~ **the Company' s** common stock. **On October 12** ~~Following the receipt of the stockholders' approval~~ , ~~our~~ **2023, the Company announced that its** board of directors **had** approved the reverse stock split at the ratio of 1 post- split share for every ~~50~~ **100** pre- split shares, which was effective as of October 12, ~~2022~~ **2023** . On October 31, ~~2022~~ **2023** , ~~we~~ **the Company** received ~~a letter~~ **written notice** from Nasdaq informing ~~us~~ **the Company** that ~~we~~ **it has** regained compliance with the **Minimum** Bid Price Rule. **The Company will be subject to a Mandatory Panel Monitor for a period of one year. If, within that one- year monitoring period, the Company fails to comply with the Minimum Bid Price Rule, the Company will not be permitted additional time to regain compliance with the Minimum Bid Price Rule.** However, ~~there~~ -- **the** ~~is~~ **Company will have an opportunity to request a new hearing with the Nasdaq Hearings Panel prior to the Company' s securities being delisted from Nasdaq. On November 20, 2023, the Company received written notice from Nasdaq**

informing the Company that it no **longer satisfied the MVLS Rule. In accordance with the terms of the Mandatory Panel Monitor, the Company was not granted a grace period but rather issued a delist determination, which will be stayed if the Company exercises its right to appeal by requesting a hearing and paying a non- refundable $ 20, 000 fee. The Company has paid the $ 20, 000 applicable fee and requested a new hearing, which will stay any further action by Nasdaq at least pending the** ~~assurance -~~ **issuance of its decision and the expiration of any extension** that **may be granted to** the ~~market price per share~~ **Company as a result** of ~~our~~ **the hearing. The Company' s** common stock will ~~continue to~~ remain **listed and eligible to trade on** ~~in excess of the $ 1. 00 minimum bid price as required by~~ Nasdaq **pending the outcome of the hearing. On February 15** , **2024, the Company appealed to the Nasdaq Hearings Panel** ~~or~~ **for an extension to the time period in which to regain compliance with the MVLS Rule. On March 11, 2024, the Company received notice from the Nasdaq Hearings Panel** that **it** ~~we will otherwise meet the requirements of Nasdaq for continued inclusion for trading on The Nasdaq Capital Market. On November 22, 2022, we received a letter from Nasdaq indicating that, for the last thirty consecutive business days, the Market Value of Listed Securities, as defined by Nasdaq (" MVLS ")~~ had **granted** ~~been below~~ the **Company' s request** ~~$ 35 million minimum requirement~~ for continued listing on ~~The~~ Nasdaq **, subject to the Company demonstrating compliance** ~~Capital Market under Nasdaq Listing Rule 5550 (b) (2). In accordance~~ with Nasdaq ~~Listing~~ **' s MVLS** Rule **on** ~~5810 (c) (3) (C), we have been provided an initial period of 180 calendar days,~~ or ~~until May 22, 2023, to regain compliance. The letter states that the Nasdaq staff will provide written notification that we have achieved compliance with Rule 5550 (b) (2) if at any time~~ before May ~~22~~ **20** , ~~2023~~ **2024** ~~, our MVLS closes at $ 35 million or more for a minimum of ten consecutive business days. The letter has no immediate effect on the listing or trading of our common stock. If compliance in not achieved by May 22, 2023, we expect that Nasdaq would provide written notification to us that our securities are subject to delisting. We will continue to monitor our MVLS and consider our available options to regain compliance with the Nasdaq minimum MVLS requirements, which may include applying for an additional extension of the compliance period or appealing to a Nasdaq Hearings Panel~~ . The delisting of our common stock from Nasdaq may make it more difficult for us to raise capital on favorable terms in the future. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. Further, if we were to be delisted from Nasdaq, our common stock would cease to be recognized as covered securities and we would be subject to regulation in each state in which we offer our securities. Moreover, there is no assurance that any actions that we take to restore our compliance with the **MVLS Rule** ~~minimum bid price requirement~~ would stabilize the market price or improve the liquidity of our common stock, prevent our common stock from falling below the minimum ~~bid price~~ **value of listed securities** required for continued listing again, or prevent future non- compliance with Nasdaq' s listing requirements. We have incurred significant losses since inception and expect to incur losses in the future. We cannot be certain that we will achieve or sustain profitability. We have incurred significant losses since inception through December 31, ~~2022~~ **2023** and expect to incur losses in the future. Our accumulated deficit as of December 31, ~~2022~~ **2023** was $ ~~534~~ **584** . ~~2~~ **3** million and we incurred net losses of $ **50. 1 million and $** 62. 0 ~~million and $ 49. 2~~ million for the years ended December 31, **2023 and** 2022 ~~and 2021~~ , respectively. We expect that our losses will continue for at least the next few years as we will be required to invest significant additional funds toward the continued development and commercialization of our technology. Our ability to achieve or sustain profitability depends on numerous factors, many of which are beyond our control, including the market acceptance of our products and future product candidates, future product development, our ability to achieve marketing clearance from the FDA and international regulatory clearance or certification for future product candidates, our ability to compete effectively against an increasing number of competitors and new products, and our market penetration and margins. In spite of efforts to reduce expenses, we may never be able to generate sufficient revenue to achieve or sustain profitability. As noted above, management has identified conditions and events that raise doubt about our ability to continue as a going concern. **A reassessment of** ~~Adverse outcomes in legal proceedings could subject us to substantial damages and adversely affect~~ our **sales demand forecast has recently** ~~results~~ **resulted** ~~of operations~~ **in impairment charges to certain long- lived assets,** and ~~profitability~~ **we may recognize additional impairment charges in the future due to similar or other events** . We **categorize** ~~may become party to legal proceedings, including matters involving personnel and employment issues, contract disputes, personal injury, environmental matters, and other proceedings. Some of these potential proceedings could result in substantial damages or~~ **our long** payment awards that exceed our insurance coverage..... 70, 000 square foot, state - **lived assets** of- the- art life sciences..... commercial company and may face difficulties encountered by ~~companies early in their commercialization in competitive and rapidly evolving markets. We applied the CE mark to~~ **two assets groups** ~~the T2Dx Instrument and T2Candida Panel in July 2014 and received marketing authorization from the FDA for them on September 22~~ , ~~2014 and began commercializing these products in the fourth quarter of 2014. We applied the CE mark to the T2Bacteria Panel in June 2017 and received marketing clearance from the FDA for it on May 24, 2018 and began commercializing it promptly thereafter. We applied the CE mark to the T2Resistance Panel in the EU on November 20, 2019. We received Emergency Use Authorization, or~~ **our owned assets** EUA, from the FDA for the..... • implement and maintain systems and processes that are ~~compliant with applicable regulatory standards~~ **placed at customer sites as rental instruments and all other assets which support our product research and manufacturing. The value of these long- lived assets is driven in part by prospective demand for our products, and if demand for our products should fall, our return on these rental instruments and other assets could be diminished. In the third quarter of 2023, we determined that a triggering event occurred that required us to evaluate these long- lived assets for impairment. As a result of this evaluation, we recorded impairment charges for our owned non- lease instruments and reagent manufacturing assets totaling $ 2. 5 million for the year ended December 31, 2023** . We **review** ~~may not have~~ the **value of** ~~institutional knowledge or experience to be able to effectively address~~ these ~~and other risks~~ **long- lived assets for impairment when events or changes in circumstances indicate** that **the carrying amount of the assets** ~~may face our business. In addition, we~~ may not be ~~able to develop insights into trends~~ **recoverable. Should the markets for our products experience similar demand changes in the**

