UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the year ended December 31, 2020

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-36571

T2 Biosystems, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-4827488**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
101 Hartwell Avenue, Lexington, MA	**02421**
(Address of principal executive offices)	**(Zip code)**

Registrant's telephone number, including area code: 781-761-4646

Securities registered pursuant to Section 12(b) of the Act

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001	TTOO	The Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act of 1933, as amended. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended. YES ☐ NO ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer" "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of June 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates was approximately $147.9 million based on the closing price for the common stock of $1.27 on that date. Shares of common stock held by each executive officer, director, and their affiliated stockholders have been excluded from this calculation as such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant's common stock on March 26, 2021 was 148,491,673.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy, prospective products and product candidates, their expected performance and impact on healthcare costs, marketing clearance from the U.S. Food and Drug Administration, or the FDA, regulatory clearance, reimbursement for our product candidates, research and development costs, timing of regulatory filings, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "forecast," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Annual Report on Form 10-K are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described under the sections in this Annual Report on Form 10-K entitled "Item 1A.—Risk Factors". Unless required by U.S. federal securities laws, we do not intend to update any of these forward-looking statements to reflect circumstances or events that occur after the statement is made or to conform these statements to actual results.

Summary of Principal Risk Factors

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 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 status as an early commercial-stage company;*
- *our expectation to incur losses in the future;*
- *the market acceptance of our T2MR 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 relatively limited sales history;*
- *our ability to gain the support of leading hospitals and key thought leaders and publish the results of our clinical trials in peer-reviewed journals;*
- *our ability to successfully manage our growth;*
- *our future capital needs and our ability to raise additional funds;*
- *the performance of our diagnostics;*
- *our ability to compete in the highly competitive diagnostics market;*
- *our ability to obtain marketing clearance from the FDA or regulatory clearance for new product candidates in the United States or any other jurisdiction;*
- *impacts of and delays caused by future federal government shutdowns;*
- *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 T2MR;*
- *our ability to recruit, train and retain key personnel;*
- *our dependence on third parties;*

- *manufacturing and other product risks;*
- *the impact of the adoption of new accounting standards;*
- *the impact 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;*
- *the impact of cost-cutting measures;*
- *unforeseen interruptions in our supply chain;*
- *our ability to maintain compliance with Nasdaq listing requirements;*
- *the Tax Cuts and Jobs Act of 2017 (Tax Reform) and the impact of future tax legislation;*
- *the impact of the COVID-19 pandemic on our business, results of operations and financial positions; and*
- *the continued market demand for SARS-CoV-2 testing and 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 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 an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. We are using our T2MR technology to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. T2MR 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. Our products include the T2Dx Instrument, T2Candida Panel, the T2Bacteria Panel, the T2Resistance Panel, and the T2SARS-CoV-2 Panel that are all powered by our proprietary T2MR technology. Our development efforts target sepsis, which is an area of significant unmet medical need in which existing therapies could be more effective with improved diagnostics.

On September 22, 2014, we received market clearance from the FDA for our first two products, the T2Dx® Instrument, or the T2Dx and the T2Candida® Panel, or T2Candida, which have the ability to rapidly identify the five clinically relevant species of *Candida*, a fungal pathogen known to cause sepsis, directly from whole blood. On May 24, 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 of the most common and deadly sepsis-causing bacteria directly from whole blood. We have also developed and sell a research use only *Candida auris* assay, the T2Cauris™ Panel, for the rapid identification of *Candida auris*, a species of *Candida* that is highly drug resistant. We have developed a T2Resistance™ Panel for the early and sensitive detection of resistance markers, which can assist clinicians in selecting effective antibiotics. The T2Resistance Panel received FDA Breakthrough Device designation in February 2019 and was granted a CE Mark in November 2019. An additional diagnostic application in development is the T2Lyme™ Panel, or T2Lyme, which is focused on the detection of the bacteria that cause Lyme disease. Diagnostic applications for additional bacteria species and resistance markers were developed as part of a collaboration with CARB-X, a public-private partnership with the U.S. Department of Health and Human Services, or HHS, and the Wellcome Trust of London, focused on combatting antibiotic resistant bacteria. On August 2, 2019, the Centers for Medicare & Medicaid Services, or CMS, granted approval for a New Technology Add-on Payment (NTAP) for the T2Bacteria Panel for fiscal year 2020 and in September 2020, CMS extended the approval for 2021. In September 2019, the Biomedical Advanced Research and Development Authority ("BARDA") awarded us a milestone-based contract, with an initial value of $6 million, and a potential value of up to $69 million, for the development of new direct-from-blood diagnostic panels that will run on the T2Dx. In September 2020, BARDA exercised the first contract option valued at $10.5 million. On June 30, 2020, we announced the U.S. launch of our COVID-19 molecular diagnostic test, the T2SARS-CoV-2 Panel, after validation of the test meeting the FDA's requirements for an Emergency Use Authorization (EUA). In August 2020, the FDA issued EUA for the T2SARS-CoV-2 Panel. The test is designed to detect the presence of the SARS-CoV-2 virus extracted from a nasopharyngeal swab sample. The existing reimbursement codes support our sepsis products and anticipate the same for our Lyme disease product candidates. In 2020, CMS authorized Medicare fixed reimbursement to Clinical Laboratory Improvement Amendments, or CLIA, certified laboratories for materials and services to perform COVID testing. The T2SARS-CoV-2 Panel is covered under this reimbursement. The economic savings associated with our sepsis products are realized directly by hospitals. In the United States, we have a commercial team that is primarily targeting hospitals with the highest concentration of patients at risk for sepsis-related infections. Internationally, we have primarily partnered with distributors that target large hospitals in their respective international markets.

Sepsis is one of the leading causes of death in the United States, claiming more lives annually than the top three cancers combined: lung, colorectal and breast cancer, and it is the most expensive hospital-treated condition. Most commonly afflicting immunocompromised, critical care, and elderly patients, sepsis is a severe inflammatory response to a bacterial or fungal infection with a mortality rate of approximately 30%. Based on a 2020 study from the Department of Health and Human Services (HHS), it was estimated that the annual cost of sepsis to the US healthcare system was $62 billion. The rate of Medicare beneficiaries hospitalized with sepsis has increased by 40% over from 2012 to 2018, the HHS study found. The CDC estimates that sepsis causes more than 270,000 American deaths per year. Sepsis is typically caused by one or more of five *Candida* species or over 25 bacterial pathogens, and effective treatment requires the early detection and identification of these specific target pathogens in a patient's bloodstream. Today, sepsis is typically diagnosed through a series of blood cultures followed by post-blood culture species identification if a blood culture tests positive. These methods have substantial diagnostic limitations that lead to a high rate of false negative test results, a delay of up to several days in administration of targeted treatment, and the incurrence of unnecessary hospital expense. 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 and switch therapies every 12 to 24 hours if a patient is not responding. These 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 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 *Candid*a mortality rate can be reduced 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.

We believe our sepsis products, which include T2Candida, T2Bacteria, T2Resistance, and T2Cauris, will redefine the standard of care in sepsis management while lowering healthcare costs by improving both the precision and the speed to detection of sepsis-causing pathogens. According to a study published in the Journal of Clinical Microbiology in 2010, targeted therapy for patients with bloodstream infections can be delayed up to 72 hours due to the wait time for blood culture 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 and, on that basis, the study concluded that more rapid and accurate diagnostic techniques are needed.

Our pivotal clinical trial for T2Candida demonstrated that it can deliver actionable 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 and the pivotal clinical trial for T2Bacteria demonstrated that it can deliver actionable results in an average of 5.4 hours, compared to an average of 60 hours for detecting the same species by blood culture. We believe the speed of the T2Candida and T2Bacteria tests will enable physicians to potentially make treatment decisions and administer targeted treatment to patients in four to six hours versus 24 to 144 hours for blood culture. 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 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 can potentially reduce the costs of care by $26,887 per *Candida* patient and that rapid detection of *Candida* reduces 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 60% of the patients (33 cases) with blood culture.

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 and T2Bacteria coupled with their 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 United States Centers for Disease Control and Prevention, or the CDC, recently called “one of our most serious health threats.” The addition of the use of our products, T2Bacteria and T2Candida, which both run on the T2Dx Instrument, with the standard of care for the management of patients suspected of sepsis, enables clinicians to potentially treat 90% of patients with sepsis pathogen infections with the right targeted therapy within the first twelve hours of development of the symptoms of disease. Currently, high risk patients are typically initially treated with broad spectrum antibiotic drugs that typically cover approximately 60% of patients with 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 identify pathogens commonly not covered by broad spectrum antibiotic drugs.

Our Strategy

T2MR enables rapid and sensitive direct detection of a range of targets, and we believe it can be used in a variety of diagnostic applications that will improve patient outcomes and reduce healthcare costs. Our objective is to establish T2MR as a standard of care for clinical diagnostics. To achieve this objective, our strategy is to:

- ***Sell T2Dx Instruments to Establish a Recurring, Consumables-Based Business.*** We are pursuing a consumables-based business model for our products by building an installed base of T2Dx Instruments at hospitals and driving utilization of our diagnostic panels, including T2Candida, T2Bacteria, and T2Resistance. We believe this strategy will foster a sustainable and predictable business model with recurring revenue streams.

- ***Drive Further Commercial Adoption of Our Sepsis Products.*** We expect our sepsis products to meaningfully improve patient outcomes while reducing costs to hospitals. We have established a direct sales force in the United States, and have partnered with distributors internationally, to demonstrate our clinical and economic value proposition to hospitals that have the highest populations of at-risk critical care and immunocompromised patients. We believe a sustained focus on these hospitals will drive adoption of the T2Dx Instrument, T2Candida, T2Bacteria, T2Resistance and future T2MR-based diagnostics. As a part of this effort, we will continue to work with thought leaders, conduct clinical and health economic studies and seek publication and presentation of these studies.
- ***Convert T2SARS-CoV-2 Customer to Our Core Sepsis Test Products.*** In 2020, with the commercial launch of our molecular diagnostic test for COVID-19, the T2SARS-CoV-2 Panel, we initiated a targeted market penetration strategy to sell T2Dx Instruments and T2SARS-CoV-2 tests to U.S hospitals. We strategically focused on U.S. hospitals treating critical care patients including both COVID-19 patients and sepsis patients. While most of these instruments sold during 2020 were dedicated to COVID-19 testing, our strategy is to convert these new U.S. hospital accounts to our sepsis test panels.
- ***Broaden Our Addressable Markets in Infectious Disease.*** Our product development pipeline includes additional diagnostic panels that provide near-term and complementary market expansion opportunities. We will seek to expand our panels through partnerships to share the costs of our development of certain additional products, as well as through funding from other non-dilutive and government sources. We also are utilizing T2MR to address the challenges of providing a rapid and sensitive diagnosis of Lyme disease.
- ***Broaden Our Addressable Markets Beyond Infectious Disease.*** We may expand our product offerings by applying T2MR to new applications beyond sepsis and Lyme disease. We may conduct internal development and will continue to work with thought leaders, physicians, clinical researchers and business development partners to pursue new applications for T2MR. We believe the benefits of our proprietary technology, including the ability to rapidly and directly detect a broad range of targets, in a wide variety of sample types, may have potential applications within and outside of the in vitro diagnostics market, including environmental, food safety, industrial and veterinary applications.
- ***Expand International Distribution Channels.*** We are currently selling the T2Dx Instrument, T2Candida, T2Bacteria, and T2Resistance internationally through distributors that target large hospitals in their respective markets. We intend to continue to expand in international markets through similar distribution channels.

Our Technology Platform

T2 Magnetic Resonance Technology Overview

We have built an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. T2MR is a miniaturized, magnetic resonance-based approach that measures how water molecules react in the presence of magnetic fields. Our proprietary platform is capable of detecting a variety of targets, including:

- molecular targets, such as DNA;
- immunodiagnostics targets, such as proteins; and
- a broad range of hemostasis measurements.

For molecular and immunodiagnostics targets, T2MR utilizes advances in the field of magnetic resonance by deploying particles with magnetic properties that enhance the magnetic resonance signals of specific targets. When particles coated with target-specific binding agents are added to a sample containing the target, the particles bind to and cluster around the target. This clustering changes the microscopic environment of water in that sample, which in turn alters the magnetic resonance signal, or the T2 relaxation signal that we measure, indicating the presence of the target.

We also believe T2MR is the first technology that can rapidly and accurately detect the presence of molecular targets within samples without the need for time- and labor-intensive purification or extraction of target molecules from the sample, such as that required by traditional polymerase chain reaction, or PCR, where 90% or more of the target can be lost. We can eliminate these steps because the T2 relaxation signal is not compromised or disrupted by the sample background, even the highly complex sample background that is present after a target amplification process, such as thermocycling. This enables T2MR's low limit of detection, such as 1 CFU/mL, compared to the 100 to 1,000 CFU/mL typically required for PCR-based methods. More than 100 studies published in peer-reviewed journals have featured T2MR in a breadth of applications, including the direct detection and measurement of targets in various sample types, such as whole blood, plasma, serum, saliva, sputum and urine. We believe our T2MR technology will have potential applications within and outside of the *in vitro* diagnostics market, including environmental, food safety, industrial and veterinary applications.

Our Instruments

Utilizing T2MR, we have developed and received FDA marketing clearance for the T2Dx Instrument, a bench-top instrument for detecting pathogens associated with sepsis and Lyme disease, as well as other applications.

T2Dx

Our FDA-cleared T2Dx Instrument is an easy-to-use, bench-top instrument that is capable of running a broad range of diagnostic tests and is fully automated from patient sample input to result, 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 sample is snapped onto a disposable test cartridge, which is pre-loaded with all necessary reagents. The cartridge is then inserted into the T2Dx Instrument, which automatically processes the sample and then delivers a diagnostic test result. Test results are displayed on screen and printed out.

By utilizing our proprietary T2MR technology for direct detection, the T2Dx Instrument eliminates the need for sample purification and analyte extraction, which are necessary for other optical-detection devices. Eliminating these sample processing steps increases diagnostic sensitivity and accuracy, 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 a simple user interface and is designed to efficiently process up to seven specimens simultaneously.

The panels designed to run on the T2Dx are T2Candida, T2Bacteria, T2Resistance, and T2Cauris, which are focused on identifying life-threatening pathogens associated with sepsis and COVID-19. In 2014 we received FDA market clearance for the T2Dx and T2Candida. In May 2018, we received FDA market clearance for T2Bacteria. In November 2019, we received CE Mark for T2Resistance. In August of 2020, we received FDA EUA clearance for the T2SARS-CoV-2 Panel, which runs on the T2Dx.

Sepsis

Overview

Sepsis is an illness in which the body has a severe, inflammatory response to a bacterial or fungal infection. It is a life-threatening condition to which individuals with weakened immune systems or chronic illnesses are highly susceptible. Sepsis can lead to shock and organ failure, and is a leading cause of death in the United States with a mortality rate of approximately 30%, almost double the mortality rate of acute myocardial infarction, or heart attack. One out of every two hospital deaths in the United States is attributable to sepsis.

Sepsis is one of the leading causes of death in the United States, claiming more lives annually than the top three cancers combined: lung, colorectal and breast cancer, and it is the most expensive hospital-treated condition. Most commonly afflicting immunocompromised, critical care, and elderly patients, sepsis is a severe inflammatory response to a bacterial or fungal infection with a mortality rate of approximately 30%. Based on a 2020 study from HHS, it was estimated that the annual cost of sepsis to the US healthcare system was $62 billion. The rate of Medicare beneficiaries hospitalized with sepsis has increased by 40% over from 2012 to 2018, the HHS study found. The CDC estimates that sepsis causes more than 270,000 American deaths per year. The high cost of treating sepsis is primarily driven by the extended hospitalization of patients. We believe there are many effective, targeted therapeutic choices that could reduce overall hospitalization costs if applied earlier, but clinicians need to more rapidly identify the specific sepsis-causing pathogens in order to make more informed, targeted treatment decisions. Today, the diagnostic standard to identify these pathogens is blood culture-based, despite typically requiring one to six or more days to generate species-specific results and despite blood cultures inherent low sensitivity of 50% to 65%.

Sepsis contributes to 1 in 5 deaths globally. Virtually all of these patients are rapidly treated with broad-spectrum antibiotic drugs because there is no diagnostic manner for determining the type of infection. Of these 1.35 million patients with sepsis and at high risk for infection, approximately 40% do not respond to broad-spectrum antibiotic treatment. Of these patients that are non-responsive, approximately 25% of them have a *Candida* infection, with the remaining patients having a bacterial infection. Broad-spectrum antibiotics do not treat these *Candida* and bacterial infections; therefore more targeted drugs are required.

We estimate that approximately 15 million patients are tested for bloodstream infections in the United States annually. Of these, approximately 8.75 million are at high risk for a Sepsis infection, 90% of whom are at a high risk for a bacterial infection and 10% of whom are at a high risk for a *Candida* infection. Of these 8.75 million patients, 6.75 million patients present in in-patient settings and an additional 2.0 million present in emergency departments. We believe that our sepsis products have the potential to enable clinicians to make earlier therapeutic decisions that can reduce the mortality rate for sepsis by over 50% and save the hospitals an estimated $12 billion annually by testing all high risk patients with T2Candida and T2Bacteria.

Each year, over 30 million people worldwide are affected by sepsis with approximately 11 million mortalities, according to Rudd et al, (2020). Global, regional, and national sepsis incidence and mortality, 1990–2017: analysis for the Global Burden of Disease Study. The Lancet, VOLUME 395, ISSUE 10219, P200-211, making sepsis a leading cause of death worldwide.

Limitations of Traditional In Vitro Diagnostics for Sepsis

The current standard for identifying bloodstream infections that cause sepsis requires a series of lengthy and labor-intensive analyses that begin with blood culture. Completing a blood culture requires a large volume of a patient's blood, typically 20 mLs or more, which is obtained in two 10 mL draws and placed into two blood culture bottles containing nutrients formulated to grow fungi and bacteria. Before blood culture indicates if a patient is infected, pathogens typically must reach a concentration of 1,000,000 to 100,000,000 CFU/mL. This growth process typically takes one to six or more days because the pathogen's initial concentration in the blood specimen is often less than 10 CFU/mL. A negative test result always requires a minimum of five days. A positive blood culture typically means that some pathogen is present, but additional steps must be performed to identify the specific pathogen in order to provide targeted therapy. These additional steps, which typically must be performed by a highly trained technician, may involve any of (i) a staining procedure for inspection on a microscope slide, (ii) PCR amplification and (iii) mass spectrometry. These steps require a preceding positive blood culture specimen because they need a high concentration of cells generated by the blood culture process for analysis.

For most PCR-based diagnostics, nucleic acid extraction of target cells from the sample is performed to remove inhibitory substances that may interfere with the amplification reaction. While PCR amplifies the target signal, this loss of target cells impairs the ability to detect, resulting in typical limits of detection of 100 to 1,000 CFU/mL, which is insufficient for species-specific sepsis diagnostics.

Blood culture-based diagnostics have substantial limitations, including:

- **Time to Result Delays Targeted Treatment.** Blood culture-based diagnostics typically require a minimum of one and as many as six or more days to identify a pathogen species, and blood culture always requires at least five days to generate a negative test result.
- **Antimicrobial Therapy Can Cause False Negative Results.** Antimicrobial therapies may be administered to a patient prior to taking a blood sample. As a result, the therapeutic agent is contained in the blood sample and its ability to stop or slow the growth of pathogens can delay or completely inhibit the growth of the pathogen during the blood culture process leading to time delays in detection or false negative results.

- **Slow-Growing Pathogens Can Cause False Negative Results.** Some sepsis pathogens grow slowly or not at all and can require up to five or more days to reach sufficient concentrations to be detected by blood culture-based diagnostics. Blood culture procedures are typically stopped after five days and declared negative. Often, pathogens that grow too slowly are not detected by blood culture during this time frame, leading to a false negative diagnosis. For example, *C. glabrata*, one of the most lethal species of *Candida* due to its growing resistance to antifungal therapy, often requires more than five days of growth to reach a detectable concentration, and therefore is frequently undetected by blood culture.
- **Labor-Intensive Workflow Increases Costs and May Delay Targeted Treatment.** Blood culture is only the first step in identifying a pathogen that causes sepsis. After a blood culture is determined to be positive, highly trained technicians are required to perform multiple post-culture procedures on the blood culture specimen to identify the specific pathogen. These additional procedures can be expensive and time-consuming and may delay targeted treatment.

Given the typical one-to-six day time to result for blood culture-based diagnostics, the first therapy for a patient at risk of sepsis is often broad-spectrum antibiotics, which treat some but not all bacteria types and do not address fungal infections. Some physicians may use first-line, antifungal therapy for patients at very high risk for fungal infection, or use antifungal therapy if the patient is not responding to broad-spectrum antibiotics while they are still awaiting the blood culture-based result. This therapeutic approach may still not treat the growing number of patients infected with the antimicrobial-resistant species nor may it be the best choice, as the type of therapy is dependent on the specific pathogen causing the infection, which is unknown.

This inefficient therapeutic approach has resulted in unnecessary treatment of a significant number of high-risk patients with expensive and often toxic therapies that can worsen a patient's condition. Such treatments may extend for many days while clinicians await blood culture-based diagnostic results. The overuse of ineffective, or even unnecessary, antimicrobial therapy is also a driving force behind the spread of antimicrobial-resistant pathogens, which the CDC recently called "one of our most serious health threats." The CDC has specifically noted increasing incidence of *Candida* infections due to azole- and echinocandin-resistant strains and considers it a "serious" threat level. According to the CDC, at least two million people in the United States acquire serious infections each year that are resistant to one or more of the antimicrobial therapies used to treat these patients. At least 23,000 of these people are estimated to die as a direct result of the resistant infections and many more may die from other conditions that are complicated by a resistant infection. Further, antimicrobial-resistant infections add considerable and avoidable costs to the already overburdened U.S. healthcare system, with the total economic cost estimated to be as high as $20 billion in excess of direct healthcare costs, with additional costs to society as high as $35 billion, due to lost productivity.

Our T2Biosystems Product Portfolio

We believe T2MR delivers what no conventional technology currently available can: a rapid, sensitive and simple diagnostic platform to enable sepsis applications that can identify specific sepsis pathogens directly from an unpurified blood sample in hours instead of days at a level of accuracy equal to or better than blood culture-based diagnostics. The addition of the use of our products, T2Bacteria and T2Candida, with the standard of care for the management of patients suspected of sepsis enables clinicians to potentially treat 90% of patients with sepsis pathogen infections with the right targeted therapy within the first twelve hours of developing the symptoms of disease. Currently, high risk patients are typically initially treated with broad spectrum antibiotic drugs that typically cover approximately 60% of patients with infections. Of the remaining 40% of patients, approximately 30% of the patients have a bacterial infection and 10% have *Candida* infections. T2Candida and T2Bacteria are designed to identify pathogens commonly not covered by broad spectrum antibiotic drugs.

We believe our products provide a pathway for more rapid and targeted treatment of infections, potentially reducing the mortality rate by as much as 50% if a patient is treated within 12 hours of suspicion of infection and significantly reducing the cost burden of sepsis. Each year, more than 270,000 patients in the United States die from sepsis. According to a study published by *Critical Care Medicine* in 2006, in sepsis patients with documented hypotension, administration of effective 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%. According to such study, the survival rate for septic patients who remained untreated for greater than 36 hours was approximately 5%. The toll of sepsis on a patient's health can be severe: more than one-in-five patients die within two years as a consequence of sepsis. Sepsis is also the most prevalent and costly cause of hospital readmissions.

We believe the T2Biosystems Product Portfolio addresses a significant unmet need in *in vitro* diagnostics by providing:

- **Limits of Detection as Low as 1 CFU/mL.** T2MR is the only technology currently available that can enable identification of sepsis pathogens directly from a patient's blood sample at limits of detection as low as 1 CFU/mL.
- **Rapid and Specific Results in as Few as Three Hours.** T2MR is the only technology that can enable species-specific results for pathogens associated with sepsis, directly from a patient's blood sample, without the need for blood culture, to deliver an actionable result in three hours.

- **Accurate Results Even in the Presence of Antimicrobial Therapy.** T2MR is the only technology that can reliably detect pathogens associated with sepsis, including slow-growing pathogens, such as *C. glabrata*, directly from a patient's blood sample, even in the presence of an antimicrobial therapy.
- **Easy-to-Use Platform.** T2MR eliminates the need for sample purification or extraction of target pathogens, enabling sample- to-result instruments that can be operated on-site by hospital staff, without the need for highly skilled technicians.

Our first U.S. Food and Drug Administration, or FDA-cleared products, the T2Dx and T2Candida, focus on the most lethal form of common blood stream infections that cause sepsis, *Candida*, which has an average mortality rate of approximately 40%. According to a 2005 report published in Antimicrobial Agents and Chemotherapy, this high mortality rate 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.

We believe that by identifying the specific species of *Candida*, physicians can administer the most effective therapy, significantly improving patient outcomes and reducing hospital costs. We further believe that the adoption of the T2Dx and T2Candida can decrease both the high mortality rate and excessive costs 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.

T2Bacteria, a multiplex diagnostic panel that detects the major bacterial pathogens associated with sepsis that are frequently not covered by first-line antibiotics, is FDA-cleared in the United States and CE-Marked and available commercially in Europe and other countries that accept the CE mark. T2Bacteria runs on the T2Dx and addresses the same approximately 6.75 million symptomatic high-risk patients as T2Candida while also expanding our reach to an additional two million people presenting with symptoms of infection in the emergency room setting. We believe that these factors make the United States market opportunity for T2Bacteria over $1.0 billion, and that T2Bacteria has the potential to achieve similar performance capabilities and provide similar benefits as T2Candida.

On August 2, 2019, CMS granted approval for an NTAP payment for the T2Bacteria Panel for fiscal year 2020. In its fiscal 2020 inpatient prospective payments system final rule, CMS explained: "the T2Bacteria Test 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." With this designation, hospitals in the United States treating Medicare inpatients with sepsis will now be eligible for an NTAP, in addition to the standard payment amount. In the final rule, CMS determined a maximum NTAP amount of $97.50 for the T2Bacteria Panel in addition to the diagnosis-related group (MS-DRG)-based reimbursement that hospitals receive under the Medicare Hospital Inpatient Prospective Payment System (IPPS). Hospitals were eligible for the NTAP payment for any in-patient T2Bacteria Panel tests performed on Medicare patients beginning October 1, 2019. The maximum NTAP reimbursement for a qualifying case involving the use of the T2Bacteria Panel is $97.50, (65 percent of the list price of one T2Bacteria Panel test) in addition to the standard hospital payment under the appropriate sepsis MS-DRG codes. According to CMS there are more than 30 million Medicare patients in the United States enrolled in Medicare fee-for-service.

Clinical Utility

T2Candida

DIRECT Clinical Trial—Clinical Infectious Disease

In 2013 and 2014, we conducted a pivotal clinical trial for our T2Dx Instrument and T2Candida, or the DIRECT trial. Our DIRECT trial consisted of two patient arms. The first arm, known as the Prospective Arm, consisted of 1,501 samples from patients with a possible infection. The second arm, known as the Contrived Arm, consisted of 300 samples, of which 250 patient specimens were labeled contrived because each contained a known quantity of *Candida* CFUs that were manually added to each sample, or spiked, at clinically relevant concentrations, while the remaining 50 patient specimens were specifically known not to contain *Candida*. The DIRECT trial was designed to evaluate the sensitivity and specificity of T2Candida on the T2Dx.

Sensitivity is the percent concordance, or the percentage of sample results that agree with a reference, or comparative, method for positive results. Specificity is the percent concordance to a reference method for negative results. If a sample does not agree with the result of a referenced method, it is considered discordant. In our clinical trial, the Prospective Arm was compared to blood culture and the Contrived Arm was compared to the known state, which means that it was in the known presence or absence of added *Candida* organisms.

The design of the DIRECT trial was reviewed by the FDA as part of pre-submission communications. The purpose of the DIRECT trial was to determine the clinical performance of T2Candida running on the T2Dx by identifying the following:

- clinical specificity of T2Candida results as compared to *Candida* negative blood culture results in specimens collected from patients in the Prospective Arm;
- clinical specificity of T2Candida results as compared to *Candida* negative samples collected from patients in the Contrived Arm;
- clinical sensitivity of T2Candida results as compared to the known *Candida*-positive specimens collected from patients in the Contrived Arm; and
- clinical sensitivity calculations of T2Candida results compared to the *Candida*-positive blood culture results in specimens collected from patients in the Prospective Arm.

50 known negative samples and 250 contrived samples (50 samples for each of the five *Candida* species included in the T2Candida Panel) were prepared and run in a blinded manner at the same clinical sites used for processing the prospective samples. The positive contrived samples were prepared by spiking clinical isolates into individual patient specimens at concentrations determined through publications and discussions with the FDA to be equivalent to the clinical state of patients who presented with symptoms of a *Candida* infection. 20% of the positive contrived samples were spiked at concentrations levels of less than 1 CFU/mL. The contrived samples were collected from patients referred for a diagnostic blood culture per routine standard of care — the same population of patients from whom prospective samples were collected. Unique isolates of the species were used for each patient sample, which means a total of 50 unique isolates were tested for each of the five species of *Candida* for a total of 250 unique isolates.

In addition to the pivotal clinical trial data that we submitted to the FDA, we also provided data from an analytical verification study to determine the limit of detection, or LoD, for each species identified by our T2Candida. The LoD was defined as the lowest concentration of *Candida* that can be detected in 95% of at least 20 samples tested at a single concentration.

The T2Candida Panel reports three results, where species are grouped together according to their responsiveness to therapy. *Candida albicans* and/or *Candida tropicalis* are reported as a single result, *Candida parapsilosis* is a single result, and *Candida krusei* and/or *Candida glabrata* are reported as a single result. Specificity and sensitivity are calculated for each reported result.

There are five relevant species of *Candida*, each of which were analyzed in the DIRECT trial. Each are listed in abbreviated form in the tables below. These species are *Candida albicans*, *Candida tropicalis*, *Candida parapsilosis*, *Candida krusei*, and *Candida glabrata*. The typical naming convention for a species is to abbreviate by using the first letter of the first word and the full second word; for example, *Candida krusei* is abbreviated as *C. krusei*. In the tables below, we also abbreviate each species name by the first letter of the second word; for example, *Candida albicans* and *Candida tropicalis* is A/T.

The following tables illustrate the results of the DIRECT trial. The primary sensitivity and specificity analysis is presented in Table A, followed by sub-analyses in Tables B and C. Additional data on the LoD and the time to results of T2Candida and the T2Dx are included in the remaining tables.

Table A
T2Candida Performance Characteristics

	Overall Sensitivity	Overall Specificity
Number of Tests (%)	234/257 (91.1%)	5114/5146 (99.4%)

Table B
Overall Sensitivity and Specificity by Test

		95% Confidence Interval	
Specificity:			
A/T *(C. albicans/C. tropicalis)*	1679/1697 (98.9%)	98.3 -	99.4%
P *(C. parapsilosis)*	1736/1749 (99.3%)	98.7 -	99.6%
K/G *(C. krusei/C. glabrata)*	1699/1700 (99.9%)	99.7 -	100.0%
Total:	5114/5146 (99.4%)	99.1 -	99.6%
Sensitivity:			
A/T *(C. albicans/C. tropicalis)*	96/104 (92.3%)	85.4 -	96.6%
P *(C. parapsilosis)*	49/52 (94.2%)	84.1 -	98.8%
K/G *(C. krusei/C. glabrata)*	89/101 (88.1%)	80.2 -	93.7%
Total:	234/257 (91.1%)	86.9 -	94.2%

Table C
Study Arm Sensitivity and Specificity by Test

		95% Confidence Interval	
Specificity (Prospective tests):			
A/T *(C. albicans/C. tropicalis)*	1479/1497 (98.8%)	98.1 -	99.3%
P *(C. parapsilosis)*	1487/1499 (99.2%)	98.6 -	99.6%
K/G *(C. krusei/C. glabrata)*	1499/1500 (99.9%)	99.6 -	100.0%
Total:	4465/4496 (99.3%)	99.0 -	99.5%
Sensitivity (Prospective tests):			
A/T *(C. albicans/C. tropicalis)*	2/4 (50.0%)	6.8 -	93.2%
P *(C. parapsilosis)*	2/2 (100.0%)	15.8 -	100.0%
K/G *(C. krusei/C. glabrata)*	1/1 (100.0%)	2.5 -	100.0%
Total:	5/7 (71.4%)	29.0 -	96.3%
Specificity (Contrived tests):			
A/T *(C. albicans/C. tropicalis)*	200/200 (100.0%)	98.2 -	100.0%
P *(C. parapsilosis)*	249/250 (99.6%)	97.8 -	100.0%
K/G *(C. krusei/C. glabrata)*	200/200 (100.0%)	98.2 -	100.0%
Total:	649/650 (99.8%)	99.1 -	100.0%
Sensitivity (Contrived tests):			
A/T *(C. albicans/C. tropicalis)*	94/100 (94.0%)	87.4 -	97.8%
P *(C. parapsilosis)*	47/50 (94.0%)	83.5 -	98.7%
K/G *(C. krusei/C. glabrata)*	88/100 (88.0%)	80.0 -	93.6%
Total:	229/250 (91.6%)	87.4 -	94.7%

Table D
T2Candida Limit of Detection

Species	Final LoD CFU/mL
C. albicans	2
C tropicalis	1
C. parapsilosis	3
C. glabrata	2
C. krusei	1