future or should other circumstances arise, it is possible that ~~could emerge and negatively affect our business and may fail to respond effectively to those trends. As a result of these or other risks,~~ we **will** ~~may not~~ be ~~able~~ **required** to **record** ~~execute key components of our business strategy, and our business, financial condition and operating results may suffer. The COVID- 19 pandemic has had, and may continue to have, an adverse impact on our business, including our marketing and research activities, and results of operations. The global outbreak of COVID- 19 continues to and has had adverse effects on general commercial activity and the global economy, including research, manufacturing and distributions. We have a significant development contract with a United States government agency and should the agency reduce, cancel or not grant~~ additional **impairment charges** ~~milestone projects, our ability to continue our future product development may be impacted. The COVID- 19 pandemic also caused us to reassess our build plan and evaluate inventories accordingly. In addition, the trading prices for our and other life sciences companies' stock have been highly volatile as a result of the COVID- 19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. The extent to which COVID- 19 may continue to impact our business, research and development programs and operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, travel restrictions and social distancing~~ in **that** ~~the United States and other countries, business closures or business disruptions, supply chain disruptions, and the effectiveness of actions taken in the United States and other countries to contain and manage the disease. In addition, if we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted, which~~ could have a material adverse effect on our ~~business and our financial~~ results ~~. Until we achieve scale in our business model our revenue will be primarily generated from the T2Dx Instrument, T2Candida, T2Bacteria, T2Resistance and T2SARS- CoV- 2 Panels, and research revenue, and any factors that negatively impact sales~~ of **operations and** ~~these products may adversely affect our business,~~ financial condition **. Our total revenues are concentrated among a small number of large customers. Sales to our two largest customers together represented 29 % of our revenues for the fiscal year ended December 31, 2023. In September 2019, BARDA awarded us a milestone- based contract for the development of a next- generation diagnostic instrument, a comprehensive sepsis panel** and ~~operating~~ **a multi- target biothreat panel. BARDA exercised certain options under this contract, but it nonetheless expired in September 2023. Revenue associated with our BARDA contract represented 50 % of our total revenue for the fiscal year ended December 31, 2022 and less than 10 % of our total revenue for the fiscal year ended December 31, 2023. Our customer concentration and the loss of any such customers or changes in the amount of business we do with them has in the past and could in the future materially and adversely impact our** results ~~. We began to offer our sepsis products for sale, including the T2Candida Panel and T2Dx Instrument, in the fourth quarter~~ of **operations** ~~2014, T2Bacteria in 2018, T2Resistance in 2019~~ and ~~T2SARS- CoV- 2 in 2020 and expect that we will be dependent upon the sales of these products for the majority of our revenue until we receive regulatory clearance, approval or certification for our other product candidates currently in development. Because we currently rely on a limited number of products to generate a significant portion of our revenue, any factors that negatively impact sales of these products, or result in sales of these products increasing at a lower rate than expected, could adversely affect our business,~~ financial condition ~~and operating~~ **. Failure to comply with the terms of our debt instruments may** ~~results~~ **result in a default under their terms,** and ~~negatively impact~~ **otherwise restrict** our ability to **pursue our business strategies** ~~successfully launch future product candidates currently under development~~ . If our T2Dx Instrument, T2Candida, T2Bacteria..... individuals with their skillset is high, there is ~~no assurance we will be able to hire and~~ **an event** ~~retain additional personnel on commercially reasonable terms. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our products and our business and operating results may be adversely affected. Outside~~ of **default to** ~~the United States, we sell~~ our ~~products through distribution partners and~~ **current credit facility, which includes if** there is ~~no guarantee~~ **any change** that ~~we will~~ **has an material adverse effect on our business or our ability to perform our obligations under the credit facility documents, and such event of default is not cured or waived, the lender could terminate commitments to lend and cause all amounts outstanding with respect to the debt to** be **due** ~~successful in attracting or retaining desirable distribution partners for these markets or that we will be able to enter into such arrangements on favorable terms. Distributors may not commit the necessary resources to market~~ and **payable immediately** ~~sell our products effectively or may choose to favor marketing the products of our competitors. If distributors do not perform adequately, or if we are unable to enter into effective arrangements with distributors in particular geographic areas, we may not realize international sales and growth. The sales cycle and implementation and adoption timeline are lengthy and variable~~ , which **in turn could result in cross defaults under** ~~makes it difficult for us to forecast revenue and~~ other ~~operating results~~ **debt instruments** . Our **assets** ~~sales process involves numerous interactions with multiple individuals within an~~ **and** organization and often includes in- depth..... the future. We currently have limited cash **flow** and cash equivalents and in the future..... requirements on a timely basis, we will not be ~~able to have~~ sufficient ~~ability~~ to ~~meet user demand, which may have~~ **fully repay borrowings under all of our outstanding debt instruments if some or all of these instruments are accelerated upon** a ~~negative impact~~ **default. As security for its obligations under the Term Loan Agreement, the Company entered into a security agreement with CRG whereby the Company granted a lien** on **substantially all of its assets** ~~our operations and financial results. If we are unable to recruit, train and retain key personnel, we may not achieve our goals. Our future success depends on our ability to recruit, develop, retain and motivate key personnel~~ , including individual on our senior management, research..... more established distribution networks; • substantial intellectual property portfolios; • larger and more established..... our ability to pursue our business strategies . Our credit ~~facilities~~ **facility** ~~require~~ **requires** us, and any debt instruments we may enter into in the future may require us, to comply with various covenants that limit our ability to, among other things: • convey, lease, sell, transfer, assign or otherwise dispose of assets; • change the nature or location of our business; • complete mergers or acquisitions; • incur indebtedness; • encumber assets; • pay dividends or make other distributions to

holders of our capital stock (other than dividends paid solely in common stock); • make specified investments; • change certain key management personnel; and • engage in material transactions with our affiliates. These restrictions could inhibit our ability to pursue our business strategies. ~~If we default, which includes a material adverse change, under our credit facilities, and such event of default was not cured or waived, the lenders could terminate commitments to lend and cause all amounts outstanding with respect to the debt to be due and payable immediately, which in turn could result in cross defaults under other debt instruments. Our assets and cash flow will not be sufficient to fully repay borrowings under all of our outstanding debt instruments if some or all of these instruments are accelerated upon a default. As security for its obligations under the Term Loan Agreement the Company entered into a security agreement with CRG whereby the Company granted a lien on substantially all of its assets, including intellectual property.~~ We may incur additional indebtedness in the future. The debt instruments governing such indebtedness could contain provisions that are as, or more, restrictive than our existing debt instruments. If we are unable to repay, refinance or restructure our indebtedness when payment is due, the lenders could proceed against the collateral granted to them to secure such indebtedness or force us into bankruptcy or liquidation ~~face claims against us or our reputation could suffer as a result of such failures.The failure of our current products or planned diagnostic product candidates to perform reliably or as expected could significantly impair our reputation and the public image of our products,and we may be subject to legal claims arising from any defects or errors.The diagnostics market is highly competitive.If we fail to compete effectively,our business and operating results will suffer.While the technology of our products and product candidates is different than other products currently available,we compete with commercial diagnostics companies for the limited resources of our customers.In this regard,our principal competition is from a number of companies that offer platforms and applications in our target markets,most of which are more established commercial organizations with considerable name recognition and significant financial resources.Other than our products,we are not aware of any other FDA- cleared or CE marked products available in the market that are able to detect sepsis causing pathogens and antibiotic resistant genes directly from whole blood.However,since hospitals continue to rely on blood culture based diagnostics as the standard of care for the detection of sepsis causing pathogens,we compete with companies that currently provide traditional blood culture- based diagnostics,including Becton Dickinson & Co.,bioMerieux,Inc.(and its affiliate,BioFire Diagnostics,Inc.) Bruker Corporation,Accelerate Diagnostics,Luminex,Roche,Cepheid and Beckman Coulter,a Danaher company.Most of our expected competitors are either publicly traded,or are divisions of publicly traded companies,and have a number of competitive advantages over us,including:• greater name and brand recognition,financial and human resources;• established and broader product lines;• larger sales forces and more established distribution networks;• substantial intellectual property~~ portfolios;• larger and more established customer bases and relationships;and • better established,larger scale and lower- cost manufacturing capabilities.We believe that the principal competitive factors in all of our target markets include:• impact of products on the health of the patient;• impact of the use of products on the cost of treating patients in the hospital;• cost of capital equipment;• reputation among physicians,hospitals and other healthcare providers;• innovation in product offerings;• flexibility and ease- of- use;• speed,accuracy and reproducibility of results;and • ability to implement a consumables- based model for panels.We believe that additional competitive factors specific to the diagnostics market include:• breadth of clinical decisions that can be influenced by information generated by diagnostic tests;• volume,quality and strength of clinical and analytical validation data;• availability of adequate reimbursement for testing services and procedures for healthcare providers using our products;and • economic benefit accrued to hospitals based on the total cost to treat a patient for a health condition.We cannot assure you that we will effectively compete or that we will be successful in the face of increasing competition from new products and technologies introduced by our existing competitors or new companies entering our markets.In addition,we cannot assure you that our future competitors do not have or will not develop products or technologies that enable them to produce competitive products with greater capabilities or at lower costs than our products and product candidates.Any failure to compete effectively could materially and adversely affect our business,financial condition and operating results.Undetected errors or defects in our products or product candidates could harm our reputation,decrease market acceptance of our products or expose us to product liability claims.Our products or product candidates may contain undetected errors or defects.Disruptions or other performance problems with our products or product candidates may damage our customers' businesses and could harm our reputation.If that occurs,we may incur significant costs,the attention of our key personnel could be diverted or other significant customer relations problems may arise.We may also be subject to warranty and liability claims for damages related to errors or defects in our products or product candidates.A material liability claim or other occurrence that harms our reputation or decreases market acceptance of our products or product candidates could harm our business and operating results.The sale and use of products or product candidates or services based on our technologies,or activities related to our research and clinical studies,could lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect.A product liability claim could result in substantial damages and be costly and time consuming to defend,either of which could materially harm our business or financial condition.We cannot assure you that our product liability insurance would adequately protect our assets from the financial impact of defending a product liability claim.Any product liability claim brought against us,with or without merit,could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.We may not be able to develop new product candidates or enhance the capabilities of our systems to keep pace with our industry' s rapidly changing technology and customer requirements,which could have a material adverse impact on our revenue,results of operations and business.Our industry is characterized by rapid technological changes,frequent new product introductions and enhancements and evolving industry standards.Our success depends on our ability to develop new product candidates and applications for our technology in new markets that develop as a result of technological and scientific advances,while improving the performance and cost- effectiveness of our existing product candidates.New technologies,techniques or products could emerge that might offer better combinations of price and performance than the products and systems that we plan to sell.Existing markets for our intended diagnostic product candidates