Table E
Sensitivity Sub-Analysis: Sensitivity by Species Relative to LoD

		≥ LoD			< LoD		
	LoD (CFU/ml)	Sensitivity	95% Confidence Interval		Sensitivity	95% Confidence Interval	
C. albicans	2	39/39 (100.0%)	91.0 -	100.0%	9/11 (81.8%)	48.2 -	97.7%
C. glabrata	2	35/37 (94.6%)	81.8 -	99.3%	7/13 (53.8%)	25.1 -	80.8%
C. krusei	1	40/40 (100.0%)	91.2 -	100.0%	6/10 (60.0%)	26.2 -	87.8%
C. parapsilosis	3	32/32 (100.0%)	89.1 -	100.0%	15/18 (83.3%)	58.6 -	96.4%
C. tropicalis	1	38/40 (95.0%)	83.1 -	99.4%	8/10 (80.0%)	44.4 -	97.5%
Total:		184/188 (97.9%)	94.6 -	99.4%	45/62 (72.6%)	59.8 -	83.1%

Table F
Sensitivity Sub-Analysis: Sensitivity by Titer Level

	<1 CFU/ml Sensitivity	1 — 10 CFU/ml Sensitivity	11 — 30 CFU/ml Sensitivity	31 — 100 CFU/ml Sensitivity
C. albicans	8/10 (80.0%)	18/18 (100.0%)	17/17 (100.0%)	5/5 (100.0%)
C. glabrata	5/10 (50.0%)	16/18 (88.9%)	16/17 (94.1%)	5/5 (100.0%)
C. krusei	6/10 (60.0%)	18/18 (100.0%)	17/17 (100.0%)	5/5 (100.0%)
C. parapsilosis	8/10 (80.0%)	17/18 (94.4%)	17/17 (100.0%)	5/5 (100.0%)
C. tropicalis	8/10 (80.0%)	16/18 (88.9%)	17/17 (100.0%)	5/5 (100.0%)
Total:	35/50 (70.0%)	85/90 (94.4%)	84/85 (98.8%)	25/25 (100.0%)

Table G
Sensitivity Sub-Analysis: Sensitivity by Species Relative to Clinically Relevant Concentrations

Species	Clinically Relevant Concentration	Sensitivity ≤ Relevant CFU	Sensitivity ≥ Relevant CFU
C. tropicalis	1-10 CFU/mL	80%	95%
C. krusei	11-30 CFU/mL	85.7%	100%
C. glabrata	11-30 CFU/mL	75%	96%
C. albicans	1-10 CFU/mL	80%	100%
C. parapsilosis	11-30 CFU/mL	89.3%	100%
Total		82.7%	98%

Table H
Time to species identification or negative result for T2MR and Blood Culture

	Blood Culture	T2Dx
Time to Results (hours)		
Mean ± SD (N)	126.5 ± 27.3 (1470)	4.2 ± 0.9 (1470)
Median	121.0	4.1
(Min, Max)	(12.4, 247.2)	(3.0, 7.5)
Time to Positive Results(1),(2) (hours)		
Mean ± SD (N)	43.6 ± 11.1 (4)	4.4 ± 1.0 (4)
Median	46.1	4.6
(Min, Max)	(28.1, 54.1)	(3.2, 5.4)
Time to Negative Results(1),(2) (hours)		
Mean ± SD (N)	126.7 ± 27.0 (1466)	4.2 ± 0.9 (1466)
Median	121.1	4.1
(Min, Max)	(12.4, 247.2)	(3.0, 7.5)

(1) Includes samples that are 100% concordant for both methods (i.e. does not include discordant results). We do not include discordant results because a comparison of the duration of time to positive result requires that both the blood culture result and the T2Candida result be positive for a given specimen. Similarly, a comparison of the duration of time to negative result requires that both the blood culture result and the T2Candida result be negative for a given specimen. We therefore would exclude any sample with a discordant result where blood culture yields one result and T2Candida yields the opposite result.

(2) Refers to time to species identification or final negative result.

Results from the study were published in *Clinical Infectious Disease* in 2015 in an article entitled: "T2 Magnetic Resonance Assay for the Rapid Diagnosis of Candidemia in Whole Blood: A Clinical Trial." The study findings include:

- the overall sensitivity (Prospective and Contrived Arm combined) of T2Candida was 91.1%;
- the average specificity of the three test results for the Prospective and Contrived Arms combined was 99.4% (see Table A) with the specificity by test result ranging from 98.9% to 99.9% (see Table B);
- in the Contrived Arm of the study, the average specificity was 99.8%, with the specificity by test result ranging from 99.6% to 100% (see Table C);
- in the Prospective Arm of the study, the average specificity was 99.3%, with the specificity by test result ranging from 98.8% to 99.9% (see Table C);
- in the Contrived Arm of the study, the average sensitivity was 91.6%, with the sensitivity by test result ranging from 88.0% to 94.0% (see Table C); and
- in the Prospective Arm of the study, the average sensitivity was 71.4% (see Table C).

In this study, the following observations were reported:

- within the Prospective Arm, T2Candida accurately detected a rare co-infection in one study patient with *C. albicans* and *C. parapsilosis* in their bloodstream;
- T2Candida detected at least one infection that was not identified by blood culture, which was determined to be a *Candida* infection seven days after the T2Candida result was obtained. This case is considered a discordant result for the purposes of the FDA filing because of the disagreement between T2Candida and the blood culture-based results, despite the accurate identification by T2Candida. Along with ten other patients with clinical symptoms or microbiological evidence of infection, the study findings indicate that the true sensitivity and specificity of T2Candida may be higher than the reported values;
- the LoD of T2Candida was demonstrated to be 1 to 3 CFU/mL depending upon the species of *Candida* (see Table D). In the Contrived Arm of the study, T2Candida positively detected 97.9% of the samples spiked at and above the LoD while also detecting 72.6% of all samples spiked at concentration levels below the LoD (see Table E);
- in the Contrived Arm of the study, T2Candida detected 97% of cases at or above 1 CFU/mL and 70% of cases below 1 CFU/mL (see Table F);
- in the Contrived Arm of the study, T2Candida detected 98% of cases at or above clinically relevant concentrations of *Candida*, ranging from 95% to 100% detection depending on the *Candida* species (see Table G);
- T2Candida demonstrated an average time to positive result of 4.4 hours compared to blood culture average time to result of 129 hours;

- T2Candida demonstrated an average time to negative result of 4.2 hours compared to blood culture average time to result of >120 hours; and
- T2Candida has a negative predictive value of 99.8% in a standard population. Negative predictive value is the probability that subjects with a negative result truly do not have the disease.

The authors of the study made the following conclusions based on the study results:

- Because mortality due to invasive candidiasis has remained high and unchanged for the past two decades and early initiation of appropriate antifungal therapy has been reported to reduce mortality by at least two-thirds, the rapid and accurate diagnostic capability offered by this novel technology has the potential to change the management and prognosis of the disease.
- The ability to rapidly and accurately exclude the possibility of candidemia can have significant implications in clinical practice, by decreasing the number of patients who need to be on empiric antifungal therapy, and thus decreasing the incidence of resistant strains, the potential of side effects of antifungal treatment, and substantial healthcare costs.
- A key advantage of T2MR over other biosensors is that it does not require culture and sample purification or preparation.

Massachusetts General Hospital Study — Science Translational Medicine

We co-authored a study with investigators from Massachusetts General Hospital, or MGH, to evaluate the sensitivity and specificity of T2MR to detect *Candida* compared to blood culture-based diagnostics. Results from the study were published in an article entitled "T2 Magnetic Resonance Enables Nanoparticle-Mediated Rapid Detection of Candidemia in Whole Blood" in *Science Translational Medicine* in 2013. In this study:

- T2MR was tested across 320 contrived whole blood samples, each containing one of the five clinically relevant species of *Candida*, and was able to detect each of the species at a LoD ranging from 1 to 3 CFU/mL.
- T2MR was tested across 24 whole blood specimens from patients exhibiting symptoms of sepsis, with eight *Candida* positive, eight bacteria positive and eight negative samples. Results showed 100% sensitivity and 100% specificity of T2MR when compared with blood culture results for identification of *Candida*.
- In patients with *Candida* treated with antifungal therapy, T2MR detected the presence of *Candida* in patient samples drawn up to four days after antifungal administration, while blood culture failed to identify the infection upon administration of antifungal therapy.

University of Houston Study — Diagnostic Microbiology and Infectious Disease

We sponsored an independent study at the University of Houston to directly compare the sensitivity and time to result of T2Candida running on the T2Dx and blood culture-based diagnostics. In this study, contrived blood samples were split between T2Candida using the T2Dx and standard blood culture. The study showed improved performance of T2Candida over blood culture in terms of speed and sensitivity. The following findings were published in an article entitled "Comparison of the T2Dx Instrument with T2Candida Diagnostic Panel and Automated Blood Culture in the Detection of *Candida* Species Using Seeded Blood Samples" in *Diagnostic Microbiology and Infectious Disease* in 2013:

- T2Candida detected all of the samples of *C. glabrata* at concentrations of 2.8 CFU/mL, while blood culture was not able to detect *C. glabrata* in any of the samples, even at a higher concentration of 11 CFU/mL and with the standard five-day run time.
- T2Candida detected all of the samples for all of the species of *Candida* at concentration levels of 3.1 to 11 CFU/mL.
- The average time to species identification was approximately three hours for T2Candida, as opposed to over 60 hours for blood culture.

The following table summarizes the results of our University of Houston study. The five relevant species of *Candida* were analyzed in the University of Houston study.

Contrived blood samples at concentrations between 3.1 — 11 CFU/mL

	Blood Culture (n=20 per species)			T2Candida (n=13-20 per species)		
Average time to positive result	63.23 ± 30.27 hours			3 hours		
Detection rate	*C. albicans*	=	100%	*C. albicans*	=	100%
	C. tropicalis	=	100%	*C. tropicalis*	=	100%
	C. parapsilosis	=	100%	*C. parapsilosis*	=	100%
	C. glabrata	=	0%	*C. glabrata*	=	100%
	C. krusei	=	100%	*C. krusei*	=	100%
Sensitivity				100%		
Specificity				98%		

Clinical Data Review of T2MR and T2Candida—Future Microbiology

Dr. Michael Pfaller (former T2 Biosystems Chief Medical Officer), Donna Wolk, PhD (Geisinger Health System), and Tom Lowery, PhD (T2 Biosystems' former Chief Scientific Officer) collaborated to perform a meta-analysis of T2MR and T2Candida data that was published in *Future Microbiology* in 2015 with the title *T2MR and T2Candida: novel technology for the rapid diagnosis of candidemia and invasive candidiasis.* The article had the following overall summary statements and conclusions:

- There is an urgent need to rapidly and accurately detect and identify fungal pathogens. Current culture-based methodologies are too slow and, with some organisms like *C. glabrata*, may fail altogether due to the insensitivity of some blood culture systems to detect this slow-growing species.
- The development and FDA approval of T2Candida represents the advent of a new class of infectious disease diagnostics that enable rapid, direct detection and identification of pathogens in a culture-independent manner. The new panel will reduce the time to detection and species identification for common *Candida* species.
- As of the date of publication of the article, the T2Candida Panel had identified over 31 cases of candidemia and 12 cases of candidiasis. In the latter 12 cases, blood culture was unable to detect any of those proven infections. There were an additional ten patients with probable or suspected invasive candidiasis, but patient record review was not available to include these cases. More specifically, across all studies to date, T2Candida had successfully detected 43 of 45 patients with confirmed candidemia (31/33) or candidiasis (12/12). When including patients with probable candidiasis, T2Candida detected 10 of 10 patients, totaling 53 of 55 cases detected for candidemia or candidiasis. In this aggregate population, blood culture only detected 33 of 55 patients. Table 7 from the article summarizes the data showing increases in sensitivity for T2Candida vs. blood culture.

Table 7. Summary of T2Candida detection of invasive candidiasis and candidemia.

Disease detected	T2Candida	Blood culture	Total *Candida* infections
Candidemia	31	33	33
Invasive candidiasis	12	0	12
Probable or suspected invasive candidiasis	10	0	10
Total cases	53	33	55
Sensitivity	96.4% (53/55)	60% (33/55)	

- Across all studies to date, T2Candida had an overall specificity of greater than 99.4% from more than 1,560 patients.
- Application of the T2Candida Panel facilitates the diagnosis of candidemia and other forms of invasive candidiasis and promises to have major clinical impact resulting from the diagnosis of previously unrecognized, deep-seated candidiasis as well as from the 'real-time' (hours) detection of candidemia. The earlier species-level diagnosis provided by T2Candida will allow targeted pre-emptive antifungal therapy which should result in a decrease in *Candida* -associated morbidity, mortality, and excess length of stay in the hospital and at the same time reduce unnecessary empiric antifungal therapy. T2Candida provides breakthrough performance in the detection and identification of *Candida* direct from patient samples and may significantly impact patient mortality and hospital costs.

DIRECT2 Pivotal Clinical Trial – Clinical Infectious Diseases

The DIRECT2 study, published in *Clinical Infectious Diseases*, was a multi-center study involving 14 sites and evaluated the performance of T2Candida and blood culture in N=152 candidemic patients. T2Candida detected 89% of infections across this patient population, validating the 91.1% clinical sensitivity reported from the FDA pivotal study for the T2Candida in a much larger patient population. Additionally, T2Candida detected almost twice as many confirmed infections as blood culture in patients receiving antifungal therapy. This indicates that T2Candida is a more effective diagnostic tool for patients treated with pre-emptive or empiric antifungal therapy. Consistent with other studies, the time savings afforded by T2Candida was significant. The median time to detection of *Candida* by diagnostic blood cultures and subsequent species identification was 3.4 days. In comparison, T2Candida provides diagnostic results in an average time of 4.4 hours. The authors noted that T2Candida "ushers in a new era in which rapid molecular testing for invasive candidiasis will serve as an adjunct to microbiologic cultures."

STAMP Study – Journal of Clinical Microbiology

The STAMP study, published in the *Journal of Clinical Microbiology*, compared blood culture to T2Candida for monitoring the clearance of an infection when a patient is being treated with antifungal drugs. The study demonstrated that T2Candida can detect the ongoing presence of a *Candida* infection while blood culture often yields false negative test results because the administration of antifungal drugs can impede the growth of cells that blood culture requires to detect an infection. These observations are consistent with the DIRECT2 study. The authors concluded that T2Candida can be an effective tool for reliably identifying patients that have cleared an infection, which can reduce the unnecessary and expensive antifungal therapy. The STAMP study evaluated running multiple diagnostic tests for patients with confirmed *Candida* infections who were receiving antifungal drugs. The study demonstrated that T2Candida outperforms blood culture for monitoring the clearance of *Candida* infections.

- T2Candida was positive in 23 patient samples, compared to only 7 for blood culture in cases of true infection.
- T2Candida identified every infection that was detected by blood culture and provided actionable results 3 days earlier than blood culture.
- T2Candida detected a *Candida* infection that blood culture missed in one patient during the study.
- T2Candida results were a better indicator of disease clearance than blood culture, as two consecutive T2Candida negative results indicated that the patient no longer had an active infection in the blood that required aggressive management.
- STAMP study data suggest that serial testing of patients with the T2Candida Panel may enable more timely management of infections, de-escalation of therapy, better source control and overall reduced costs of care.

T2 Magnetic Resonance Assay Improves Timely Management of Candidemia – The Journal of Antimicrobial Stewardship

Another study published in *The Journal of Antimicrobial Stewardship* entitled "T2 Magnetic Resonance Assay Improves Timely Management of Candidemia" compared the management of candidemic patients before and after the implementation of T2Candida and was designed to evaluate time to appropriate therapy. Patients tested with the T2MR platform were treated in a median of 5 hours, a more than 8-fold reduction as compared to that based on blood culture, which delayed appropriate therapy by a median of 44 hours. This speed advantage demonstrates that the T2MR platform may be a valuable clinical tool to aid antifungal stewardship's goal to deliver timely antifungal therapy for infected patients. In addition to speed, the use of the T2MR platform provided increased identification of *Candida* infections. Consistent with the performance of blood culture and T2MR published in other studies, the *Candida* species was definitively identified in 93% of patients after implementation of T2MR and in only 57% of patients prior to implementation of T2MR. Prior to implementation of T2Candida, the only diagnostic tests used at Henry Ford Health System were blood culture and beta-D-glucan (BDG). The authors also identified an additional clinically relevant improvement in patient outcomes after the implementation of T2MR: a significant reduction of *Candida* ocular involvement from 30% to 12% was observed. The authors point out this could be associated with improved sensitivity of T2MR or due to improved timeliness of patient management by T2MR. Although the study was not adequately powered to evaluate reduction in patient mortality rates, the authors note that appropriately treating patients within 24 hours of the onset of disease is proven to reduce mortality rates from 41% to below 16%. T2MR is the only diagnostic method presented in this study with the speed and accuracy necessary to enable therapeutic decisions that achieve this reduction in mortality.

Customer Presentations

Since receiving FDA clearance in 2014, customers have regularly reported on their experiences with T2Candida at conferences and in publications. Below is a summary of some those reports.

- Investigators at the Henry Ford Health System reported data that demonstrated that after the implementation of T2Candida in their hospital system, the hospital system projected that it may save an estimated $2.3M annually, reduced median ICU length of stay by seven days per patient (p=0.009), and reduced total length of stay by four days per patient (p=0.164). Additionally, 75% of negative patients had antifungals discontinued or deescalated.

- Investigators at the Lee Health System reported that after the implementation of T2Candida, they have experienced a reduction in the average length of stay per patient by 7 days, unnecessary antifungal therapy was avoided in 41% of patients, and unnecessary antifungal therapy was discontinued after 1 dose in another 15% of patients, and the average net antifungal savings was $195 for every patient tested with T2Candida.
- Investigators at Riverside Community Hospital reported that implementation of T2Candida led to therapy being discontinued for 100% of patients who tested negative, and for patients who tested positive and had not been on antifungals prior to testing, 83% of patients who tested positive received appropriate therapy within six hours of blood drawing and 100% within nine hours of blood draw.
- Investigators at the University Di Roma reported that T2Candida detected invasive candidiasis that were not identified by blood culture. T2Candida identified three cases of *C. albicans* and one case of *C. glabrata* that were proven accurate with additional *in vitro* diagnostic testing and diagnostic imaging.
- An investigator from Rigshospitalet, Denmark evaluated the performance of T2Candida, Mannan Ag and blood culture for diagnosis of invasive candidiasis infections across 126 patients. The sensitivity for invasive candidiasis was higher for T2Candida compared to blood culture and Mannan Ag and the positive predictive value was highest for T2Candida.
- Investigators from Bambino Gesu Pediatrics Hospital in Rome, Italy presented a comparison of T2Candida, SeptiFast and blood culture in pediatric and neonatal patients showing an 89% concordance between blood culture and T2MR.
- Investigators in Detroit, Michigan evaluated the impact of utilizing T2Candida on anti-fungal de-escalation in patients with malignancy/chemotherapy, transplant, and immunosuppression. T2Candida testing decreased turnaround time for results from 4 days to 6 hours compared with blood culture. For *C. albicans/tropicalis*, 50% of patients were de-escalated to fluconazole in 4 days.
- Investigators in Huntsville, Alabama evaluated the utility of T2Candida for managing candidemia at a large community hospital, comparing 89 patients diagnosed using T2Candida to 163 patients diagnosed using blood culture. Candidemia was detected in an average of 9 hours with T2Candida vs 41 hours with blood culture. Antifungal therapy was initiated within 4 hours with T2Candida vs 37 hours with blood culture. The same group evaluated the impact of T2Candida on antifungal stewardship in a 900 bed hospital. The patient population included critical care and febrile neutropenic patients. 628 T2Candida results were evaluated. Antifungal therapy was avoided in 60.4% of negative cases. Additionally, antifungal optimization occurred in 54% of patients on antifungals at the time of test.

T2Bacteria

T2Bacteria Panel Pivotal Clinical Study Information

On May 24, 2018, we received market clearance from the FDA for T2Bacteria, a multiplex diagnostic panel that runs on the T2Dx instrument and detects five major bacterial pathogens associated with sepsis and, in conjunction with T2Candida and standard empiric therapy regimens, may enable the early, appropriate treatment of 90% of sepsis patients. T2Bacteria addresses the same approximately 6.75 million symptomatic high-risk patients as T2Candida and also a new population of patients who are at increased risk for bacterial infections, including an additional two million patients presenting with symptoms of infection in the emergency room setting.

On August 4, 2017 we completed a pivotal clinical study of T2Bacteria, which is a qualitative T2MR assay designed for the direct detection of bacterial species in human whole blood specimens from patients with suspected bacteremia. T2Bacteria is designed to identify five species of bacteria directly from human whole blood specimens: *Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa,* and *Staphylococcus aureus.* Outside of the United States, the CE marked T2Bacteria panel identifies all 5 of these species along with a 6th species, *Acinetobacter baumannii*.

To the extent that T2Bacteria is performed on an outpatient basis, third-party payors may separately reimburse our customers using existing CPT codes for patients who are not admitted to the hospital. By way of example, Medicare payment for outpatient clinical laboratory services is the lesser of the amount billed, the local fee for a geographic area, or the national limit established by the CMS under the Clinical Laboratory Fee Schedule, or CLFS, on an annual basis. For 2020, the national limit for the series of CPT codes used to bill T2Bacteria is approximately $175. Effective January 1, 2018, CLFS rates are based on weighted median private payor rates as required by the Protecting Access to Medicare Act of 2014. We believe 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 diagnostic products or additional pricing pressures.

The performance characteristics of T2Bacteria were evaluated through a series of analytical studies as well as a multi-center clinical study. The clinical study evaluated the performance of T2Bacteria in comparison to the current standard of care, blood culture.

The clinical study consisted of two arms, a prospective arm and a seeded arm. In the prospective arm, a total of 1,427 subjects were tested at eleven geographically dispersed and demographically diverse sites in the United States. In the seeded arm, 300 specimens of known bacterial composition were evaluated at three sites. Seeded specimens were prepared by spiking whole blood with multiple strains of the bacterial species detected by T2Bacteria at defined concentrations (CFU/mL). Fifty negative blood samples also were evaluated as part of the seeded arm of the study. In total, 1,777 (1,427 prospective specimens and 350 seeded and negative) clinical samples were tested to evaluate the clinical performance of T2Bacteria.

Data from the pivotal clinical trial was presented at the Association of Molecular Pathology annual meeting in November 2017. Results from the trial demonstrated that T2Bacteria can deliver actionable results in an average of 5.4 hours, compared to an average of 60 hours for detecting the same species by blood culture. In addition, T2Bacteria identified 63 infected patients that were missed by the paired blood culture that was simultaneously run. The reported sensitivity was 96%, compared to a sensitivity of 38% for the paired blood culture as measured by the total of 102 patients with confirmed infections by any culture result. More specifically, the study findings include:

- The overall sensitivity for the prospective and seeded arms combined was 95.8% (see Table I below);
    - In the seeded arm of the study, the average sensitivity was 96.8% (see Table K), with the sensitivity by bacterial target ranging from 90.9% to 100.0% (see Table L);
    - In the prospective arm of the study, the average sensitivity was 89.7% (see Table M), with the sensitivity by bacterial target ranging from 81.3%% to 100.0% (see Table N);
- The average specificity for the prospective and seeded arms combined was 98.1% (see Table I);
    - In the seeded arm of the study, the average specificity of the test was 99.0% (see Table K), with the specificity by bacterial target ranging from 97.3% to 100.0% (see Table L);
    - In the prospective arm of the study the average specificity of the test was 97.9% (see Table M), with the specificity by bacterial target ranging from 95.0% to 99.4% (see Table N);
- In the prospective arm of the study, results that were identified as positive by T2Bacteria but negative by blood culture were evaluated by looking at additional blood culture results obtained +/- 14 days of the paired T2 / blood culture draw. 36% of the T2 positive / blood culture negative results were found to be culture positive for the organism identified by the T2Bacteria Panel within the defined 14 day window (Table N).
- In the prospective arm of the study, four specimens that were identified as negative by T2Bacteria but positive by blood culture were evaluated by running a second archived blood sample. Two of the four samples generated positive results by T2Bacteria that were in agreement with blood culture, one for *S. aureus* and the other for *E.coli*.

Table I: T2Bacteria Panel Overall Performance for Prospective and Seeded Arms

Sensitivity	95% CI	Specificity	95% CI
95.4% (209 / 219)	91.8%-97.5%	97.9% (8,416/8,596)	97.6%-98.2%

Table J: T2Bacteria Panel Combined Performance for Prospective and Seeded Arms

	Sensitivity (PPA)		Specificity (NPA)	
Species	Sensitivity	95% CI	Specificity	95% CI
E. coli	90.9% (30/33)	76.4% - 96.9%	95.4% (1637/1716)	94.3% - 96.3%
E. faecium	100.0% (41/41)	91.4% - 100.0%	99.5% (1717/1726)	99.0% - 99.7%
K. pneumoniae	100.0% (46/46)	92.3% - 100.0%	98.6% (1697/1721)	97.9% - 99.1%
P. aeruginosa	97.7% (43/44)	88.2% - 99.6%	97.7% (1682/1722)	96.9% - 98.3%
S. aureus	89.1% (49/55)	78.2% - 94.9%	98.4% (1683/1711)	97.6% - 98.9%

- PPA (sensitivity) calculated against samples with titer levels at or above limit of detection (LoD) in Seeded Arm and blood culture positives in Prospective Arm
- NPA (specificity) calculated from all samples (including below LoD and unspiked negative samples) as the total number of negative channels divided by total number of non-spiked channels in Seeded Arm and blood culture negatives in Prospective Arm.

Table K: T2Bacteria Panel Seeded Sample Performance

Sensitivity	95% CI	Specificity	95% CI
96.7% (174 / 180)	92.9%-98.5%	98.9% (1,483/1,500)	98.2%-99.3%

- PPA (sensitivity) calculated against samples with titer levels at or above limit of detection (LoD)

Table L: T2Bacteria Panel Seeded Sample Performance

Species	Sensitivity (PPA)		Specificity (NPA)	
	PPA	95% CI	NPA	95% CI
E. coli	90.9% (20/22)	72.2 - 97.5%	97.3% (292/300)	94.8 - 98.6%
E. faecium	100% (40/40)	91.2 - 100%	100% (300/300)	98.7 - 100%
K. pneumoniae	100% (40/40)	91.2 - 100%	99.3% (298/300)	97.6 - 99.8%
P. aeruginosa	97.4% (38/39)	86.8 - 99.5%	97.7% (293/300)	95.3 - 98.9%
S. aureus	92.3% (36/39)	79.7 - 97.3%	100% (300/300)	98.7 - 100%

- PPA (sensitivity) calculated against samples with titer levels at or above limit of detection (LoD)

Table M: T2Bacteria Panel Overall Performance for Prospective Arm

Sensitivity	95% CI	Specificity	95% CI
89.7% (35/39)	76.4%-95.9%	97.7% (6,933/7,096)	97.3%-98.0%

Table N: T2Bacteria Panel Performance as Compared to Blood Culture — Prospective Arm

Species	Sensitivity (PPA)		Specificity (NPA)	
	Sensitivity	95% CI	Specificity	95% CI
E. coli	90.9% (10/11)	62.3 - 98.4%	95.0% (1345/1416)	93.7 - 96.0%
E. faecium	100.0% (1/1)	20.7 - 100%	99.4% (1417/1426)	98.8 - 99.7%
K. pneumoniae	100.0% (6/6)	61.0 - 100%	98.5% (1399/1421)	97.7 - 99.0%
P. aeruginosa	100.0% (5/5)	56.6 - 100%	97.7% (1389/1422)	96.8 - 98.3%
S. aureus	81.3% (13/16)	57.0 - 93.4%	98.0% (1383/1411)	97.1 - 98.6%

Table O: Summary of T2(+)/BC(-) Results in Prospective Arm

Species	T2(+) / BC(-) total	Other Blood Culture positive[1]	Sequencing positive[2]	T2(+) / BC(-) associated with strong evidence of infection[3]	T2(+) / BC(-) associated with other evidence of infection Non-Blood Matrices Culture Positive[4]	T2(+) / BC(-) associated with no evidence of infection
E. faecium	9	2	2	44.4% (4/9)	33.3% (3/9)	22.2% (2/9)
E. coli	63	12	9	33.3% (21/63)	12.7% (8/63)	54.0% (34/63)
K. pneumoniae	22	6	8	63.6% (14/22)	13.6% (3/22)	22.7% (5/22)
P. aeruginosa	33	3	8	33.3% (11/33)	12.1% (4/33)	54.5% (18/33)
S. aureus	28	16	3	67.9% (19/28)	17.9% (5/28)	14.3% (4/28)
Total	**155**	**39**	**30**	**44.5% (69/155)**	**14.8% (23/155)**	**40.7% (63/155)**

[1]Blood cultures positive for the T2 species identified other than the paired blood culture and processed within ± 14 days of collection of the T2 sample.
[2] Sequencing from blood samples drawn at the same time as collection of the T2 sample and positive for the T2 species identified, where this sequencing assay was only run on subjects without positive evidence from other sample sources (footnote 1 and 4).
[3] Strong evidence defined as a T2 positive result associated with a blood culture positive from a different draw than T2 draw or a sequencing positive result from a blood sample drawn concurrently with the T2 draw.
[4] Other cultures from non-blood sample matrices positive for the T2 species identified within ± 14 days of collection of the T2 sample.

Customer Presentations

- Investigators at the Catholic University School of Medicine in Rome, Italy, presented interim data from a study in which T2Bacteria achieved 100% sensitivity and 97% specificity in analytical studies, and in clinical studies, it identified patients with infection in as fast as four hours, while blood culture took up to five days, inclusive of multiple cases where T2Bacteria identified patients missed by blood culture with proven infections.
- Investigators at the Gemelli Hospital in Rome, Italy published a study in the Journal of Antimicrobial Chemotherapy (April 2018) entitled "T2Bacteria magnetic resonance assay for the rapid detection of ESKAPE pathogens directly in whole blood. This prospective study was with 129 adult patients in the ICU and ED. It showed that T2Bacteria achieved faster time to species ID than blood culture, or BC: 5.5h ±1.4h vs. BC 25.2h ± 15.2h (P<0.001) and faster time to negative results 6.1h ± 1.5h vs. BC 120.0h ± 0.0h (p<0.001). Additionally, T2Bacteria performed with a sensitivity and specificity of 90% and 98%, respectively, according to true infection criteria.
- Investigators at Lee Health in Fort Myers, FL reported at MAD-ID in May 2018 a study entitled "Early experience with the T2Bacteria Research Use Only (RUO) Panel at a community hospital". This prospective study was conducted at Lee Health, Fort Myers, FL in 28 adult patients presenting to the ED. It showed that T2Bacteria allowed testing from whole blood samples and provided final results within 4 hours. T2Bacteria provided positive and negative results approximately 20 hours and 122 hours sooner than BCs, respectively (p<0.001). It detected 5 organisms not identified by BC and in these 28 patients greater than 30 opportunities for de-escalation of coverage based on negative results for *S. aureus* or *P. aeruginosa* were identified.
- Another group of investigators presented at ASM Microbe in June 2018 a study entitled "Validation of a rapid diagnostic test on whole blood for early identification of pathogens in patients in the intensive care unit." This a combined prospective and retrospective study conducted by Northwestern University with 91 retrospective samples and 58 prospective samples from patients admitted to the ICU. Overall, T2Bacteria was 87% sensitive and 95% specific for the detection of six different organisms compared to BC; The calculated specificity is limited by comparison to BC because many studies demonstrate that BC itself is poorly sensitive. As further support, T2Bacteria detected organisms in the blood when BC was negative but evidence of infection in the kidney, bone, soft-tissue, intra-abdominal area, or lungs was available; a positive T2Bacteria result in this setting may indicate poor source control, inappropriate antibiotics or poor host defenses.
- Researchers from UPMC presented at ASM Microbe 2018 and ID Week in October 2018 on the pivotal T2Bacteria study in a presentation entitled "Clinical performance of T2Bacteria among patients with bloodstream infections due to five common bacterial species." This pivotal, clinical multicenter prospective trial was conducted in 11 U.S. Centers with 1427 subjects from presenting to the ICU or ED. They further reported in the pivotal study manuscript that overall, T2Bacteria detected ~66% of BSIs, excluding common contaminants. The mean time to BC+ was 38.5h ± 32.8h; the mean time to BC speciation was 71.7h ± 39.3h; mean time to T2B result was 3.6h ± 0.2h – 7.70hr ± 1.38h; T2Bacteria demonstrated 90% per patient specificity in detecting Blood Stream Infection (BSI) and per assay specificity of 90%. The study pointed out that potential advantages of T2Bacteria over Blood Culture include detection of bacteremia several days before Blood Culture (3-5 hours versus 2-3 days), diagnosing infections missed by Blood Culture, identifying patients with incorrect antibiotics and patients with extra-blood site infections.
- At the 2019 ECCMID conference, Dr. Tom Walsh from New York Presbyterian / Cornell Hospital highlighted the clinical utility of T2Bacteria in the hematologic malignancy and stem cell transplant patient population. Within his institution, T2Bacteria showed a 75% positive predictive agreement with blood culture and 98% negative predictive agreement and covered 80% of significant species detected by blood culture.
- Also at ECCMID 2019 and EIM 2019, Dr. Christopher Voigt reported on the performance of T2Bacteria in the emergency department of Ochsner Medical Center and Tampa General Hospital. Data from 137 emergency department patients were evaluated and relative to blood culture, T2Bacteria showed 100% positive percent agreement and 99.2% negative percent agreement. In addition, for species on T2Bacteria, the T2Bacteria assay detected 4 more positive results associated with infection than blood culture, the average time to identification was 56.6 hours faster than blood culture and T2Bacteria covered 70.5% of all species detected by blood culture. A review of the 16 positive results identified by T2Bacteria records revealed, relative to actual care, T2Bacteria could have potentially allowed for focused therapy in 8 patients, potentially reduced time to a species-directed therapy in 4 patients, and potentially reduced time to effective therapy in 4 patients. In this emergency department population, T2Bacteria appeared to be a more rapid and sensitive detector of bacteremia for the most common ESKAPE pathogens (*E. coli, E. faecium, S. aureus, K. pneumoniae, and P. aeruginosa*) and showed the theoretical potential to influence subsequent patient therapy, ranging from antibiotic de-escalation to faster time to effective therapy.
- At ECCMID 2020, several investigators submitted data on T2Bacteria, including the following:
    - Paggi et al evaluated the accuracy and clinical impact of T2Bacteria in 61 patients with sepsis. T2Bacteria demonstrated 100% sensitivity and 94.6% specificity compared to blood culture. The percentage of patients in which antibiotic therapy was switched to targeted therapy the same day as sample collection based on results was significantly higher in patients with positive T2Bacteria results (37.5% vs 11.4%, p = 0.0312). Duration of empirical therapy was also shorter in these patients (34.11 h vs 80.48 h).