are characterized by rapid technological change and innovation.It is critical to our success that we anticipate changes in technology and customer requirements and physician,hospital and healthcare provider practices and successfully introduce new,enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost- effective basis.At the same time,however,we must carefully manage our introduction of new products.If potential customers believe that such products will offer enhanced features or be sold for a more attractive price,they may delay purchases until such products are available.We may also have excess or obsolete inventory of older products as we transition to new products,and we have no experience in managing product transitions.If we do not successfully innovate and introduce new technology into our anticipated product lines or manage the transitions of our technology to new product offerings,our revenue,results of operations and business will be adversely impacted.Competitors may be able to respond more quickly and effectively than we can to new or changing opportunities,technologies,standards or customer requirements.We anticipate that we will face strong competition in the future as expected competitors develop new or improved products and as new companies enter the market with new technologies and products.We are developing additional product candidates and we may have problems applying our technologies to other areas and our new applications may not be as effective in detection as our initial applications.Any failure or delay in creating a customer base or launching new applications may compromise our ability to achieve our growth objectives.Manufacturing risks may adversely affect our ability to manufacture products and could reduce our gross margins and negatively affect our operating results.Our business strategy depends on our ability to manufacture and assemble our current and proposed products in sufficient quantities and on a timely basis so as to meet consumer demand,while adhering to product quality standards,complying with regulatory requirements and managing manufacturing costs.We are subject to numerous risks relating to our manufacturing capabilities,including:• Highly accurate levels of detection which require raw materials free of contamination lest test results include false positives for contaminants and not actual patient borne pathogens making paramount quality or reliability defects in product components that we source from third party suppliers;• our inability to secure product components in a timely manner,in sufficient quantities or on commercially reasonable terms;• our failure to increase production of products to meet demand;• the challenge of implementing and maintaining acceptable quality systems while experiencing rapid growth;• our inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements;and • difficulty identifying and qualifying alternative suppliers for components in a timely manner.As demand for our products increases,we will need to invest additional resources to purchase components,hire and train employees,and enhance our manufacturing processes and quality systems.If we fail to increase our production capacity efficiently while also maintaining quality requirements,our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline.In addition,although we expect some of our product candidates to share product features and components with the T2Dx Instrument ~~and ,~~ T2Candida,T2Bacteria, ~~T2Biothreat,and~~ T2Resistance ~~Panels~~ **and T2SARS- CoV- 2** manufacturing of these products may require the modification of our production lines,the hiring of specialized employees,the identification of new suppliers for specific components,or the development of new manufacturing technologies.It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable.Any future interruptions we experience in the manufacturing or shipping of our products could delay our ability to recognize revenues in a particular quarter and could also adversely affect our relationships with our customers.We currently develop,manufacture and test our products and product candidates and some of their components in two facilities.If these or any future facility or our equipment were damaged or destroyed,or if we experience a significant disruption in our operations for any reason,our **ability to continue to operate our business could be materially harmed.We currently develop our diagnostic products exclusively in a facility in Lexington,Massachusetts and manufacture and test some components of our products and product candidates in,both,Wilmington and Lexington,Massachusetts.If these or any future facility were to be damaged,destroyed or otherwise unable to operate,whether due to fire,floods,hurricanes,storms,tornadoes,other natural disasters,employee malfeasance,terrorist acts,power outages,or otherwise,or if our business is disrupted for any other reason,we may not be able to develop or test our products and product candidates as promptly as our potential customers expect,or possibly not at all.The manufacture of components of our products and product candidates at our Wilmington facility involves complex processes,sophisticated equipment and strict adherence to specifications and quality systems procedures.Any unforeseen manufacturing problems,such as contamination of our facility,equipment malfunction,or failure to strictly follow procedures or meet specifications,could result in delays or shortfalls in production of our products.Identifying and resolving the cause of any manufacturing issues could require substantial time and resources.If we are unable to keep up with future demand for our products by successfully manufacturing and shipping our products in a timely manner,our revenue growth could be impaired and market acceptance of our product candidates could be adversely affected.We maintain insurance coverage against damage to our property and equipment,subject to deductibles and other limitations that we believe is adequate.If we have underestimated our insurance needs with respect to an interruption,or if an interruption is not subject to coverage under our insurance policies,we may not be able to cover our losses.Provisions of our debt instruments may restrict our ability to pursue our business strategies** . As part of our current business model, we may enter into strategic relationships with third parties to develop and commercialize diagnostic products. We may enter into strategic relationships with third parties for future diagnostic products. However, there is no assurance that we will be successful in doing so. Establishing strategic relationships can be difficult and time- consuming. Discussions may not lead to agreements on favorable terms, if at all. To the extent we agree to work exclusively with a party in a given area, our opportunities to collaborate with others or develop opportunities independently could be limited. Potential collaborators or licensors may elect not to work with us based upon their assessment of our financial, regulatory or intellectual property position. Even if we establish new strategic relationships, they may never result in the successful development or commercialization of future products. Acquisitions or joint ventures could disrupt our business, cause dilution to our stockholders and otherwise harm our business. We may acquire other businesses,

products or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses. We have not made any acquisitions to date, and our ability to do so successfully is unproven. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including: • disruption in our relationships with future customers or with current or future distributors or suppliers as a result of such a transaction; • unanticipated liabilities related to acquired companies; • difficulties integrating acquired personnel, technologies and operations into our existing business; • diversion of management time and focus from operating our business to acquisition integration challenges; • increases in our expenses and reductions in our cash available for operations and other uses; • possible write- offs or impairment charges relating to acquired businesses; and • inability to develop a sales force for any additional product candidates. Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries. Also, the anticipated benefit of any acquisition may not materialize. 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. Our ability to use net operating losses to offset future taxable income may be subject to certain limitations. As of December 31, ~~2022~~ **2023**, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of $ ~~256~~ **273**. 7 million, which are available to offset future taxable income, if any, of which $ ~~34~~ **10**. ~~9~~ **4** million begin to expire in 2026 and $ ~~221~~ **263**. ~~8~~ **3** million carry forward indefinitely. Since 2020 and through ~~2022~~ **2023**, we have conducted and updated studies of our historic ownership changes pursuant to Internal Revenue Code Sections 382 and 383 (the " 382 study ") of our cumulative net operating loss and tax credit carryforwards. From the results of these studies, we determined there are limitations on the use of our loss and credit carryforwards. Future changes in our stock ownership, as well as other changes that may be outside of our control, could result in additional ownership changes under Section 382 of the Code. As a result, even if we achieve profitability, we may not be able to use a material portion of our NOLs. We have recorded a full valuation allowance related to our NOLs due to the uncertainty of the ultimate realization of the future benefits of those assets. We face risks related to handling hazardous materials and other regulations governing environmental safety. Our operations are subject to complex and stringent environmental, health, safety and other governmental laws and regulations that both public officials and private individuals may seek to enforce. Our activities that are subject to these regulations include, among other things, our use of hazardous materials and the generation, transportation and storage of waste. We may not be in material compliance with these regulations. Existing laws and regulations may also be revised or reinterpreted, or new laws and regulations may become applicable to us, whether retroactively or prospectively, that may have a negative effect on our business and results of operations. It is also impossible to eliminate completely the risk of accidental environmental contamination or injury to individuals. In such an event, we could be liable for any damages that result, which could adversely affect our business. We generate a portion of our revenue internationally and are subject to various risks relating to our international activities which could adversely affect our operating results. A portion of our revenue comes from international sources. Engaging in international business involves a number of difficulties and risks, including: • required compliance with existing and changing foreign healthcare and other regulatory requirements and laws, such as those relating to patient privacy or handling of bio-hazardous waste; • required compliance with anti- bribery laws, such as the U. S. Foreign Corrupt Practices Act and U. K. Bribery Act, data privacy requirements, labor laws and anti- competition regulations; • export or import restrictions; • various reimbursement and insurance regimes; • laws and business practices favoring local companies; • longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems; • political and economic instability; • potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers; • foreign exchange controls; • difficulties and costs of staffing and managing foreign operations; • difficulties protecting or procuring intellectual property rights; and • pandemics and public health emergencies, such as the coronavirus (COVID- 19), could result in disruptions to travel and distribution in geographic locations where our products are sold. As we expand internationally, our results of operations and cash flows may become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Our expenses are generally denominated in the currencies in which our operations are located, which is in the United States. If the value of the U. S. dollar increases relative to foreign currencies in the future, in the absence of a corresponding change in local currency prices, our future revenue could be adversely affected in the event we convert future revenue from local currencies to U. S. dollars. If we dedicate resources to our international operations and are unable to manage these risks effectively, our business, operating results and prospects will suffer. Our employees, independent contractors, principal investigators, consultants, commercial partners, distributors and vendors 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, independent contractors, principal investigators, consultants, commercial partners, distributors and vendors. Misconduct by these parties could include intentional, reckless or negligent failures to: comply with the regulations of the FDA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar regulatory authorities or notified bodies; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws and regulations in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately, or disclose unauthorized activities to us. These laws may impact, among other things, our activities with principal investigators and research subjects, as well as our sales, marketing and education programs. In particular, the promotion, 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 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 the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with 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 have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Any of these actions or investigations could result in substantial costs to us, including legal fees, and divert the attention of management from operating our business. We depend on our information technology systems, and any failure of these systems could harm our business. We depend on information technology systems for significant elements of our operations, including the storage of data and retrieval of critical business information. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including systems handling human resources, financial controls and reporting, contract management, regulatory compliance, sales management and other infrastructure operations. These information technology systems may support a variety of functions, including laboratory operations, test validation, quality control, customer service support, billing and reimbursement, research and development activities and general administrative activities. Our clinical trial data is currently stored on a third party' s servers. Information technology systems are vulnerable to damage from a variety of sources, including network failures, malicious human acts and natural disasters. Moreover, despite network security and back- up measures, some of our servers are potentially vulnerable to physical or electronic break- ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology systems, failures or significant downtime of our information technology systems or those used by our third- party service providers could prevent us from conducting our general business operations. Any disruption or loss of information technology systems on which critical aspects of our operations depend could have an adverse effect on our business. Further, we store highly confidential information on our information technology systems, including information related to clinical data, product designs and plans to create new products. If our servers or the servers of the third party on which our clinical data is stored are attacked by a physical or electronic break- in, computer virus or other malicious human action, our confidential information could be stolen or destroyed. Our internal computer systems, or those used by our third- party research institution collaborators, vendors or other contractors or consultants, may fail or suffer security breaches. Despite the implementation of security measures, our internal computer systems and those of our vendors and other contractors and consultants may be vulnerable to security breaches and damage from computer viruses and unauthorized access, including the unauthorized encryption of data stored on our computer network. **If** ~~In August 2019, we were the subject of a ransomware attack that resulted in the encryption of certain data stored on our computer network. Although we did not pay the ransom; the attack did not materially affect business operations; and there was no evidence of a loss of data or inappropriate disclosure of confidential or proprietary information, we did incur additional cost, expense and the diversion of time and resources to recover from the attack and the Company' s management concluded that our disclosure controls and procedures were not effective at that time due to a material weakness in our internal control over the quality, frequency and periodic testing of the backup of our Information System data. We have strengthened our network security and infrastructure following the attack, however, if~~ such an event were to occur again and cause interruptions in our operations, it could result in a material disruption of our business operations. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed, which could adversely affect our business, results of operations and financial condition. Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer. In the ordinary course of our business, we store sensitive data, including intellectual property, our proprietary business information and that of our customers, and personally identifiable information of our employees, in our data centers and on our networks. The secure maintenance and transmission of this information is critical to our operations. **We face risks related to the protection of information that we maintain — or engage a third- party to maintain on our behalf — including unauthorized access, acquisition, use, disclosure, or modification of such information.** Despite our security measures and data backup, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions **. Cyberattacks are increasing in their frequency, sophistication and intensity and have become increasingly difficult to detect. Cyberattacks could include the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information** . Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties, disrupt our operations and damage our reputation, which could adversely affect our business / operating margins, revenues and competitive position. Risks Related to Government Regulation and Diagnostic Product Reimbursement Approval, clearance and certification by the FDA and foreign regulatory authorities or notified bodies for our diagnostic tests takes significant time and requires significant research, development and clinical study expenditures and ultimately may not succeed. The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies. The regulations are very complex and are subject to rapid change and varying interpretations. Regulatory restrictions or changes could limit our ability to carry on or expand our operations or result in higher than anticipated costs or lower than anticipated