- Seitz et al evaluated the clinical impact of T2Bacteria compared to blood culture for the diagnosis of bloodstream infections in 44 patients. T2Bacteria demonstrated 100% sensitivity compared to blood culture. The time from admission to targeted antibiotic therapy was 6.6 with T2Bacteria vs 77.7 with blood culture. Although not statistically significant, length of stay was 2.4 days shorter with T2Bacteria (10.6 days vs 13 days).

- Douka et al reported on an evaluation of the performance of T2Bacteria in 26 ICU patients. Mean time to culture positivity was 84 hours while mean time to T2Bacteria result was 3.5 hours. The negative predictive value of T2Bacteria was 100%

- Kalligeros et al published an in-depth analysis of T2Bacteria positive results in patients with concurrent negative blood culture in BMC Infectious Diseases in 2020. This study was a sub-study of a larger, multi-center clinical trial and reviewed data from one site. Medical records of patients with a positive T2Bacteria and concurrent negative blood culture (discordant results) were reviewed. Of 233 participants, 21 patients were found meeting the above criteria. Discordant results were often associated with patients with closed space and localized infections. 16 out of 20 patients had received an antimicrobial agent active against the T2Bacteria-detected pathogen within the 2 preceding days. In the majority of discrepant results, T2Bacteria detected a plausible pathogen supported by clinical and/or microbiologic data.

T2Resistance

We have also developed the T2Resistance Panel, which detects 13 resistance genes from both gram-positive and gram-negative pathogens. These targets include the most clinically important carbapenem resistance genes (KPC, OXA-48, NDM, VIM, IMP), which are listed on the CDC Urgent Threat list for antibiotic resistance; CTXM-14 and CTXM-15, a major source of extended spectrum beta lactamases (ESBLs); AmpC beta-lactamase genes (CMY, DHA); detection of *vanA/B* 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 (MRSA). Initial clinical performance data demonstrates the carbapenemase targets on the T2Resistance Panel identify these resistance genes with an average time of 5.3 hours compared to an average of 30 hours (and up to 95 hours) with conventional methods. Antibiotic resistance is recognized by the WHO as ‘one of the biggest threats to global health, food security, and development today’. We believe the T2Resistance Panel has the potential to prevent the spread of multidrug-resistant organisms and improve patient outcomes by enabling rapid identification of the genes and species associated with antibiotic resistance – enabling the reduction of unnecessary antibiotic use which is the primary cause of antibiotic resistance. Most importantly, these tests can enable more patients to get on the right targeted therapy quicker, potentially reducing mortality and hospitalization cost. Finally, these tests could also be used to accelerate clinical trials for new antibiotics and reduce the time to commercial availability. The T2Resistance Panel received FDA Breakthrough Device designation in February 2019 and was granted a CE Mark in November 2019 and is available for purchase in the United States as a Research Use Only product.

T2Cauris

In September 2017, we entered into an agreement with the CDC, pursuant to which the CDC agreed to validate the T2Dx in its laboratory for potentially testing and monitoring the emergence and outbreaks of the superbug *Candida auris.*

Candida auris is a multi-drug resistant pathogen recognized by the CDC as a serious global health threat because it can be resistant to all three major classes of antifungal drugs and is difficult to identify. The CDC has also reported that more than one-in-three patients with *Candida auris* infections have died. Unlike most other species of *Candida*, *Candida auris* can spread quickly in a hospital making rapid identification and hospital environment surveillance a critical component of containing these outbreaks. Existing laboratory methods that detect *Candida 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. According to the European Centre for Disease Prevention and Control, hospital outbreaks have occurred in the United Kingdom and Spain. Because *Candida auris* can be resistant to most treatment options and can spread so quickly, these hospital outbreaks have been difficult to contain by even the most enhanced control measures.

The goals of the CDC collaboration were to use the T2Dx Instrument to (i) validate the detection of *Candida auris* from patient skin samples and hospital environmental samples, (ii) validate a process for surveillance of *Candida auris* in healthcare facilities from skin and environmental samples, and (iii) assist state and local public health labs in combating the outbreak. In a study presented at ASM Microbe 2018 regarding the detection of *Candida auris*, it was found that the T2MR technology provided accurate diagnostic results from patient skin samples. The study concluded that T2MR could be used to provide a more rapid detection of *Candida auris* in patient skin swabs. This study was subsequently published as an article entitled “Evaluation of a new T2 Magnetic Resonance assay for rapid detection of emergent fungal pathogen *Candida auris* on clinical swab samples” in the journal Mycoses.

T2Lyme

We believe that T2MR can also 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.

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 360,000 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.

Our product candidate, T2Lyme, will identify the bacteria that cause Lyme disease directly from the patient's blood, without the need for blood culture which, for the bacteria associated with Lyme disease, can take several weeks. The test panel is expected to be run on the T2Dx, the same instrument currently used to run all commercially available test panels. We anticipate the T2Lyme test panel to benefit from similar advantages provided by T2MR, including high sensitivity, high specificity, ease of use and rapid time to result. T2Lyme may provide accurate and timely diagnosis of Lyme disease and may prevent the evolution of the disease to its later stages with associated neurological and musculoskeletal diseases. Based on feedback from the FDA and the dynamics of the Lyme disease testing market, we believe that the most expeditious path for commercializing the T2Lyme panel may be by offering the test with a single partner as a lab developed test our and our current goal is to potentially have T2Lyme validated in a partner's lab for commercial launch.

We expect that existing CPT codes will be used to facilitate reimbursement of our T2Lyme diagnostic panel.

T2Lyme identifies the microorganisms responsible for most cases of Lyme disease in North America and Europe and are detected directly in whole blood using T2MR and the same methodology used in the T2Candida and T2Bacteria tests. Preliminary data demonstrate that the detection of three species of *Borrelia* at limits of detection as low as 10 cells/mL was achieved in spiked whole blood and detection of spirochetes in clinical samples from patients with early stage Lyme disease using T2MR.

T2SARS-CoV-2

On March 24, 2020, we announced that we had licensed certain technology for the development of a rapid test for COVID-19 from the Center for Discovery and Innovation (CDI) at Hackensack Meridian Health. Under this license agreement, T2 Biosystems is authorized to use the CDI technology and adapt the CDI-developed COVID-19 test to the T2 Biosystems platform, and market and distribute the test in places of need amid the expanding pandemic. On June 30, 2020, we announced the US launch of our COVID-19 molecular diagnostic test, the T2SARS-CoV-2 Panel, after validation of the test meeting the FDA's requirements for an Emergency Use Authorization (EUA). On July 1, 2020, we submitted an EUA request to the FDA for the T2SARS-CoV-2 Panel. In August 2020, the FDA issued EUA for our T2SARS-CoV-2 Panel.

The T2SARS-CoV-2 Panel is designed to detect SARS-CoV-2, the virus that is responsible for COVID-19 infections. The T2SARS-CoV-2 Panel provides sample-to-answer results in less than two hours, utilizing a nasopharyngeal swab sample. Clinical testing on known positive and negative patient samples showed a sensitivity of 95% and specificity of 100%. The T2SARS-CoV-2 Panel runs on our FDA-cleared T2Dx Instrument, and is capable of performing seven tests simultaneously. An *in silico* analysis conducted by the Company in March of 2021 demonstrated that the T2SARS-CoV-2 is capable of detecting all known variants of the SARS-CoV-2 virus.

Clinical data from Wuhan, China showed that for COVID-19 patients, bacterial and fungal co-infections are a significant burden with 71% of patients treated for potential bacterial infections and 15% treated for potential fungal infections. Given the high incidence of bacterial and fungal co-infections, we believe the T2 Biosystems technology has the potential to address the diagnostic needs of COVID-19 patients by helping identify these secondary infections associated with coronavirus and detecting the virus directly. Taken together, these capabilities have the potential to enable clinicians to diagnose and target therapy for patients with secondary bacterial or fungal infections associated with primary COVID-19 infections.

Sales, Marketing and Distribution

We are working to drive awareness and adoption of our T2MR technology and related products by building a direct sales force in the United States, targeting hospitals that treat critical care patients, and continuing 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. We have a small team of employees in Europe and the Middle East primarily to support our network of distributors in those regions.

At the end of 2020, our commercial organization consisted of 13 people, including 9 people in sales and marketing and 4 people in medical affairs. In January 2021, we separated the medical affairs team from the commercial organization and hired a Chief Medical Officer to lead the team, which is comprised of United States based Doctor of Pharmacy (PharmD) clinicians. Our sales team employs a strategic approach focusing on clinical data, the 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 diagnostics and empiric therapy practices. We plan to continue to invest in our sales force as we execute our strategy of converting COVID accounts to sepsis accounts and expand our customer reach.

Today, our sales force markets the T2Dx, T2Candida, T2Bacteria and T2SARS-CoV-2 products directly to hospitals in the United States, targeting large hospitals that treat the largest number of high-risk patients. If these institutions optimize the full extent of our technology, we expect a positive network effect in the hospital community, accelerating adoption of T2Candida and T2Bacteria. 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, contributing positively to their adoption. We believe the key decision-makers at hospitals are infectious disease and critical care physicians, laboratory directors, hospital pharmacy, Chief Medical Officers, and hospital administrators. In response to the severity and complexity of managing bloodstream infections, a growing number of hospitals have instituted 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 industry conferences and conduct and support clinical trials to provide additional data relative to the performance of T2Candida and T2Bacteria to these decision-makers.

Outside of the United States, we have received regulatory approvals in Europe, Australia, and certain countries in the Middle-East and Africa, and expect to seek regulatory approvals in additional international markets. We market our platform primarily through distribution partners who utilize a similar model as our sales approach in the United States. In July 2014, we received CE marking for T2Candida and the T2Dx, in September 2017 we received CE marking for T2Bacteria and in November 2019, we received CE marking for T2Resistance. As of the end of 2020, we had distributors throughout the European Union (EU), Caribbean, Australia and the Middle East. These distributors have knowledge of infectious diseases and/or microbiology. They typically have strong, existing relationships with international thought leaders in these areas and have good relationships with important hospitals in their respective countries. We continue to develop partner relationships in other key international markets and will further investigate potential distribution channels in other key markets around the world. We have employed a small team of regional distributor managers and field service personnel primarily to support the efforts of our distributors in the EU and Middle East.

For the year ended December 31, 2020, we derived approximately 36% of our total revenue from one customer, 11% from a second customer and 6% from a third customer.

Manufacturing

We manufacture our proprietary T2Dx at our manufacturing facility in Lexington, Massachusetts and our T2Candida, T2Bacteria, T2SARS-CoV2-2 and T2Resistance reagent trays at our manufacturing facility in Wilmington, Massachusetts. We perform all instrument and tray manufacturing and packaging of final components in accordance with applicable guidelines for medical device manufacturing. We outsource manufacturing of our T2Candida, T2Bacteria, T2Resistance and T2SARS-CoV-2 consumable cartridges to a contract manufacturer. Our particles are supplied by a sole source supplier, 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 and service of diagnostic products as well as raw material receipt and control. We have received ISO 13485:2012 registration 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 manufacture 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.

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. 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.

We own or exclusively license over 35 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 T2Candida, T2Bacteria, T2Resistance, T2Cauris products, and our T2Lyme product candidates, as well as protection of certain aspects of the conduct of the assays and detection of analytes. The issued patents in our patent families that cover 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.

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 “Risks Related to Intellectual Property.”

Trademarks

We have trademarks and intend to continue to seek trademark protection.

License Agreements

License Agreement with Massachusetts General Hospital

In 2006, we entered into an exclusive license agreement with 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 T2Candida, T2Bacteria and other particle-based T2MR 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 T2Candida and T2Bacteria and other potential particle-based T2MR 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 are used across all T2 product lines. 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 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.

Competition

While we believe that we are currently the only diagnostic company with commercial products capable of detecting pathogens associated with bloodstream infections from direct from whole blood samples, at limits of detection as low as 1 CFU/mL without the need of culturing 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 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, Genmark, 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 T2MR. 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:

- T2MR's ability to detect targets directly in complex and high volume samples, including whole blood, eliminating the need for sample extraction and purification;
- T2MR's 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;
- T2MR's ability to provide rapid and highly-sensitive diagnostic results, which can provide timely information to assist physicians and hospitals to make therapeutic decisions that can improve patient outcomes and reduce healthcare costs;
- our ability to develop easily operable products for end users;
- 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 to identifying sepsis-causing pathogens, T2MR technology can also identify the existence of the SARS-CoV-2 virus. Competition for 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. In 2020, many of these companies have experienced supply shortages for the tests due to high demand. We believe one competitive advantage in this space is the availability of tests due to our ability to produce more tests than our installed base of customers can consume.

Government Regulation

Our products under development and our operations are subject to significant government regulation. In the United States, our products are regulated as medical devices by the FDA and other federal, state, and local regulatory authorities.

FDA Regulation of Medical Devices

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 trials;
- product safety;
- marketing, sales and distribution;
- pre-market clearance 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.

In the United States, numerous laws and regulations govern all the processes by which medical devices are brought to market and marketed. These include the Federal Food, Drug and Cosmetic Act, or FDCA, and the FDA's implementing regulations, among others.

FDA Pre-market Clearance and Approval Requirements

Each medical device we seek to commercially distribute in the United States must first receive 510(k) clearance, *de novo* down classification, or pre-market approval from the FDA, unless specifically exempted by the FDA. For some devices we may seek Breakthrough Device Designation to aid in communications with the FDA during the pre-submission process. The FDA classifies all medical devices into one of three classes. Devices deemed to pose the lowest risk are categorized as either Class I or II, which requires the manufacturer to submit to the FDA a 510(k) pre-market notification submission requesting clearance of the device for commercial distribution in the United States. Some low risk devices are exempted from this requirement. 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 premarket approval, or PMA, application.

Emergency Use Authorization

In response to the public health emergency association with the SARS-CoV-2 virus, the FDA has established an Emergency Use Authorization (EUA) submission and approval process for molecular diagnostics for SARS-CoV-2 detection. FDA guidance for submission and approval for the testing of respiratory samples for SARS-CoV-2 virus is outlined in Section V.A. of the FDA guidance document "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (January 27, 2020)". The T2SARS-CoV-2 Panel was approved by the FDA for EUA in August 2020.

Breakthrough Device Program

The FDA offers a voluntary Breakthrough Devices Program where companies can apply to be granted Breakthrough Device Designation from the FDA. To be eligible for Breakthrough Designation a device must (A) "provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions and (B) one of the following: (1) represent breakthrough technology; (2) no approved or cleared alternatives can exist; (3) must offer significant advantages over existing approved or cleared alternatives; or (4) device availability is in the best interest of patients. The program 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, which can help manufacturers receive feedback from the FDA and identify areas of agreement in a timely way. Manufacturers can also expect prioritized review of their submission. The T2Resistance Panel received Breakthrough Device designation in February 2019.

510(k) Clearance Process

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. In rare cases, Class III devices may be cleared through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to 12 months from the date the application is submitted and filed with the FDA, but may take significantly longer and clearance is never assured. Although many 510(k) pre-market notifications are cleared without clinical data, in some cases, the FDA requires significant clinical data to support substantial equivalence. In reviewing a pre-market notification submission, the FDA may request additional information, including clinical data, which may significantly prolong the review process.

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 could require pre-market approval. 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 or approval of a PMA is obtained. Under these circumstances, the FDA may also subject a manufacturer to significant regulatory fines or other penalties. In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to industry requirements, including which devices are eligible for 510(k) clearance, the ability to rescind previously granted 510(k)s and additional requirements that may significantly impact the process.

Pre-market Approval Process

A PMA application must be submitted if the medical device is in Class III (although the FDA has the discretion to continue to allow certain pre-amendment Class III devices to use the 510(k) process) or cannot be cleared through the 510(k) process. A PMA application must be supported by, among other things, extensive technical, preclinical, and clinical trials, as well as manufacturing and labeling data to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

After a PMA application is submitted and filed, 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 will usually be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the

FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with Quality System Regulation, or QSR, which imposes elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process. 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. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. New PMA applications or supplements are required for significant modifications to the manufacturing process, labeling of the product and design of a device that is approved through the PMA process. 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 advisory panel.