sales. The FDA, other U. S. governmental agencies and foreign regulatory bodies regulate numerous elements of our business, including: • product design and development; • pre- clinical and clinical testing and trials; • establishment registration and product listing; • labeling and storage; • marketing, manufacturing, sales and distribution; • pre- market clearance, approval or certification; • servicing and post- market surveillance; • advertising and promotion; and • recalls and field safety corrective actions. Before we begin to label and market our product candidates for use as clinical diagnostics in the United States, we are required to obtain clearance from the FDA under Section 510 (k) of the Federal Food, Drug, and Cosmetic Act, or FDCA, approval of a de novo classification request for our product, or approval of pre- market approval, or PMA, application from the FDA, unless an exemption from pre- market review applies. ~~In the 510 (k) clearance process, the FDA must determine that a proposed device is " substantially equivalent " to a device legally on the market, known as a " predicate " device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life- sustaining, life- supporting or implantable devices. However, some devices are automatically subject to the PMA pathway regardless of the level of risk they pose because they have not previously been classified into a lower risk class by the FDA. Manufacturers of these devices may request that FDA review such devices in accordance with the de novo classification procedure, which allows a manufacturer whose novel device would otherwise require the submission and approval of a PMA prior to marketing to request down- classification of the device on the basis that the device presents low or moderate risk. If the FDA agrees with the down- classification, the applicant will then receive approval to market the device. This device type can then be used as a predicate device for future 510 (k) submissions.~~ The process of obtaining regulatory clearances or approvals, or completing the de novo classification process, to market a medical device can be costly and time consuming, and we may not be able to successfully obtain pre- market reviews on a timely basis, if at all. The FDA and other regulators or bodies can delay, limit or deny authorization or certification 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 products are substantially equivalent to a predicate device or are safe and effective for their intended uses; • the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical studies or the interpretation of data from preclinical studies or clinical studies; • the data from our preclinical studies and clinical studies may be insufficient to support clearance, de novo classification, approval or certification, 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 marketing authorization or certification policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for marketing authorization or certification **.** Any delay in, or failure to receive or maintain, clearance, certification or approval for our product candidates could prevent us from generating revenue from these product candidates and adversely affect our business operations and financial results. Obtaining FDA clearance, de novo classification, or approval for diagnostics can be expensive and uncertain, and generally takes from several months to several years, and may require detailed and comprehensive scientific and clinical data. Notwithstanding the expense, these efforts may never result in the receipt of FDA marketing authorization. Even if we were to obtain such marketing authorizations for our products, it may not be for the uses we believe are important or commercially attractive, in which case we would not be permitted to market our product for those uses. Any delay in, or failure to receive or maintain, marketing authorization for our products could prevent us from generating revenue from these products and adversely affect our business operations and financial results. The EU regulatory landscape concerning in vitro diagnostic medical devices ~~recently evolved~~ **is evolving** . On May 26, 2022, the EU In Vitro Diagnostic Medical Devices Regulation, or IVDR, entered into force, which ~~repeals~~ **repealed** and ~~replaces~~ **replaced** the EU In Vitro Diagnostic Medical Devices Directive (See – International Regulation- Regulation of Medical Devices in the European Union) and these modifications ~~may~~ **will** have an effect on the way we conduct our business in the EU and the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland. Subject to the transitional provisions (i. e., a tiered system extending the grace period for many devices (depending on their risk classification) before they have to be fully compliant with the regulation) and in order to sell our products in the member states of the EU our products must comply with the general safety and performance requirements of the IVDR. Compliance with these requirements is a prerequisite to be able to affix the European Conformity, or CE, mark to our products, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must meet the general safety and performance requirements laid down in Annex I to the IVDR including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and – where applicable – other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. To demonstrate compliance with the general safety and performance requirements we must undergo a conformity assessment procedure, which varies according to the type of in vitro diagnostic medical device and its (risk) classification. A conformity assessment procedure generally requires the intervention of a notified body. The notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. If satisfied that the relevant product conforms to the relevant general safety and performance requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. If we fail to comply with applicable EU laws and regulations, and corresponding EU member state laws, we would be unable to affix the CE mark to our

products, which would prevent us from selling them within the EU. If we fail to comply with applicable laws and regulations, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the EU. The aforementioned EU rules are generally applicable in the EEA. Non- compliance with the above requirements would also prevent us from selling our products in these three countries. Following Brexit, EU laws no longer apply directly in Great Britain. The regulations on medical devices and in vitro diagnostic medical devices in Great Britain continue to be based largely on the three EU Directives which preceded the EU Medical Devices Regulation, or MDR and the (EU) IVDR, as implemented into national law. However under the terms of the Protocol on Ireland / Northern Ireland, the (EU) MDR and (EU) IVDR do apply to Northern Ireland. Consequently, there are currently different regulations in place in Great Britain as compared to both Northern Ireland and the EU, respectively. Ongoing compliance with both sets of regulatory requirements may result in increased costs for our business. Furthermore, the UK Government is currently drafting amendments to the existing legislation which is likely to result in further changes to the Great Britain regulations in the near future. For example, subject to transitional periods for validly- certified devices, the new Great Britain regulations are likely to require medical devices and in vitro diagnostic medical devices placed on the Great Britain market to be " UKCA " certified by a UK Approved Body in order to be lawfully placed on the market. The UK Government has stated that the amended regulations are likely to apply from July 2024; understanding and ensuring compliance with any new such requirements is likely to lead to further complexity and increased costs to our business. If there is insufficient UK Approved Body capacity, there is a risk that our product certification could be delayed which might impact our ability to market products in Great Britain after the respective transition periods **.** Even if granted, a 510 (k) clearance, de novo classification, PMA approval, or similar authorization or certification from other regulators or notified bodies for any future product would likely place substantial restrictions on how our device is marketed or sold, and the FDA and other regulatory authorities or bodies will continue to place considerable restrictions on our products and operations. For example, the manufacture of medical devices in the United States must comply with the FDA' s Quality System Regulation, or QSR. In addition, manufacturers must register their manufacturing facilities, list the products with the FDA, and comply with requirements relating to labeling, marketing, complaint handling, adverse event and medical device reporting, reporting of corrections and removals, and import and export. The FDA monitors compliance with the QSR and these other requirements through periodic inspections. If our facilities or those of our manufacturers or suppliers are found to be in violation of applicable laws and regulations, or if we or our manufacturers or suppliers fail to take satisfactory corrective action in response to an adverse inspection, the FDA and other regulatory authorities could take enforcement action, including any of the following sanctions: • adverse publicity, untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; • customer notifications or repair, replacement, refunds, detention or seizure of our products; • operating restrictions or partial suspension or total shutdown of production; • refusing or delaying requests for 510 (k) clearance or PMA approvals or foreign regulatory authorizations or certifications of new products or modified products; • withdrawing 510 (k) clearances, PMA approvals or foreign regulatory authorizations or certifications that have already been granted; • refusing to issue certificates to foreign governments needed to export products for sale in other countries; • refusing to grant export approval for our products; or • pursuing criminal prosecution. Any of these sanctions could impair our ability to produce our products and product candidates in a cost- effective and timely manner in order to meet our customers' demands, and could have a material adverse effect on our reputation, business, results of operations and financial condition. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits. ~~Moreover~~ **In addition** , **the EU regulatory landscape concerning in vitro diagnostic medical devices recently evolved and a new regulation governing in vitro diagnostic medical devices became applicable on May 26, 2022 (See – International Regulation- Regulation of Medical Devices in the European Union) and** ~~the~~ **these modifications may have an effect on the way we conduct our business in the EU and the EEA. For example, as a result of the transition towards the new regime, notified body review times have lengthened, and product introductions could be delayed or canceled, which could adversely affect our ability to grow our business. In addition,** FDA ~~' s~~ and **foreign regulations and guidance are often revised or reinterpreted by** ~~other~~ -- **the FDA and foreign** regulatory authorities **in ways** ~~' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also cannot predict the likelihood, nature or extent of government regulation~~ that may **significantly affect** ~~arise from future legislation or~~ **our** ~~administrative~~ **business and** ~~or~~ **our products** ~~executive action, either in the United States or abroad~~ . For example, on ~~February 23~~ **January 31** , ~~2022~~ **2024** , the FDA issued a ~~proposed~~ **final** rule to amend the QSR ~~, which establishes current good manufacturing practice requirements for medical device manufacturers,~~ to align more closely with ISO: 13485 (2016), as established by the International Organization for Standardization ~~. This proposal has not yet been finalized or adopted. Accordingly, it is unclear the extent to which this or any other proposals, if adopted, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create competition that may negatively affect our business. In addition, the EU regulatory landscape concerning in vitro diagnostic medical devices recently evolved and a new regulation governing in vitro diagnostic medical devices became applicable on May 26, 2022 (See – International Regulation- Regulation of Medical Devices in the European Union) and these modifications may have an effect on the way we conduct our business in the EU and the EEA. For example, as a result of the transition towards the new regime, notified body review times have lengthened, and product introductions could be delayed or canceled, which could adversely affect our ability to grow our business. In addition, FDA and foreign regulations and guidance are often revised or reinterpreted by the FDA and foreign regulatory authorities 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. 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 as a result of a changing regulatory landscape, we may lose any marketing authorizations that we have already obtained or fail to obtain new marketing approvals or clearances, and we may not be able to achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. Our products could become subject to more onerous regulation by the FDA or other regulatory agencies in the future, which could increase our costs and delay or prevent commercialization of our products, thereby materially and adversely affecting our business, financial condition, results of operations and prospects. We make certain of our products, including our T2Resistance Panel and T2Cauris Panel, available to customers as research use only, or RUO, products. RUO products ~~are regulated by the FDA as medical devices, and~~ include in vitro diagnostic products in the laboratory research phase of development that are being shipped or delivered for an investigation that is not subject to the FDA' s investigational device exemption requirements. ~~Although medical devices are subject to stringent FDA oversight, products~~ **Products** that are intended for RUO and are labeled as RUO are exempt from compliance with most FDA requirements, including premarket clearance or approval, manufacturing requirements, and others. A product labeled RUO but which is actually intended for clinical diagnostic use may be ~~viewed by the FDA as adulterated and misbranded under the FDCA, and~~ subject to FDA enforcement action **as an adulterated and misbranded device** . The FDA ~~has indicated that~~ **will consider the totality of the circumstances surrounding distribution and use of the product, including how the product is marketed and to whom,** when determining the intended use of a product labeled RUO ~~, the FDA will consider the totality of the circumstances surrounding distribution and use of the product, including how the product is marketed and to whom~~ . The FDA could disagree with our assessment that our products are properly marketed as RUOs, or could conclude that products labeled as RUO are actually intended for clinical diagnostic use, and could take enforcement action against us, including requiring us to stop distribution of and recalling our products ~~until we are in compliance with applicable regulations~~ , which would reduce our revenue, increase our costs and adversely affect our business, prospects, results of operations and financial condition. In the event that the FDA requires us to obtain marketing authorization of our RUO products in the future, there can be no assurance that the FDA will grant any such marketing authorization requested by us in a timely manner, or at all ~~. We are subject to extensive regulatory requirements in connection with the EUA we received for our T2SARS- CoV- 2 Test Panel. If we fail to comply with these requirements, or if the FDA otherwise determines that the conditions no longer warrant such authorization, we will be unable to market our products pursuant to this authorization and our business may be harmed. In August 2020, the FDA granted an EUA to our T2SARS- CoV- 2 Panel, authorizing its commercial sale and use for the qualitative direct detection of nucleic acid from SARS- CoV- 2 in upper respiratory specimens (such as nasal, mid- turbinate, nasopharyngeal, and oropharyngeal swab specimens) and bronchoalveolar lavage specimens from individuals suspected of COVID- 19 by their healthcare provider, for the duration of the COVID- 19 public health emergency, without the need to obtain premarket clearance or approval under the FDA' s standard review pathways. The FDA has also established certain conditions which must be met in order to maintain authorization under this EUA. The requirements that apply to the manufacture and sale of these products may be unclear and are subject to change. Under section 564 of the FDCA, the FDA has authority to issue an EUA under certain circumstances, such as during a public health emergency, pursuant to a declaration by the Secretary of the Department of Health and Human Services, or HHS, that an emergency exists justifying the issuance of EUAs for certain types of products (referred to as EUA declarations). On February 4, 2020 the Secretary of HHS declared that circumstances exist justifying authorization of in vitro diagnostic devices during the COVID- 19 pandemic, subject to the terms of any EUA that is issued for a specific product. Once an EUA declaration has been issued, the FDA can issue EUAs for products that fall within the scope of that declaration. To issue an EUA, the FDA Commissioner must conclude that (1) the chemical, biological, radioactive or nuclear agent, or CBRN, that is referred to in the EUA declaration can cause serious or life- threatening diseases or conditions; (2) based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the disease or condition attributable to the CBRN and that the product' s known and potential benefits outweigh its known and potential risks; and (3) there is no adequate, approved, and available alternative to the product. These standards for marketing authorization are lower than if the FDA had reviewed our test under its traditional marketing authorization pathways, and we cannot assure you that the T2SARS- CoV- 2 Panel would be cleared or approved under those more onerous clearance and approval standards. Moreover, the FDA' s policies regarding EUAs can change unexpectedly, and the FDA may revoke an EUA where it determines that the underlying health emergency no longer exists or warrants such authorization or if problems are identified with the authorized product. We cannot predict how long our EUA will remain in place. FDA policies regarding diagnostic tests, therapies and other products used to diagnose, treat or mitigate COVID- 19 remain in flux as the FDA responds to new and evolving public health information and clinical evidence. For example, in December 2021, the FDA issued a draft guidance describing a potential transition plan for the regulation and distribution of emergency- use- authorized medical devices in the event that the current EUA declaration is terminated. Changes to FDA regulations or requirements could require changes to our authorized test, necessitate additional measures or make it impractical or impossible for us to market our test. The termination of an EUA for our T2SARS- CoV- 2 Panel would adversely impact our business, financial condition and results of operations~~ . Modifications to our products, if cleared, approved or certified, may require new 510 (k) clearances or pre- market approvals or certifications, or may require us to cease marketing or recall the modified products until clearances or certifications are obtained. Any modification to a device authorized for marketing that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510 (k) clearance or, possibly, approval of a PMA or de novo classification. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer' s decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. If the FDA disagrees with our determination and requires us to submit new 510 (k)

notifications, de novo classification requests or PMAs for modifications to previously cleared products for which we conclude that new marketing authorizations are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our business. In the EU, in vitro diagnostic medical devices lawfully placed on the market pursuant to the IVDD prior to May 26, 2026 may generally continue to be made available on the market or put into service until May 26, 2025, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid and no substantial change must be made to the device as such a modification would trigger the obligation to obtain a new certification under the IVDR and therefore to have a notified body conducting a new conformity assessment of the devices. Once our devices will be certified under the IVDR, we must inform the notified body that carried out the conformity assessment of the devices that we market or sell in the EU and EEA of any planned substantial changes to our quality system or substantial changes to our in vitro diagnostic medical devices that could affect compliance with the general safety and performance requirements laid down in Annex I to IVDR or cause a substantial change to the intended use for which the device has been CE marked. The notified body will then assess the planned changes and verify whether they affect the products' ongoing conformity with the IVDR. If the assessment is favorable, the notified body will issue a new certificate of conformity or an addendum to the existing certificate attesting compliance with the essential requirements and quality system requirements laid down in the Annexes to the IVDR. The notified body may disagree with our proposed changes and product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business. A recall of our products, either voluntarily or at the direction of the FDA or foreign regulatory authorities, or the discovery of serious safety issues with our products that leads to corrective actions, could have a significant adverse impact on us. The FDA and similar foreign governmental authorities 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. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government- mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Under the FDA' s medical device reporting regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall. We are subject to similar requirements under foreign regulations. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost- effective and timely manner in order to meet our customers' demands. Depending on the corrective action we take to redress a product' s deficiencies or defects, the FDA or foreign regulatory authorities may require, or we may decide, that we will need to obtain new approvals, clearances or certifications for the device before we may market or distribute the corrected device. Seeking such approvals, clearances or certifications 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. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future. Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results. The clinical study process is lengthy and expensive with uncertain outcomes, and the results of earlier studies may not be predictive of future clinical trial results. Clinical testing is difficult to design and implement, can be a lengthy and expensive process and carries uncertain outcomes. 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 institutional review boards, or IRBs, or ethics committees, at the medical institutions where the clinical studies are conducted. Clinical studies must be conducted with supplies of our devices produced under current good manufacturing practice requirements and other applicable regulations. Furthermore, we rely on contract research organizations, or CROs, and clinical study sites to ensure the proper and timely conduct of our clinical studies and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical studies in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical studies, 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. The results of preclinical studies and clinical studies of our products conducted to date and ongoing or future studies of our current, planned or future products may not be predictive of the results of later clinical studies, and interim results of a clinical study 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 studies. 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 studies have nonetheless failed to replicate results in later clinical studies. Products in later stages of clinical studies may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical studies. Failure can occur at any stage of clinical testing. The