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 Food and Drug Administration Modernization Act of 1997 established a new 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. 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 manufacturers to request *de novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. 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 reclassification petition 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 special controls cannot be developed. We utilized the *de novo* classification process to obtain marketing clearance for our T2Dx and T2Candida, which were given a Class II designation. We received marketing clearance for these devices from the FDA on September 22, 2014. We received marketing clearance for our T2Bacteria on May 24, 2018.

Clinical Trials

A clinical trial is typically required to support a PMA application and is sometimes required for a 510(k) pre-market notification. Clinical trials generally require submission of an application for an Investigational Device Exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the investigational protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA as well as the appropriate institutional review boards, or IRBs, at the clinical trial sites, and the informed consent of the patients participating in the clinical trial is obtained. After a trial begins, the FDA may place it on hold or terminate it if, among other reasons, it concludes that the clinical subjects are exposed to an unacceptable health risk. Any trials we conduct must be conducted in accordance with FDA regulations as well as other federal regulations and state laws concerning human subject protection and privacy. Moreover, the results of a clinical trial may not be sufficient to obtain clearance or approval of the product.

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:

- the Quality System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the 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;

- labeling regulations, which prohibit "misbranded" devices from entering the market, as well as prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; and
- post-market surveillance 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.

The FDA enforces these requirements by inspection and market surveillance. 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

Sales of medical devices outside the United States are subject to foreign government regulations, which vary substantially from country to country. In order to market our products in other countries, we must obtain regulatory approvals 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.

In the European Economic Area, or EEA, which comprises the 28 Member States of the EU plus Liechtenstein, Norway and Iceland, in vitro medical devices are required to conform with the essential requirements of the EU Directive on in vitro diagnostic medical devices (Directive 98/79/EC, as amended). To demonstrate compliance with the essential requirements, the manufacturer must undergo a conformity assessment procedure. The conformity assessment varies according to the type of medical device and its classification. For low-risk devices, the conformity assessment can be carried out internally, but for higher risk devices (self-test devices and those included in List A and B of Annex II of Directive 98/79/EC) it requires the intervention of an accredited EEA Notified Body. If successful, the conformity assessment concludes with the drawing up by the manufacturer of an EC Declaration of Conformity entitling the manufacturer to affix the CE mark to its products and to sell them throughout the EEA. We concluded an assessment of the conformity of the T2Dx and T2Candida with the EU in vitro diagnostic medical devices directive 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. For T2Bacteria we obtained a declaration of conformity on June 30, 2017. For T2Resistance, we obtained a notification to market as a CE-IVD on November 14, 2019.

Other Healthcare Laws

Our current and future business activities are subject to healthcare regulation and enforcement by the federal government 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, privacy and security and physician sunshine laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing 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 are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to 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.

Further, the recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback Statute and certain criminal statute governing healthcare fraud statutes to a stricter standard. A person or entity no longer needs to have actual knowledge of these

statutes or specific intent to violate them. In addition, the Affordable Care Act codifies case law that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. 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 False Claims Act prohibits, among other things, knowingly presenting or causing the presentation of a false or fraudulent claim for payment to, or approval by, the U.S. government. 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. 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 intervenes 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 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. 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.

The Federal Health Insurance Portability and Accountability Act of 1996, or 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 in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused 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, Section 6002 of the Affordable Care Act included new requirements for device manufacturers, among others, to report certain payments or "transfers of value" provided to physicians and teaching hospitals, and to report ownership and investment interests held by physicians and their immediate family members during the preceding calendar year. Section 6002 of the Affordable Care Act 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. We collect data annually and report it to the CMS, no later than the last day of March each year. Failure to report 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 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.

Coverage and Reimbursement

Maintaining and growing sales of our products and product candidates depends 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. 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. Decreases in third-party reimbursement for our products and/or product candidates or a decision by a third-party payor to not cover our products and/or product candidates could reduce physician utilization of our products, 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. We currently expect that the majority of our diagnostic tests will be 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. To the extent that our diagnostic tests will be performed in an outpatient setting, our products and/or product candidates may be eligible for separate payment using existing Current Procedural Terminology, or CPT, codes. Third-party payors may deny coverage, however, 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. 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 increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs; implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded eligibility criteria for Medicaid programs; 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 Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, in 2017, Congress enacted the Tax Cuts and Jobs Act, which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review this case, although it is unclear when or how the Supreme Court will rule. It is also unclear how other efforts to challenge, repeal, or replace the ACA will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers, which will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2020, absent additional congressional action. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices

Research and Development

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. We incurred research and development expenses of $16.9 million for the year ended December 31, 2020 and $16.3 million for the year ended December 31, 2019. Research and development expenses represented 28% of our total costs and expenses for the year ended December 31, 2020 and 27% of our total costs and expenses for the year ended December 31, 2019. 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 T2MR 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.

Employees

As of December 31, 2020, we had 148 full-time employees, of which 76 work in operations (which includes manufacturing, service and support, regulatory support, quality control, quality assurance, supply chain and facilities), 41 in research and development, 13 in sales and marketing (which includes medical affairs), and 18 in general and administrative.

Corporate and Available Information

We were incorporated under the laws of the state of Delaware in 2006. Our principal corporate offices are located at 101 Hartwell Avenue, Lexington, MA 02421.

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. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations. 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.

At December 31, 2020, we had an accumulated deficit of $423.0 million. We have experienced cash outflows from operating activities over the past years and are required to maintain a minimum cash balance under our Term Loan Agreement with CRG Servicing LLC ("CRG"). 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.

While we believe that the existing cash, cash equivalents, marketable securities and restricted cash of $52.7 million at December 31, 2020 will be sufficient to fund our current operating plan at least a year from issuance of these financial statements, certain elements of our operating plan cannot be considered probable. Under ASC 205-40, the future receipt of potential funding from our Co-Development partners and other resources cannot be considered probable at this time because none of the plans are entirely within our control. During the year ended December 31, 2020, we implemented a cost improvement strategy which is focused on reducing operating expenses and improving cost of goods sold.

The Term Loan Agreement with CRG (Note 6) has certain covenants which require us to achieve certain annual revenue targets, whereby we are required to pay double the amount of any shortfall as an acceleration of principal payments, and maintain a minimum cash balance of $5.0 million. As of the date of these financial statements, we achieved the revenue target of $15.0 million for the twenty-four month period ended December 31, 2020; however there are no assurances that we will achieve the revenue target for the twenty-four month period ended December 31, 2021. Should we fail to meet the revenue target, we would seek a waiver of this provision. There can be no assurances that we would be successful in obtaining a waiver. If we are unsuccessful in obtaining a waiver, we would pay the cure amount set forth under the Term Loan Agreement. While we believe we can continue as a going concern for at least a year from issuance of these financial statements, there can be no assurances that we will continue to be in compliance with the cash covenant in future periods without additional funding. In January 2021, CRG amended the Term Loan Agreement to significantly reduce the revenue covenant for the twenty-four month period ended December 31, 2021.

These conditions 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 are issued. Our plans to alleviate the conditions that raise substantial doubt include raising additional funding, earning payments pursuant to our Co- Development agreements, 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 the financial statements are issued. We have concluded the likelihood that our 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 consolidated financial statements.

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, 2020 and expect to incur losses in the future. Our accumulated deficit as of December 31, 2020 was $423.0 million and we incurred net losses of $46.8 million and $59.0 million for the years ended December 31, 2020 and 2019, 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 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, we and our auditors have identified conditions and events that raise doubt about our ability to continue as a going concern.

We have a limited operating history and may face difficulties encountered by companies early in their commercialization in competitive and rapidly evolving markets.

We received marketing clearance from the FDA for the T2Dx instrument and T2Candida on September 22, 2014 and began commercializing these products in the fourth quarter of 2014. We received marketing clearance from the FDA for T2Bacteria on May 24, 2018 and began commercializing thereafter. We received Emergency Use Authorization from the FDA for the T2SARS-CoV-2 Panel in August 2021. Accordingly, we have a relatively limited operating history upon which to evaluate our business and forecast our future sales and operating results. In assessing our business prospects, you should consider the various risks and difficulties frequently encountered by companies early in their commercialization in competitive and rapidly evolving markets, particularly companies that develop and sell medical devices. These risks include our ability to:

- implement and execute our business strategy;
- expand and improve the productivity of our sales and marketing infrastructure to grow sales of our products and product candidates;
- increase awareness of our brand;
- manage expanding operations;

- expand our manufacturing capabilities, including increasing production of current products efficiently while maintaining quality standards and adapting our manufacturing facilities to the production of new product candidates;
- respond effectively to competitive pressures and developments;
- enhance our existing products and develop new products;
- obtain and maintain regulatory clearance or approval to commercialize product candidates and enhance our existing products;
- effectively perform clinical trials with respect to our proposed products;
- attract, retain and motivate qualified personnel in various areas of our business; and
- implement and maintain systems and processes that are compliant with applicable regulatory standards.

We may not have the institutional knowledge or experience to be able to effectively address these and other risks that may face our business. In addition, we may not be able to develop insights into trends 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 may not be able to 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 rapidly evolve and has had adverse effects on general commercial activity and the global economy, including research, manufacturing and distributions. The COVID-19 pandemic could lead to a long-term, global economic downturn and, at this point in time, there is significant uncertainty relating to its effect on our business, operating and research activities, including but not limited to:

- delays, difficulties or postponement in expanding the range of hospitals utilizing our T2Dx Instrument, T2Candida, T2Bacteria and T2SARS-CoV-2 Panels;
- the inability to convert customers that have purchased a T2Dx Instrument for use with the T2SARS-CoV-2 Panels to our other test panels in the future;
- the reduction in the rate and need for COVID-19 testing, including as a result of the FDA no longer categorizing COVID-19 as a public health emergency and the potential loss of EUA;
- the diversion of healthcare resources away from our T2SARS-CoV-2 Panel and our other products;
- the interruption of marketing and research activities due to limitations on travel and stay-at-home orders related to COVID-19;
- limitations in employee resources that would otherwise be focused on the conduct of our research activities, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruptions or delays in the operations of the FDA, which may impact approval timelines;
- impacts from prolonged remote work arrangements, such as increased cybersecurity risks and strains on our business continuity plans;
- the inability to obtain additional financing or access the financial markets; and
- manufacturing challenges, such as scarcity of the components or raw materials required to produce our products or contamination of our manufacturing facility, could harm 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.

We have a significant development contract with a United States government agency and should the agency reduce, cancel or not grant additional milestone projects, our ability to continue its future product development may be impacted. The COVID-19 pandemic also causes us to reassess our build plan and evaluate inventories accordingly, which resulted in an additional charge to cost of product revenue in the first quarter of 2020 for excess inventories. In June 2020, we vacated a portion of our office space and determined that subleasing it to a tenant was unlikely due to the impact of the COVID-19 pandemic on the local commercial real estate sub-lease market. As a result, we recorded an impairment charge.

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 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 research revenue and the T2Dx Instrument, T2Candida, T2Bacteria, and T2SARS-CoV-2 and any factors that negatively impact sales of these products may adversely affect our business, financial condition and operating results.

We began to offer our sepsis products for sale in the fourth quarter of 2014, T2Bacteria in 2018 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 or approval 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 results and negatively impact our ability to successfully launch future product candidates currently under development.

If T2MR, our T2Dx Instrument, T2Candida, T2Bacteria, and T2SARS-CoV-2 products or any of our other product candidates fail to achieve and sustain sufficient market acceptance, we will not generate expected revenue and our growth prospects, operating results and financial condition may be harmed.

The commercialization of T2MR, our T2Dx Instrument, T2Candida, T2Bacteria, and T2SARS-CoV-2 products and the future commercialization of our other product candidates in the United States and other jurisdictions in which we intend to pursue marketing clearance are key elements of our strategy. If we are not successful in conveying to hospitals that our current products and future product candidates provide equivalent or superior diagnostic information in a shorter period of time compared to existing technologies, or that these products and future product candidates improve patient outcomes or decrease healthcare costs, we may experience reluctance, or refusal, on the part of hospitals to order, and third-party payors to pay for performing a test in which our product is utilized. For example, T2Candida is labeled for the presumptive diagnosis of candidemia. The results of the web-based survey we conducted of decision makers involved with laboratory purchasing may not be indicative of the actual adoption of T2Candida. In addition, our expectations regarding cost savings from using our products may not be accurate.

These hurdles may make it difficult to demonstrate to physicians, hospitals and other healthcare providers that our current diagnostic products and future product candidates are appropriate options for diagnosing sepsis, may be superior to available tests and may be more cost-effective than alternative technologies. Furthermore, we may encounter significant difficulty in gaining inclusion in sepsis treatment guidelines, gaining broad market acceptance by healthcare providers, third-party payors and patients using T2MR and our related products and product candidates. Furthermore, healthcare providers may have difficulty in maintaining adequate reimbursement for sepsis treatment, which may negatively impact adoption of our products.

If we fail to successfully commercialize our products and product candidates, we may never receive a return on the significant investments in product development, sales and marketing, regulatory, manufacturing and quality assurance we have made and further investments we intend to make, and may fail to generate revenue and gain economies of scale from such investments.

If T2Lyme does not successfully identify Lyme disease in clinical patients, does not receive FDA marketing clearance, or we are not successful in engaging a partner to develop a lab developed test, our addressable market could be negatively impacted.

If T2Lyme does not successfully identify Lyme disease in clinical patients with adequate clinical sensitivity and specificity or does not receive FDA marketing clearance, or we are not successful in engaging a partner to develop a lab developed test for Lyme disease, the addressable market opportunity for this product candidate could be limited or not realized at all.

We have relatively limited experience in marketing and selling our products, and if we are unable to expand, manage and maintain our direct sales and marketing organizations, or otherwise commercialize our products, our business may be adversely affected.

Because we received FDA clearance to sell our initial sepsis products in the third quarter of 2014 and our T2Bacteria product in 2018, and Emergency Use Authorization to sell T2SARS-CoV-2 in August 2020, we have limited experience marketing and selling our products. As of December 31, 2020, our commercial organization consisted of 13 employees, including a medical affairs team of four United States based Doctor of Pharmacy (PharmD) clinicians. In January 2021, we separated the medical affairs team from the commercial organization and hired a Chief Medical Officer to lead the team. Our financial condition and operating results are highly dependent upon the sales and marketing efforts of our sales and marketing employees with the assistance of the medical affairs team. If our sales and marketing efforts fail to adequately promote, market and sell our products, our sales may not increase at levels that are in line with our forecasts.

Our future sales growth will depend in large part on our ability to successfully expand the size and geographic scope of our direct sales force and medical affairs team in the United States. Accordingly, our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled sales, marketing and medical affairs personnel. Because the competition for individuals with their skillset is high, there is no assurance we will be able to hire and 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 the United States, we sell our products through distribution partners and there is no guarantee that we will be 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 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 and we have a relatively limited sales history, which makes it difficult for us to forecast revenue and other operating results.

Our sales process involves numerous interactions with multiple individuals within an organization and often includes in-depth analysis by potential customers of our products, performance of proof-of-principle studies, preparation of extensive documentation and a lengthy review process. As a result of these factors and the budget cycles of our potential customers, the time from initial contact with a potential customer to our receipt of a purchase order from such potential customer and then implementation and adoption of our products, varies significantly and can be up to 12 months or longer. Given the length and uncertainty of our anticipated sales cycle and implementation and adoption timeline, we likely will experience fluctuations in our product sales on a period-to-period basis. Expected revenue streams are highly dependent on hospitals' adoption of our consumables-based business model, and we cannot assure you that our potential hospital clients will follow a consistent purchasing pattern. Moreover, it is difficult for us to forecast our revenue as it is dependent upon our ability to convince the medical community of the clinical utility and economic benefits of our products and their potential advantages over existing diagnostic tests, the willingness of hospitals to utilize our products and the cost of our products to hospitals. In addition, we started selling the T2Dx Instrument and T2Candida products in the fourth quarter of 2014, T2Bacteria in May of 2018 and T2SARS-CoV-2 in August 2020 and have a limited sales history to rely on when forecasting revenue and other operating results.

We may not be able to gain and retain the ongoing support of leading hospitals and key thought leaders, or to continue the publication of the results of new clinical trials in peer-reviewed journals, which may make it difficult to establish T2MR as a standard of care and may limit our revenue growth and ability to achieve profitability.

Our strategy includes developing relationships with leading hospitals and key thought leaders in the industry. If these hospitals and key thought leaders determine that T2MR and related products are not clinically effective or that alternative technologies are more effective, or if we encounter difficulty promoting adoption or establishing T2MR as a standard of care, our revenue growth and our ability to achieve profitability could be significantly limited.

We believe that the publication of scientific and medical results in peer-reviewed journals and presentation of data at leading conferences are critical to the broad adoption of T2MR. Publication in leading medical journals is subject to a peer-review process, and peer reviewers may not consider the results of studies involving T2MR sufficiently novel or worthy of publication.

If we are unable to successfully manage our growth, our business will be harmed.