initiation and completion of any of clinical studies may be prevented, delayed, or halted for numerous reasons. We may experience delays in our ongoing clinical studies for a number of reasons, which could adversely affect the costs, timing or successful completion of our clinical studies, including related to the following: • we may be required to submit an investigational device exemption application, or IDE, to the FDA, which must become effective prior to commencing certain human clinical studies of medical devices, and FDA may not approve our IDE 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 studies; • regulators and / or IRBs or other reviewing bodies may not authorize us or our investigators to commence a clinical study, or to conduct or continue a clinical study at a prospective or specific trial site; • we may not reach agreement on acceptable terms with prospective CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs; • the number of subjects or patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate, and the number of clinical studies being conducted at any given time may be high and result in fewer available patients for any given clinical study, or patients may drop out of these clinical studies at a higher rate than we anticipate; • our third - party contractors, including those manufacturing products or conducting clinical studies 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 studies for various reasons; • we may have to amend clinical study 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 studies may be greater than we anticipate; • clinical sites may not adhere to the clinical protocol or may drop out of a clinical study; • we may be unable to recruit a sufficient number of clinical study sites; and / or • 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 studies may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply. ~~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 studies.~~ Any of these occurrences may significantly harm our business, financial condition and prospects. Furthermore, patient enrollment in clinical studies and completion of patient follow - up depend on many factors, including the size of the patient population, the nature of the study protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical study, patient compliance, competing clinical studies and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical studies if the study protocol requires them to undergo extensive post - treatment procedures or follow - up to assess the safety and efficacy of a product candidate, or they may be persuaded to participate in contemporaneous clinical trials of a competitor' s product candidate. In addition, patients participating in our clinical studies may drop out before completion of the study or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical study may delay commencement or completion of the clinical study, cause an increase in the costs of the clinical study and delays, or result in the failure of the clinical study. Disruptions at the FDA, other government agencies and notified bodies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared, approved, certified or commercialized in a timely manner, or at all, which could negatively impact our business. The ability of the FDA, other government agencies, and notified bodies to review, and authorize or certify new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, their ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency' s or notified bodies' ability to perform routine functions. Average review times at the FDA, other government agencies and notified bodies have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA, other agencies and notified bodies may also slow the time necessary for new medical devices or modifications to authorized or certified medical devices to be reviewed and / or cleared or approved or certified by necessary government agencies or notified bodies, which would adversely affect our business. For example, over the last several years, the United States government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. ~~Separately, in response to the COVID- 19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID- 19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. 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 hinder or 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~~ For instance, in the EU, notified bodies must be officially designated to certify products and services in accordance with the

IVDR. Only a few notified bodies have been designated so far ~~but the COVID- 19 pandemic has significantly slowed down their designation process~~ . Without IVDR designation, notified bodies may not yet start certifying devices in accordance with the new regulation. As only a few notified bodies ~~has~~ **have** been IVDR- designated they are facing a heavy workload and their review times have lengthened. This situation could impact the way we are conducting our business in the EU and the EEA, and the ability of our notified body to timely review and process our regulatory submissions and perform its audits. Our customers are highly dependent on payment from third- party payors, and inadequate coverage and / or reimbursement for diagnostic tests using our technology or for procedures using our products and product candidates would compromise our ability to successfully commercialize our diagnostic products and product candidates. Successful commercialization of our diagnostic products and product candidates depends, in large part, on the extent to which the costs of our products and product candidates purchased by our customers are reimbursed, either separately or through bundled payment, by third- party private and governmental payors, including Medicare, Medicaid, managed care organizations and private insurance plans. There is significant uncertainty surrounding third- party coverage and reimbursement for the use of tests that incorporate new technology, such as our technology. There may be significant delays in obtaining coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Third- party payors may deny coverage if they determine that our diagnostic tests are not cost- effective compared to the use of alternative testing methods as determined by the payor, or is deemed by the third- party payor to be experimental or medically unnecessary. Even if third- party payors make coverage and reimbursement available, such reimbursement may not be adequate or these payors' reimbursement policies may have an adverse effect on our business, results of operations, financial condition and cash flows. In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Hospitals, clinical laboratories and other healthcare provider customers that may purchase our products and product candidates, if approved, generally bill various third- party payors to cover all or a portion of the costs and fees associated with diagnostic tests, including the cost of the purchase of our products and product candidates. The majority of our diagnostic tests are performed in a hospital inpatient setting, where governmental payors, such as Medicare, generally reimburse hospitals a single bundled payment that is based on the patients' diagnosis under a classification system known as the Medicare severity diagnosis- related groups, classification for all items and services provided to the patient during a single hospitalization, regardless of whether our diagnostic tests are performed during such hospitalization. In addition, new products may be eligible for a new technology add- on payment, or NTAP, for up to three years under the Medicare Hospital Inpatient Prospective Payment System, or IPPS, if they meet certain criteria, including, among other things, demonstrating a substantial clinical improvement relative to services or technologies previously available. For fiscal years 2021 through 2022, hospitals paid under the IPPS were eligible to receive a NTAP for T2Bacteria, which was incremental to the MS- DRG reimbursement for qualifying Medicare inpatient cases based on the cost of the case. Effective fiscal year 2023, T2Bacteria is no longer eligible for NTAP. To the extent that our diagnostic tests are performed in an outpatient setting, certain of our tests ~~, including our T2SARS- CoV- 2 Panel,~~ may be eligible for separate payment under the Clinical Laboratory Fee Schedule using existing Current Procedural Terminology, or CPT, codes. Government authorities and other third- party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for various products. Our customers' access to adequate coverage and reimbursement for inpatient procedures and diagnostic tests, including our products, by government and private insurance plans is central to the acceptance of our products. We may be unable to sell our products on a profitable basis if third- party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels. In many countries outside of the United States, various coverage, pricing and reimbursement approvals are required and vary from country to country. We expect that it will take several years to establish broad coverage and reimbursement for testing services based on our products with payors in countries outside of the United States, and our efforts may not be successful. We are subject to federal, state and foreign healthcare fraud and abuse laws and other federal, state and foreign healthcare laws applicable to our business activities. If we are unable to comply, or have not complied, with such laws, we could face substantial penalties. Our operations are, and will continue to be, directly or indirectly subject to various federal, state and foreign fraud and abuse laws, including, without limitation, the federal and state anti- kickback statutes, false claims laws and transparency laws regarding payments and other transfers of value made to physicians and other licensed healthcare professionals. These laws impact, among other things, our sales and marketing and education programs and require us to implement additional internal systems for tracking certain marketing expenditures and reporting them to government authorities. In addition, we may be subject to patient data privacy and security regulation by both the federal government and the states in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include: • the federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly or willfully soliciting, receiving, offering or paying any 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, in whole or in part, under a federal healthcare program such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to commit a violation; • federal false claims laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from or approval by a governmental payor program that are false or fraudulent. In addition, a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims

Act; • the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which established additional federal crimes for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and imposes obligations, including mandatory contractual terms, on certain types of people and entities regarding the security and privacy of protected health information; • the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid, or the Children' s Health Insurance Program, with specific exceptions, to report annually to the CMS information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non- physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and • state or foreign law equivalents of each of the above federal laws, such as anti- kickback and false claims laws, which may apply to items or services reimbursed by any third- party payor, including commercial insurers; state laws that require device companies to comply with the industry' s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require manufacturers to report information related to payments and other transfers of value to physicians, hospitals and other healthcare providers, marketing expenditures, or pricing; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including significant administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, the curtailment or restructuring of our operations, integrity reporting obligations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our results of operations. Healthcare policy changes, including legislation reforming the United States healthcare system, may have a material adverse effect on our financial condition and results of operations. The Affordable Care Act, or ACA, enacted in March 2010, made changes that significantly impacted the pharmaceutical and medical device industries and clinical laboratories. Other significant measures for our industry contained in the ACA included coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures; initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians; and initiatives to promote quality indicators in payment methodologies. To the extent that the reimbursement amounts for sepsis decrease, it could adversely affect the market acceptance and hospital adoption of our technologies. The ACA also mandated a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule, or CLFS, of 1. 75 % for the years 2011 through 2015 and a productivity adjustment to the CLFS, further reducing payment rates. Some commercial payors are guided by the CLFS in establishing their reimbursement rates. Clinicians may decide not to order clinical diagnostic tests if third- party payments are inadequate, and we cannot predict whether third- party payors will offer adequate reimbursement for procedures utilizing our products and product candidates to make them commercially attractive. To the extent that the diagnostic tests using our products and product candidates are performed on an outpatient basis, these or any future proposed or mandated reductions in payments under the CLFS may apply to some or all of the clinical laboratory tests that our diagnostics customers may use our technology to deliver to Medicare beneficiaries and may indirectly reduce demand for our diagnostic products and product candidates. **Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court' s decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare.** In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011 resulted in aggregate reductions of Medicare payments to providers, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the temporary suspension from May 1, 2020 through March 31, 2022, unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our customers and accordingly, our financial operations. On January 1, 2018, CMS implemented certain provisions of the Protecting Access to Medicare Act of 2014, or PAMA, which made substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, laboratories that