During the past few years, we have significantly expanded our operations. We expect this expansion to continue to an even greater degree as we continue to commercialize our sepsis products, build a targeted sales force, and seek marketing clearance from the FDA and international regulatory bodies for our future product candidates. Our growth has placed, and will continue to place, a significant strain on our management, operating and financial systems and our sales, marketing and administrative resources. As a result of our growth, operating costs may escalate even faster than planned, and some of our internal systems and processes, including those relating to manufacturing our products, may need to be enhanced, updated or replaced. Additionally, our anticipated growth will increase demands placed on our suppliers, resulting in an increased need for us to manage our suppliers and monitor for quality assurance. If we cannot effectively manage our expanding operations, manufacturing capacity and costs, including scaling to meet increased demand and properly managing suppliers, we may not be able to continue to grow or we may grow at a slower pace than expected and our business could be adversely affected.

Our future capital needs are uncertain, and we may need to raise additional funds in the future.

We currently have limited cash and cash equivalents and in the future we may need to raise substantial additional capital to:

- expand our product offerings;
- expand our sales and marketing infrastructure;
- increase our manufacturing capacity;
- fund our operations; and
- continue our research and development activities.

Our future funding requirements will depend on many factors, including:

- our ability to obtain marketing clearance from the FDA and international regulatory clearance to market our future product candidates;
- market acceptance of our products and product candidates;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of our research and development activities;
- the ability of healthcare providers to obtain coverage and adequate reimbursement by third-party payors for procedures using our products and product candidates;
- the cost and timing of marketing clearance or regulatory clearances;
- the cost of goods associated with our products and product candidates;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for products or technology.

We cannot assure you that we will be able to obtain additional funds on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or additional equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may need to liquidate some or all of our assets or delay, reduce the scope of or eliminate some or all of our development programs.

If we do not have, or are not able to obtain, sufficient funds, we may be required to delay development or commercialization of our product candidates or license to third parties the rights to commercialize our product candidates or technologies that we would otherwise seek to commercialize ourselves. We also may need to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could harm our operating results.

Our future success is dependent upon our ability to create and expand a customer base for our products in large hospitals and to increase adoption at our existing hospital accounts.

We market and sell our current sepsis products to the largest hospitals in the United States. We are also targeting the top-tier hospitals in each of the European, African, Australian, and Middle-Eastern markets where we currently sell our products. We may not be successful in promoting adoption of our technologies in those targeted hospitals or increasing adoption at our existing hospital accounts, which may make it difficult for us to achieve broader market acceptance of these products and increase revenue.

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.

We rely on single-source suppliers for some components and materials used in our products and product candidates. Our ability to supply our products commercially and to develop any future products depends, in part, on our ability to obtain these components in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. 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. While our suppliers have generally met our demand for their products on a timely basis in the past, we cannot assure that they will in the future be able to meet our demand for their products, either because we do not have long-term agreements with those suppliers, our relative importance as a customer to those suppliers, or their ability to produce the components used in our products.

While we believe replacement suppliers exist for all components and materials we obtain from single sources, establishing additional or replacement suppliers for any of these components or materials, if required, may not be accomplished quickly. Even if we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single-source components and materials used in our products in the event of disruption, those inventories may not be sufficient.

If our third-party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of our products, the supply of our products to customers and the development of any future products would be delayed, limited or prevented, which could have an adverse impact on our business.

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 and development, science and engineering, manufacturing and sales and marketing teams. In particular, we are highly dependent on the management and business expertise of John Sperzel, our President and Chief Executive Officer. We do not maintain fixed-term employment contracts or key man life insurance with any of our employees. Competition for qualified personnel is intense, particularly in the Boston, Massachusetts area. Our growth depends, in particular, on attracting, retaining and motivating highly skilled sales personnel with the necessary clinical background and ability to understand our systems at a scientific and technical level. In addition, we may need to hire additional employees at our manufacturing facilities to meet demand for our products as we scale up our sales and marketing operations. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to attract, develop, retain and motivate qualified personnel could materially harm our operating results and growth prospects.

If our diagnostics do not perform as expected, our operating results, reputation and business will suffer.

Our future success will depend on the market's confidence that our technologies can provide reliable, high-quality diagnostic results. We believe that our customers are likely to be particularly sensitive to any defects or errors in our products. If our technology fails to detect the presence of *Candida* or another bacterial pathogen and a patient subsequently suffers from sepsis, then we could 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 sepsis and Lyme markets, most of which are more established commercial organizations with considerable name recognition and significant financial resources.

We compete with companies that currently provide traditional blood culture-based diagnostics, including 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, Genmark, Cepheid and Beckman Coulter, a Danaher company. 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 also compete with numerous companies that provide COVID-19 diagnostic testing, including, but not limited to Abbot Laboratories, BioFire Diagnostics, Inc. and Becton Dickinson & Co.

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 that we intend to be used with the T2Dx Instrument, including T2Lyme for the detection of certain strains of Lyme disease-causing bacteria. We may have problems applying our technologies to these 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:

- 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, T2Candida, T2Bacteria and T2Resistance, 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.

We may be adversely affected by fluctuations in demand for, and prices of, rare earth materials.

T2MR relies, in part, on rare earth materials and products. For example, the T2Dx Instrument utilizes magnets which are extracted from the earth. Although there are currently multiple suppliers for these rare earth materials, changes in demand for, and the market price of, these magnets could significantly affect our ability to manufacture our T2MR-based instruments and, consequently, our profitability. Rare earth minerals and product prices may fluctuate and are affected by numerous factors beyond our control such as interest rates, exchange rates, inflation or deflation, global and regional supply and demand for rare earth minerals and products, and the political and economic conditions of countries that produce rare earth minerals and products.

Provisions of our debt instruments may restrict our ability to pursue our business strategies.

Our credit facilities require 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 may 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.

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.

As part of our current business model, we will seek to enter into strategic relationships with third parties to develop and commercialize diagnostic products.

We intend to 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.

If treatment guidelines for sepsis change, or the standard of care evolves, we may need to redesign and seek new marketing clearance from the FDA for our products.

If treatment guidelines for sepsis change, or the standard of care evolves, we may need to redesign and seek new marketing clearance from the FDA for our products. For example, current treatment recommendations for *Candida* infections, including those published by the *Infectious Diseases Society of America*, call for identical treatment for two species of *Candida*, *C. albicans* and *C. tropicalis*, and identical treatment for two other species, *C. glabrata* and *C. krusei*. Although our T2Candida test is technically capable of distinguishing among these species, we have designed it based on current treatment guidelines and therefore it does not distinguish between two species if they are subject to the same recommended treatment. Our FDA clearance to market the T2Dx Instrument and T2Candida in the United States is also based on current treatment guidelines. If treatment guidelines change so that different treatments become desirable for the two species currently subject to the same recommended treatment, the clinical utility of our T2Candida test could be diminished and we could be required to seek marketing clearance from the FDA for a revised test that would distinguish between the two species. Additionally, for T2Bacteria, if antibiotic or clinical guidelines indicate that tailoring antibiotic therapy to the infectious pathogen is not needed, then the market opportunity could be diminished.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2020, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of $222.6 million, which are available to offset future taxable income, if any, of which $78.7 million will expire at various dates through 2037 and $143.9 million carryforward indefinitely. In 2020, we completed a study on 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. As a result, there were limitations placed on the use of our loss and credit carryforwards. The 2019 federal and state net operating loss carryforwards of $329.6 million and $292.4 million, respectively, were determined to be limited by $149.5 million and $78.9 million, respectively. The 2019 federal and state tax credit carryforwards of $5.5 million and $3.6 million, respectively, were limited by $5.4 million and $3.2 million, respectively. The decrease in the prior year tax attributes is attributable to change of control ownership shifts which were determined for the years 2013, 2016, and 2019 which caused the reduction in the value of the historical net operating loss carryforwards. Since the limitation affected the prior period, the Company has determined that its 2019 tax footnote presentation overstated the gross net operating loss deferred tax asset and corresponding valuation allowance. However, there was no net impact to the net deferred tax asset and tax expense as the decrease in the net operating loss carryforward was offset completely by a corresponding adjustment to the Company’s overall valuation allowance. For comparative purposes, the Company’s prior year tax footnote has been revised to reflect the adjustment to the net operating losses and valuation allowance. In addition, 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 will 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 as 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 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. We currently have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and our code of conduct and the other precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could 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. 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 Management concluded that our disclosure controls and procedures were not effective due to a material weakness in our internal control over the quality, frequency and periodic testing of the backup of our Information System data as described further in this Item 1. Although we have strengthened our network security and infrastructure following the attack, 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. 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. 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 and clearance by the FDA and foreign regulatory authorities 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 and other U.S. governmental agencies regulate numerous elements of our business, including:

- product design and development;
- pre-clinical and clinical testing and trials;
- product safety;
- establishment registration and product listing;
- labeling and storage;
- marketing, manufacturing, sales and distribution;
- pre-market clearance or approval;
- 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, approval of a *de novo* reclassification petition 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.

We received pre-market clearance for our T2Dx instrument and T2Candida under the *de novo* application procedure in September 2014 and received market clearance for T2Bacteria under the standard 510(k) process in May 2018. From time to time, we may make modifications to these products that may require a new 510(k).

If the FDA requires us to go through a lengthier, more rigorous examination for our future product candidates than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our launch to be delayed or, in the future, our sales to decline. In addition, the FDA may determine that our product candidates require the more costly, lengthy and uncertain PMA process.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that our product candidates are safe and effective, sensitive and specific diagnostic tests, for their intended users;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. For example, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) regulatory pathway, the FDA initiated an evaluation of the program, and in January 2011, announced several proposed actions intended to reform the review process governing the clearance of medical devices. The FDA intends these reform actions to improve the efficiency and transparency of the clearance process, as well as bolster patient safety. In addition, as part of the Food and Drug Administration Safety and Innovation Act, or FDASIA, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms which are further intended to clarify and improve medical device regulation both pre- and post-approval.

Any delay in, or failure to receive or maintain, clearance 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. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could affect the perceived safety and efficacy of our products and product candidates and dissuade our customers from using our products and product candidates.

Obtaining FDA clearance, *de novo* down classification, or approval for diagnostics can be expensive and uncertain, and generally takes from several months to several years, and generally requires detailed and comprehensive scientific and clinical data. Notwithstanding the expense, these efforts may never result in FDA clearance. Even if we were to obtain regulatory clearance, 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.

Even if granted, a 510(k) clearance, *de novo* down classification, or PMA approval for any future product would likely place substantial restrictions on how our device is marketed or sold, and the FDA will continue to place considerable restrictions on our products and operations. For example, the manufacture of medical devices 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 regulatory authority could take enforcement action, including any of the following sanctions:

- 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) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) marketing clearances or PMA approvals that have already been granted;
- refusing to provide Certificates for Foreign Government;
- 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.

Sales of our diagnostic products and product candidates outside the United States are subject to foreign regulatory requirements governing clinical studies, vigilance reporting, marketing approval, manufacturing, product licensing, pricing and reimbursement. These regulatory requirements vary greatly from country to country. As a result, the time required to obtain approvals outside the United States may differ from that required to obtain FDA clearance and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. Clearance by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure clearance or approval by regulatory authorities in other countries or by the FDA. Foreign regulatory authorities could require additional testing. Failure to comply with these regulatory requirements, or to obtain required clearances or approvals, could impair our ability to commercialize our diagnostic products and product candidates outside of the United States.

Global health crises, such as COVID-19, may divert regulatory resources and attention away from approval processes for our products. This could materially lengthen the regulatory approval process of new products, which would delay expected commercialization of such new products.

Although the FDA granted Emergency Use Authorization (EUA) for our T2SARS-CoV-2 Test Panel in August 2020, this authorization is only valid during the COVID-19 public health emergency, and when the federally declared public health emergency ends, we will be required to stop commercial sales of our test immediately in the United States unless we can obtain FDA clearance or approval for our test under a traditional regulatory pathway for in vitro diagnostics, which is lengthy and expensive.

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA has authority to allow certain unapproved medical products or unapproved uses of approved medical products to be used during a public health emergency under an EUA. An EUA is effective until the declaration that circumstances exist justifying the authorization of the emergency use is terminated under Section 564(b)(2) of the FD&C Act or the EUA is revoked under Section 564(g) of the FD&C Act, after which the product must be cleared or approved by the FDA under a traditional pathway and we must comply with the quality system regulation at 21 CFR 820 in order to remain on the market or to continue commercialization of the product. In August 2020, the FDA granted EUA for our T2SARS-CoV-2 Test Panel.

If the FDA's policies and guidance change unexpectedly and/or materially or if we misinterpret them, potential sales of T2 SARS-CoV-2 Test Panel could be adversely impacted. In addition, the FDA may revoke an EUA where it is determined that the underlying public health emergency no longer exists or warrants such authorization, or if new evidence becomes available that indicates the test does not meet the conditions of authorization or perform as provided in the EUA application. We cannot predict how long this EUA will remain effective. The termination or revocation of the EUA and changing policies and regulatory requirements could adversely impact our business, financial condition and results of operations. The demand for our product and our profitability may decline or be adversely impacted by the federal government's implementation of a national COVID-19 testing strategy.

Modifications to our products, if cleared or approved, may require new 510(k) clearances or pre-market approvals, or may require us to cease marketing or recall the modified products until clearances 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. 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 or PMAs for modifications to previously cleared products for which we conclude that new clearances or approvals 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.

FDA is continuing the trend to uphold safety and effectiveness of commercial devices, while maintaining the least burdensome approach provision. This provision states that FDA shall only request the "minimum required information" necessary to support a determination of substantial equivalence (sections 513(i)(l)(D)(ii)-(iii) of the FD&C Act). Their recommendations are further discussed in the 2017 Guidance on deciding when to submit a 510(k) for a change to an existing device. As written, this outwardly suggests a more efficient process of interacting with FDA; however, the demonstration of device safety now includes more comprehensive planning and reporting through the lifecycle of the device, including Risk Evaluation, Post-Marketing Surveillance, and Medical Device Reporting for adverse events.

A recall of our products, either voluntarily or at the direction of the FDA, 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. 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 may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances 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.

We may rely on third parties to conduct future studies of our product candidates that may be required by the FDA or other regulatory authorities, and those third parties may not perform satisfactorily.

We may rely on third parties, including medical investigators, to conduct such studies. Our reliance on these third parties for clinical development activities will reduce our control over these activities. These third parties may not complete activities on schedule or conduct studies in accordance with regulatory requirements or our study design. If applicable, our reliance on third parties that we do not control will not relieve us of any applicable requirement to prepare, and ensure compliance with, various procedures required under good clinical practices. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our studies may be extended, delayed, suspended or terminated, and we may not be able to obtain marketing clearance from the FDA or regulatory clearance for our product candidates.

Our customers are highly dependent on payment from third-party payors, and inadequate coverage and/or inadequate reimbursement for diagnostic tests using our technology or for procedures using our products and product candidates and the commercial success of our diagnostic products and product candidates would be compromised.

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 T2MR. 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.

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. We currently expect that the majority of our diagnostic tests will be 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. To the extent that our diagnostic tests will be performed in an outpatient setting, our products and product candidates may be eligible for separate payment, for example, under the Clinical Laboratory Fee Schedule using existing Current Procedural Terminology codes. Third-party payors may deny coverage, however, if they determine that the diagnostic tests using our products 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.

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 using our products and product candidates by government and private insurance plans is central to the acceptance of our products. We cannot 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. 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. 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 may be subject to federal and state healthcare fraud and abuse laws and other federal and state 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 and state fraud and abuse laws, including, without limitation, the federal and state anti-kickback statutes, physician payment transparency laws and false claims laws. 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;
- 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;
- 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;

- 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 under the Affordable Care 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, as defined by such law, 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. In addition, recent healthcare reforms have strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback statute. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. The Affordable Care Act also codified case law by amending the False Claims Act, such that violations of the federal Anti-Kickback Statute are now deemed violations of the False Claims Act.

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, enacted in March 2010, made changes that significantly impacted the pharmaceutical and medical device industries and clinical laboratories.

The Affordable Care Act 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.

Other significant measures for our industry contained in the Affordable Care Act 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. The Affordable Care Act also includes significant fraud and abuse measures, including required disclosures of certain financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. To the extent that the reimbursement amounts for sepsis decrease, it could adversely affect the market acceptance and hospital adoption of our technologies.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the constitutionality of the ACA, although it is unclear when or how the Supreme Court will rule. It is also unclear how other efforts to challenge, repeal, or replace the ACA will impact the law and may impact our business or financial condition.

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 of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the temporary

suspension from May 1, 2020 through December 31, 2020, 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. 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.

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.

Risks Related to Intellectual Property

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 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.

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 patents against third-party infringement, we cannot be certain that MGH will elect to enforce these patents 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 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. In the past, a third party informed us they believe we are infringing certain patents that are owned by the third party. We believe that most of the claims are not relevant to our products, and the remaining claims are not likely to be found valid by a court. Nevertheless, if the third party files a lawsuit against us, we will be forced to defend against the suit, which may incur substantial costs and be a distraction to our employees. While we expect we would prevail in court because we believe any claims against our products by the third party are not likely to be found valid, in the event we do not prevail, we may be forced to take certain actions that could include, among other things, a license agreement, royalty payment, and/or designing around the patents, which may have a materially adverse effect on our business.