receive the majority of their Medicare revenue from payments made under the CLFS or the Physician Fee Schedule are required to report to CMS, beginning in 2017 and every three years thereafter (or annually for " advanced diagnostics laboratory tests "), private payer payment rates and volumes for their tests. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. CMS uses the data to calculate a weighted median payment rate for each test, which is used to establish a revised Medicare reimbursement rate. Under PAMA, the revised Medicare reimbursement rates were scheduled to apply to clinical diagnostic laboratory tests furnished on or after January 1, 2018. The revised reimbursement methodology is expected to generally result in relatively lower reimbursement under Medicare for clinical diagnostic lab tests that has been historically available. Any reduction to payment rates resulting from the new methodology is limited to 10 % per test per year in 2018 through 2020, 0 % per test per year in 2021 through 2023, and 15 % per test per year in 2024 through 2026. The CARES Act, which was signed into law on March 27, 2020, amended the timeline for reporting private payer payment rates and delayed by one year the payment reductions scheduled for 2021. On December 10, 2021, Congress passed the Protecting Medicare and American Farmers from Sequester Cuts Act, or PMAFSA, which delayed the next data reporting period by an additional year and prevented any reduction in payment amounts from commercial payer rate implementation in 2022. The Consolidated Appropriations Act, 2023, enacted on December 29, 2022, further revised the next data reporting period for certain tests and delayed the phase- in of payment reductions for an additional year, through 2026. In the EU, similar developments may affect our ability to profitably commercialize our products, if certified. In December 2021, the EU Regulation No 2021 / 2282 on Health Technology Assessment, or HTA, amending Directive 2011 / 24 / EU, was adopted. While the regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation- related steps to take place in the interim. Once the regulation becomes applicable, it will have a phased implementation depending on the concerned products. This regulation intends to boost cooperation among EU member states in assessing health technologies, including some high- risk medical devices and in vitro diagnostic medical devices, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non- clinical (e. g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement We expect that additional state, federal and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal, state and foreign governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure. We 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, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation and the expansion in government' s effect on the United States healthcare industry may result in decreased profits to us, lower reimbursements by payors for our products and product candidates or reduced medical procedure volumes, any of which may adversely affect our business, financial condition and results of operations. If we are unable to protect our intellectual property effectively, our business would be harmed. We rely on patent protection as well as trademark, copyright, trade secret protection and confidentiality agreements to protect the intellectual property rights related to our proprietary technologies. The strength of patents in our field involves complex legal and scientific questions. Uncertainty created by these questions means that our patents may provide only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We own or exclusively license over ~~35~~ **40** issued U. S. patents and ~~over 15 pending U. S.~~ patent applications ~~, including provisional and non- provisional filings~~ . We also own or license over 50 pending or granted counterpart applications worldwide. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property. We cannot assure you that any of our currently pending or future patent applications will result in issued patents with claims that cover our products and technologies in the United States or in other foreign countries, and we cannot predict how long it will take for such patents to be issued. Further, issuance of a patent is not conclusive as to its inventorship or scope, and there is no guarantee that our issued patents will include claims that are sufficiently broad to cover our technologies or to provide meaningful protection of our products from our competitors. Further, we cannot be certain that all relevant prior art relating to our patents and patent applications has been found. Accordingly, there may be prior art that can invalidate our issued patents or prevent a patent from issuing from a pending patent application, at all or with claims that have a scope broad enough to provide meaningful protection from our competitors. Even if patents do successfully issue and even if such patents cover our products and technologies, we cannot assure you that other parties will not challenge the validity, enforceability or scope of such issued patents in the United States and in foreign countries, including by proceedings such as re- examination, inter partes review, interference, opposition, or other patent office or court proceedings. Moreover, we cannot assure you that if such patents were challenged in court or before a regulatory agency that the patent claims will be held valid, enforceable, or be sufficiently broad to cover our technologies or to provide meaningful protection from our competitors. Nor can we assure you that the applicable court or agency will uphold our ownership rights in such patents. Accordingly, we cannot guarantee that we will be successful in defending challenges made against our patents and patent applications. Any successful third- party challenge to our patents could result in the unenforceability or invalidity of such patents, or narrowing of claim scope, such that we could be deprived of patent protection necessary for the successful commercialization of our products and technologies, which could adversely affect our business. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our products and technologies or prevent others from designing around our claims. Others may independently develop similar or alternative products and technologies or duplicate

any of our products and technologies. These products and technologies may not be covered by claims of issued patents owned by our company. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of the protections provided by our intellectual property rights. If our intellectual property, including licensed intellectual property, does not adequately protect our market position against competitors' products and methods, our competitive position could be adversely affected, as could our business. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product or product candidate under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to make the inventions covered by our pending patent applications, or that we were the first to file any patent application related to a product or product candidate. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by a third party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited **. For example, recent decisions raise questions regarding the award of patent term adjustment (" PTA ") for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will / will not be viewed in the future and whether patent expiration dates may be impacted** . Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non- patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition. We depend on certain technologies that are licensed to us. We do not control the intellectual property rights covering these technologies and any loss of our rights to these technologies or the rights licensed to us could prevent us from selling our products. We are a party to a number of license agreements under which we are granted rights to intellectual property that is important to our business and we expect that we may need to enter into additional license agreements in the future. We rely on these licenses in order to be able to use various proprietary technologies that are material to our business, including an exclusive license to patents and patent applications from Massachusetts General Hospital, or MGH ~~, and Hackensack Meridian Health~~ , and non- exclusive licenses from other third parties related to materials used currently in our research and development activities, and which we use in our commercial activities. Our rights to use these technologies and employ the inventions claimed in the licensed patents are subject to the continuation of and our compliance with the terms of those licenses. Our existing license agreements impose, and we expect that future license agreements will impose on us, various diligence obligations, payment of milestones or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license. As we have done previously, we may need to obtain licenses from third parties to advance our research or allow commercialization of our products and technologies, and we cannot provide any assurances that third- party patents do not exist which might be enforced against our current products and technologies or future products in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. 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, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products and technologies, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation. In some cases, we do not control the prosecution, maintenance, or filing of the patents that are licensed to us, or the enforcement of these patents against infringement by third parties. Some of our patents and patent applications were not filed by us, but were either acquired by us or are licensed from third parties. Thus, these patents and patent applications were not drafted by us or our attorneys, and we did not control or have any input into the prosecution of these patents and patent applications either prior to our acquisition of, or entry into a license with respect to, such patents and patent applications. With respect to the ~~patents we~~ license from MGH, although we have rights under our agreement to provide input into prosecution and maintenance activities, and are actively involved in such ongoing prosecution, MGH retains ultimate control over such prosecution and maintenance. We therefore cannot be certain that the same attention was given, or will continue to be given, to the drafting and prosecution of these patents and patent applications as we may have exercised if we had control over the drafting and prosecution of such patents and patent applications, or that we will agree with decisions taken by MGH in relation to ongoing prosecution activities. We also cannot be certain that drafting or prosecution of the patents and patent applications licensed to us have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. Further, as MGH retains the right to enforce ~~these~~ **any licensed** ~~patents~~ **patent** against third- party infringement, we cannot be certain that MGH will elect to enforce ~~these~~ **the** ~~patents~~ **patent** to the extent that we would choose to do so, or in a way that will ensure that we retain the rights we currently have under our license with MGH. If MGH fails to properly enforce the ~~patents~~ **patent** subject to our license in the event of third- party infringement, our ability to retain our competitive advantage with respect to our products and product candidates may be materially affected. In addition, certain of the patents we have licensed relate to technology that was developed with U. S. government grants. Federal regulations impose certain domestic manufacturing requirements and other obligations with respect

to some of our products embodying these patents. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • our right to sublicense patent and other rights to third parties under collaborative development relationships; • our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products and technologies, and what activities satisfy those diligence obligations; and • the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners. 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 products and technologies. We may be involved in lawsuits to protect or enforce our patents and proprietary rights, to determine the scope, enforceability and validity of others' proprietary rights, or to defend against third- party claims of intellectual property infringement, any of which could be time- intensive and costly and may adversely impact our business or stock price. Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the medical device and diagnostics industries, including patent infringement lawsuits, interferences, oppositions and inter partes review proceedings before the U. S. Patent and Trademark Office, or U. S. PTO, and corresponding foreign patent offices. We have received a notice of claims of infringement or misappropriation or misuse of other parties' proprietary rights in the past, and we may from time to time receive such additional notices in the future. Some of these claims may lead to litigation. Third parties may assert that we are employing their proprietary technology without authorization. There may be third- party patents or patent applications with claims to materials, methods of manufacture or methods of use of our products and technologies. Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result in issued patents that our products and technologies may infringe, or which such third parties claim are infringed by the use of our technologies. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third- party trade secrets or infringement by us of third- party patents, trademarks or other rights, or challenging the validity of our patents, trademarks or other rights, will not be asserted against us. Litigation may be necessary for us to enforce our patent and proprietary rights or to determine the scope, enforceability or validity of the proprietary rights of others. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the medical diagnostics industry. Third parties may assert that we are employing their proprietary technology without authorization. Many of our competitors have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product revenue and against whom our own patents may provide little or no deterrence or protection. Parties making claims against us for infringement of their intellectual property rights may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our products and technologies. Further, defense of such claims in litigation, regardless of merit, could result in substantial legal fees and could adversely affect the scope of our patent protection, and would be a substantial diversion of employee, management and technical personnel resources from our business. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us. In the event of a successful claim of infringement against us, we could be required to redesign our infringing products or obtain a license from such third party to continue developing and commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. 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. We could therefore incur substantial costs for licenses obtained from third parties, if such licenses were available at all, which could negatively affect our gross margins, or prevent us from commercializing our products and technologies. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products to avoid infringing third- party rights. In addition, if we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, enforceability or scope of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. Any litigation that may be necessary in the future could result in substantial costs and the diversion of our resources and could have a material adverse effect on our business, operating results or financial condition. Further, if the scope of protection provided by our patents or patent applications is threatened or reduced as a result of litigation, it could discourage third parties from entering into collaborations with us that are important to the commercialization of our products. We cannot guarantee that we have identified all relevant third- party intellectual property rights that may be infringed by our technology, nor is there any assurance that patents will not issue in the future from currently pending applications that may be infringed by our technology or products or product candidates. We are aware of third parties that have issued patents and pending patent applications in the United States, EU, Canada, and other jurisdictions in the field of magnetic resonance devices and methods for analyte detection, including the preparation and use of reagents. While we continue to evaluate third- party patents in this area on an ongoing basis, we cannot guarantee that patents we currently are aware of will be found invalid or not infringed if we are accused of infringing them, or if our products are found to infringe, that we will be able to modify our products to cause them to be non- infringing on a timely or cost- effective basis, or at all. We currently monitor the intellectual property positions of some companies in this field that are potential competitors or are conducting research and development in areas that relate to our business and will continue to do so as we progress the development and commercialization of our products or product candidates. While we continue to evaluate third- party patents in this area on an ongoing basis, we cannot assure you that third parties do not currently have or will not in the future have issued patents or other intellectual property rights that may be

infringed by the practice of our technology or the commercialization of our products or product candidates. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or you perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. In addition, certain of our agreements with suppliers, distributors, customers and other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims relating to our technologies or products, or rights licensed to them by us. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify any of these third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to pursuing patents on our technology, we also rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our products and technologies and discovery and development processes that involve proprietary know- how, information or technology that is not covered by patents, in order to maintain our competitive position. We take steps to protect our intellectual property, proprietary technologies and trade secrets, in part, by entering into confidentiality agreements with our employees, consultants, corporate partners, 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 assign to us any inventions developed in the course of their work for us. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Our agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time - consuming, and the outcome would be unpredictable. 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, courts outside the United States may be less willing to protect trade secrets. If any of the technology or information that we protect as trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA' s disclosure policies may change in the future, if at all. We may be subject to damages resulting from claims that we or our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. Many of our employees were previously employed at universities or other medical device companies, including our competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of our employees' former employers, or we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our products and technologies. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could hamper our ability to commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our products and technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. 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. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy- Smith America Invents

Act, or the Leahy- Smith Act, was signed into law. The Leahy- Smith Act includes a number of significant changes to U. S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The U. S. PTO is currently developing regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first to file provisions, were enacted March 16, 2013. However, it is not clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be paid to the U. S. PTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non- U. S. patent agencies. The U. S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, however there are situations in which noncompliance 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, competitors might be able to enter the market earlier than would otherwise have been the case. 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. We have not yet registered certain of our trademarks in all of our potential markets, including in international markets. If we apply to register these trademarks, our applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may not be able to protect our intellectual property rights throughout the world. The laws of some non- U. S. countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to technologies relating to biotechnology, which could make it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Also, because we have not pursued patents in all countries, there exist jurisdictions where we are not protected against third parties using our proprietary technologies. Further, compulsory licensing laws or limited enforceability of patents against government agencies or contractors in certain countries may limit our remedies or reduce the value of our patents in those countries. We use third- party software that may be difficult to replace or cause errors or failures of our products that could lead to lost customers or harm to our reputation. We use software licensed from third parties in our products. In the future, this software may not be available to us on commercially reasonable terms, or at all. Any loss of the right to use any of this software could result in delays in the production of our products until equivalent technology is either developed by us, or, if available, is identified, obtained and integrated with our technologies and products, which could harm our business. In addition, any errors or defects in, or failures of, such third- party software could result in errors or defects in the operation of our products or cause our products to fail, which could harm our business and reputation and be costly to correct. Many of the licensors of the software we use in our products attempt to impose limitations on their liability for such errors, defects or failures. If enforceable, such limitations would require us to bear the liability for such errors, defects or failures, which could harm our reputation and increase our operating costs. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative: • others may be able to make diagnostic products and technologies that are similar to our products or product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed; • we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed; • we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our 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 will not lead to issued patents; • issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; and • the patents of others may have an adverse effect on our business. Should any of these events occur, they could significantly harm our business,

results of operations and prospects. Risks Related to Our Common Stock ~~An~~ **A consistent, stable and** active ~~trading~~ market for our common stock may not be sustained. Since our initial listing on The Nasdaq Global Market in August 2014 **and our transfer to the Nasdaq Capital Market in 2022** , the trading market in our common stock has ~~historically been limited~~ **experienced periods of volatility** . The listing of our common stock on The Nasdaq ~~Global~~ **Capital** Market does not assure that a meaningful, consistent and liquid trading market ~~currently~~ **will** ~~exists~~ **exist or continue** . We cannot predict whether **an** ~~a more~~ active market for our common stock will be sustained in the future. The absence of an active trading market could adversely affect our stockholders' ability to sell our common stock at current market prices in short time periods, or possibly at all. Additionally, market visibility for our common stock may be limited and such lack of visibility may have a depressive effect on the market price for our common stock. The price of our common stock has been volatile and is likely to continue to be volatile, which could result in substantial losses for purchasers of our common stock. Our stock price has been and is likely to continue be volatile. The stock market in general has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the current market price. The market price for our common stock may be influenced by many factors, including: **• the composition of our stockholders, particularly the presence of short sellers or day traders trading in our stock;** • actual or anticipated fluctuations in our financial condition and operating results; • announcements by us relating to the timing of regulatory clearance for our product candidates; • actual or anticipated changes in our growth rate relative to our competitors; • competition from existing products or new products that may emerge; • development of new technologies that may address our markets and may make our technology less attractive; • changes in physician, hospital or healthcare provider practices that may make our products or product candidates less useful; • announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; • developments or disputes concerning patent applications, issued patents or other proprietary rights; • the recruitment or departure of key personnel; • failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public; • actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; • variations in our financial results or those of companies that are perceived to be similar to us; • changes to reimbursement levels by commercial third- party payors and government payors, including Medicare, and any announcements relating to reimbursement levels; • technical factors in the public trading market for our stock that may produce price movements that may or may not comport with macro, industry or company- specific fundamentals, including, without limitation, the sentiment of retail investors (including as may be expressed on financial trading and other social media sites), the amount and status of short interest in our securities, access to margin debt, trading in options and other derivatives on our common stock and other technical trading factors; • general economic, industry and market conditions; and • the other factors described in this " Risk Factors " section. We continue to incur significant costs as a result of operating as a public company, and our management continues to devote substantial time to compliance initiatives and corporate governance practices. As a public company, we incur significant legal, accounting, insurance and other expenses. The Sarbanes- Oxley Act of 2002, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq ~~Global~~ **Capital** Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time- consuming and costly. We continue to be subject to applicable securities rules and regulations. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock. Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Pursuant to Section 404 of the Sarbanes- Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain a non- accelerated filer, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we are unable to maintain effective internal control over financial reporting, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a public company or comply with the requirements of the Securities and Exchange Commission or Section 404. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. **Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, the Company' s disclosure controls and procedures were not effective due to material weaknesses in our internal control over financial reporting. The material weaknesses remain unremediated as of December 31, 2023.**

The Company will establish enhanced evaluation and review procedures to prevent future occurrences. Provisions in our restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our Board of Directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Among other things, these provisions include those establishing: • a classified Board of Directors with three- year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our Board of Directors; • no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; • the exclusive right of our Board of Directors to elect a director to fill a vacancy created by the expansion of the Board of Directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our Board of Directors; • the ability of our Board of Directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer; • the ability of our Board of Directors to alter our amended and restated bylaws without obtaining stockholder approval; • the required approval of the holders of at least two- thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors; • a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders; • the requirement that a special meeting of stockholders may be called only by the chief executive officer, the president or the Board of Directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and • advance notice procedures that stockholders must comply with in order to nominate candidates to our Board of Directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer' s own slate of directors or otherwise attempting to obtain control of us. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. ~~General Risk Factors~~ If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline. The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. In the event any of the analysts who cover us, or any investors who have taken a short position in our stock, issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our regulatory clearance timelines, clinical trial results or operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Our ability to pay cash dividends is prohibited by the terms of our existing credit facility. Any future debt agreements may also preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. We could be subject to securities class action litigation. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business.