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, Europe, 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.

Recent 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

We may fail to maintain the continued listing requirements of The Nasdaq Capital Market, which could result in a delisting of our common stock.

Our common stock is currently listed on The Nasdaq Global Market. To maintain the listing of our common stock on The Nasdaq Global Market, we are required to meet certain listing requirements, including maintaining a minimum bid price of $1.00. If we fail to satisfy the continued listing requirements of The Nasdaq Global Market, The Nasdaq Global Market may take steps to delist our common stock, which could have a materially adverse effect on our ability to raise additional funds as well as the price and liquidity of our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair our stockholders' ability to sell or purchase our common stock when they wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below The Nasdaq minimum bid price requirement, or prevent future non-compliance with The Nasdaq Global Market's listing requirements.

There can be no assurance that we will be successful in maintaining the listing of our common stock on The Nasdaq Capital Market. This could impair the liquidity and market price of our common stock. In addition, the delisting of our common stock from a national exchange could have a material adverse effect on our access to capital markets, and any limitation on market liquidity or reduction in the price of our common stock as a result of that delisting could adversely affect our ability to raise capital on terms acceptable to us, or at all.

An active trading market for our common stock may not be sustained.

Since our initial listing on The Nasdaq Global Market in August 2014, the trading market in our common stock has historically been limited. The listing of our common stock on The Nasdaq Global Market does not assure that a meaningful, consistent and liquid trading market currently exists. We cannot predict whether 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:

- 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 will continue to incur significant costs as a result of operating as a public company, and our management will continue to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, we will incur significant legal, accounting 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 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. For example, in our December 31, 2019 Annual Report on Internal Control over Financial Reporting, management identified a material weakness in our internal control over financial reporting relating to an IT tape backup system.

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.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTY

Our corporate headquarters is located in Lexington, Massachusetts, where we currently lease approximately 32,000 square feet of office space of which 11,000 square feet was vacated in 2020, 12,200 square feet of laboratory space and 11,000 square feet of manufacturing space. Our base rent, for leases at our corporate headquarters, is between $2.2 million and $2.4 million annually for the duration of the leases. In addition, we lease approximately 7,600 square feet in Wilmington, Massachusetts for our manufacturing facility, for $0.1 million of base rent annually for the duration of the lease.

Item 3. LEGAL PROCEEDINGS

We are not party to any material legal proceedings.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II.

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information and Holders

Our common stock has been quoted on The Nasdaq Global Market under the symbol "TTOO" and has been trading since August 7, 2014. On March 26, 2021, there were 14 holders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our common stock and do not expect to pay any dividends for the foreseeable future. We currently intend to retain any future earnings to fund the operation, development and expansion of our business. Any future determination to pay dividends will be at the sole discretion of our Board of Directors and will depend upon a number of factors, including our results of operations, capital requirements, financial condition, future prospects, contractual arrangements, restrictions imposed by applicable law, any limitations on payments of dividends present in our current and future debt arrangements, and other factors our Board of Directors may deem relevant.

Issuer Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Sales of Unregistered Securities

None.

Item 6. [RESERVED]

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our consolidated financial condition and results of operations together with our consolidated financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Item 1A.—Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Business Overview

We are an in vitro diagnostics company and leader in the rapid detection of sepsis-causing pathogens, and 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 an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. We are using our T2MR technology to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. T2MR 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. Our products include the T2Dx Instrument, T2Candida Panel, the T2Bacteria Panel, the T2Resistance Panel, and the T2SARS-CoV-2 Panel that are all powered by our proprietary T2MR technology. Our development efforts target sepsis, which is an area of significant unmet medical need in which existing therapies could be more effective with improved diagnostics.

On September 22, 2014, we received market clearance from the FDA for our first two products, the T2Dx® Instrument, or the T2Dx and the T2Candida® Panel, or T2Candida, which have the ability to rapidly identify the five clinically relevant species of *Candida*, a fungal pathogen known to cause sepsis, directly from whole blood. On May 24, 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 of the most common and deadly sepsis-causing bacteria directly from whole blood. We have also developed and sell a research use only *Candida auris* assay, the T2Cauris™ Panel, for the rapid identification of *Candida auris*, a species of *Candida* that is highly drug resistant. We have developed a T2Resistance™ Panel for the early and sensitive detection of resistance markers, which can assist clinicians in selecting effective antibiotics. The T2Resistance Panel received FDA Breakthrough Device designation in February 2019 and was granted a CE Mark in November 2019. An additional diagnostic application in

development is the T2Lyme™ Panel, or T2Lyme, which is focused on the detection of the bacteria that cause Lyme disease. Diagnostic applications for additional bacteria species and resistance markers were developed as part of a collaboration with CARB-X, a public-private partnership with the U.S. Department of Health and Human Services, or HHS, and the Wellcome Trust of London, focused on combatting antibiotic resistant bacteria. On August 2, 2019, CMS granted approval for a New Technology Add-on Payment (NTAP) for the T2Bacteria Panel for fiscal year 2020 and in September 2020, CMS extended the approval for 2021. In September 2019, BARDA awarded us a milestone-based contract, with an initial value of $6 million, and a potential value of up to $69 million, for the development of new direct-from-blood diagnostic panels that will run on the T2Dx. In September 2020, we completed the initial phase and BARDA exercised the first contract option valued at $10.5 million. The existing reimbursement codes support our sepsis products and anticipate the same for our Lyme disease product candidates. The economic savings associated with our sepsis products are realized directly by hospitals. In the United States, we have a commercial team that is primarily targeting hospitals with the highest concentration of patients at risk for sepsis-related infections. Internationally, we have primarily partnered with distributors that target large hospitals in their respective international markets.

We believe our sepsis products, which include T2Candida, T2Bacteria, T2Resistance, and T2Cauris, will redefine the standard of care in sepsis management while lowering healthcare costs by improving both the precision and the speed to detection of sepsis-causing pathogens. According to a study published in the Journal of Clinical Microbiology in 2010, targeted therapy for patients with bloodstream infections can be delayed up to 72 hours due to the wait time for blood culture 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 and, on that basis, the study concluded that more rapid and accurate diagnostic techniques are needed. 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 and T2Bacteria coupled with their 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 antimicrobial therapy. The administration of inappropriate therapy is a driving force behind the spread of antimicrobial-resistant pathogens, which the United States Centers for Disease Control and Prevention, or the CDC, recently called “one of our most serious health threats.” The addition of the use of our products, T2Bacteria, T2Candida, and T2Resistance, which all run on the T2Dx Instrument, with the standard of care for the management of patients suspected of sepsis, enables clinicians to potentially treat 90% of patients with sepsis pathogen infections with the right targeted therapy within the first twelve hours of development of the symptoms of disease. Currently, high risk patients are typically initially treated with broad spectrum antibiotic drugs that typically cover approximately 60% of patients with 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 identify pathogens commonly not covered by broad spectrum antibiotic drugs.

We compete with traditional blood culture-based diagnostic companies, including Becton Dickinson & Co. and bioMerieux, Inc., as well as companies offering post-culture species identification using both molecular and non-molecular methods, including bioMerieux, Inc. (and its affiliate, BioFire Diagnostics, Inc.), Bruker Corporation, Accelerate Diagnostics, Luminex, Genmark, Cepheid and Beckman Coulter, a Danaher company. 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 have never been profitable and have incurred net losses in each year since inception. Our accumulated deficit at December 31, 2020 was $423.0 million and we have experienced cash outflows from operating activities over the past years. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations. We have incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution of our FDA-cleared products, T2Dx, T2Candida and T2Bacteria. In addition, we will continue to incur significant costs and expenses as we continue to develop other product candidates, improve existing products and maintain, expand and protect our intellectual property portfolio. We may seek to fund our operations through public equity or private equity or debt financings, as well as other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on our business, results of operations and financial condition and our ability to develop, commercialize and drive adoption of the T2Dx Instrument, T2Candida, T2Bacteria, T2Resistance, T2SARS-CoV-2 and future T2MR-based diagnostics.

We are subject to a number of risks similar to other newly commercial life science companies, including, but not limited to commercially launching our products, development and market acceptance of our product candidates, development by our competitors of new technological innovations, protection of proprietary technology, and raising additional capital.

The COVID-19 pandemic has impacted and may continue to impact our operations. We have established protocols for continued manufacturing, distribution and servicing of our products with safe social distancing and personal protective equipment measures and for remote work for employees not essential to on-site operations. To date these measures have been mostly successful but may not continue to function should the pandemic escalate and further impact our personnel. Our hospital customers have restricted our sales team's access to their facilities and as a result, we had significantly reduced our sales and general and administrative staffing levels to reduce expenses. Our customers may reduce their purchases of our products. Our customers may cease to comply with the terms of our sales agreements and this may impact our ability to recognize revenue and hinder receivables collections. We have a significant development contract with a United States government agency and should the agency reduce, cancel or not grant additional milestone projects our ability to continue our future product development may be impacted. Our shipping carrier's ability to deliver our products to customers may be disrupted. 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 for the manufacturing of reagents is in high demand, and interruptions in supply are difficult to predict. At the onset of the pandemic, we believed that the pandemic's impact on our sales would affect the recoverability of the value of our T2-owned instruments and components. The COVID-19 pandemic also caused us to reassess our build plan and evaluate our inventories accordingly, which resulted in an additional charge to cost of product revenue for excess inventories.

At December 31, 2020, we had an accumulated deficit of $423.0 million. We have experienced cash outflows from operating activities over the past years and are required to maintain a minimum cash balance under our Term Loan Agreement with CRG Servicing LLC ("CRG"). 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.

While we believe that our cash, cash equivalents, marketable securities and restricted cash of $52.7 million at December 31, 2020 will be sufficient to fund our current operating plan at least a year from issuance of these financial statements, certain elements of our operating plan cannot be considered probable. Under ASC 205-40, the future receipt of potential funding from our Co-Development partners and other resources cannot be considered probable at this time because none of the plans are entirely within our control. During the year ended December 31, 2020, management implemented a cost improvement strategy which is focused on reducing operating expenses and improving cost of goods sold.

The Term Loan Agreement with CRG (Note 6) has certain covenants which require us to achieve certain annual revenue targets, whereby we are required to pay double the amount of any shortfall as an acceleration of principal payments, and maintain a minimum cash balance of $5.0 million. As of the date of these financial statements, we achieved the revenue target of $15.0 million for the twenty-four month period ended December 31, 2020; however there are no assurances that we will achieve the revenue target for the twenty-four month period ended December 31, 2021. Should we fail to meet the revenue target, we would seek a waiver of this provision. There can be no assurances that we would be successful in obtaining a waiver. If we are unsuccessful in obtaining a waiver, we would pay the cure amount set forth under the Term Loan Agreement. While we believe we can continue as a going concern for at least a year from issuance of these financial statements, there can be no assurances that we will continue to be in compliance with the cash covenant in future periods without additional funding. In January 2021, CRG amended the Term Loan Agreement to significantly reduce the revenue covenant for the twenty-four month period ended December 31, 2021.

These conditions raise substantial doubt regarding the Company's 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, 2020 are issued. Management's plans to alleviate the conditions that raise substantial doubt include raising additional funding, earning payments pursuant to the Company's Co- Development agreements, delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels for the Company to continue as a going concern for a period of 12 months from the date the 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, the Company has concluded that substantial doubt exists about the Company's ability to continue as a going concern for a period of at least 12 months from the date of issuance of these consolidated financial statements. See Note 1 of the notes to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K for additional information about our assessment.

On April 7, 2020, we received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Global Market under Nasdaq Listing Rule 5450(a)(1). On June 16, 2020, we received a letter from the Nasdaq stating that we had regained compliance.

Financial Overview

Revenue

We generate revenue from the sale of our products, related services, reagent rental agreements and from activities performed pursuant to research and development agreements and government contributions.

Revenue earned from activities performed pursuant to research and development agreements is reported as research revenue and is recognized over time, using an input method as the work is completed, limited to payments earned. Costs incurred to deliver the services are recorded as research and development expense in the consolidated financial statements. The timing of receipt of cash from our research and development agreements generally differs from when revenue is recognized. Milestones are contingent on the occurrence of future events and are considered variable consideration being constrained until the Company believes a significant revenue reversal will not occur.

Grants received, including cost reimbursement agreements, are assessed to determine if the agreement should be accounted for as an exchange transaction or a contribution. An agreement is accounted for as a contribution if the resource provider does not receive commensurate value in return for the assets transferred.

Product revenue is generated by the sale of instruments and consumable diagnostic tests predominantly through our direct sales force in the United States and distributors in geographic regions outside the United States. We do not offer product return or exchange rights (other than those relating to defective goods under warranty) or price protection allowances to its customers, including its distributors. Payment terms granted to distributors are the same as those granted to end-user customers and payments are not dependent upon the distributors' receipt of payment from their end-user customers. We either sell instruments to customers and international distributors, or retain title and place the instrument at the customer site pursuant to a reagent rental agreement. When the instrument is placed under a reagent rental agreement, our customers generally agree to fixed term agreements, which can be extended, and incremental charges on each consumable diagnostic test purchased. Shipping and handling costs are billed to customers in connection with a product sale.

Fees paid to member-owned group purchasing organizations ("GPOs") are deducted from related product revenues.

Direct sales of instruments include warranty, maintenance and technical support services typically for one year following the installation of the purchased instrument ("Maintenance Services"). Maintenance Services are separate performance obligations as they are service based warranties and are recognized on a straight-line basis over the service delivery period. After the completion of the initial Maintenance Services period, customers have the option to renew or extend the Maintenance Services typically for additional one-year periods in exchange for additional consideration. The extended Maintenance Services are also service based warranties that represent separate purchasing decisions.

We warrant that consumable diagnostic tests will be free from defects, when handled according to product specifications, for the stated life of the product. To fulfill valid warranty claims, we provide replacement product free of charge.

Our current sales strategy is focused on driving adoption of our technology within the hospital market, increasing test utilization amongst our existing installed base on T2Dx Instruments, which includes converting our T2SARS-CoV-2 customers to our core sepsis tests, and opportunistically increasing the installed base. Accordingly, we expect the following to occur:

- recurring revenue from our consumable diagnostic tests will increase; and
- become a more predictable and significant component of total revenue; and
- we will gain manufacturing economies of scale through the growth in our sales, resulting in improving gross margins and operating margins.

Near term, however, we believe the COVID-19 pandemic may hinder our U.S. and international sales growth. Our customers may cease to comply with the terms of our sales agreements and this may impact our ability to recognize revenue and hinder receivables collections. We have a significant development contract with a United States government agency and should the agency reduce, cancel or not grant additional milestone projects our ability to continue our future product development may be impacted.

Cost of Product Revenue

Cost of product revenue includes the cost of materials, direct labor and manufacturing overhead costs used in the manufacture of our consumable diagnostic tests sold to customers and related license and royalty fees. Cost of product revenue also includes depreciation on the revenue-generating T2Dx instruments that have been placed with our customers under reagent rental agreements; costs of materials, direct labor and manufacturing overhead costs on the T2Dx instruments sold to customers; and other costs such as customer support costs, warranty and repair and maintenance expense on the T2Dx instruments that have been placed with our customers under reagent rental agreements. We manufacture the T2Dx instruments and part of our consumable diagnostic tests in our facilities. We outsource the manufacturing of components of our consumable diagnostic tests to contract manufacturers.

We expect cost of product revenue to decrease as a percentage of revenue as a result of the cost of product revenue improvement initiatives that we initiated during the year ended December 31, 2020.

At the beginning of the COVID-19 pandemic, we believed that the pandemic would reduce product sales and impair our ability to recover the cost of our T2-owned instruments and components. We assessed the impact on the related cash flows of the instruments and reduced their carrying values by $0.6 million during year ended December 31, 2020, which was recorded as cost of product revenue impairment expense. We took an additional $0.6 million charge to cost of product revenue during the year ended December 31, 2020 primarily for excess inventories as the COVID-19 pandemic also caused us to reassess our build plan and evaluate our inventories accordingly.

Research and development expenses

Our research and development expenses consist primarily of costs, incurred for the development of our technology and product candidates, technology improvements and enhancements, clinical trials to evaluate the clinical utility of our product candidates, and laboratory development and expansion, and include salaries and benefits, including stock-based compensation, research-related facility and overhead costs, laboratory supplies, equipment and contract services. Research and development expenses also include costs of delivering products or services associated with research and contribution revenue. We expense all research and development costs as incurred.

We anticipate our overall research and development expenses to decrease as a percentage of revenue. We expect to continue developing additional product candidates, improving existing products, and conducting ongoing and new clinical trials. We have a significant development contract with a United States government agency and should the agency reduce, cancel or not grant additional milestone projects our ability to continue our future product development may be impacted.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of costs for our sales and marketing, finance, legal, human resources, business development and general management functions, as well as professional services, such as legal, consulting and accounting services. We expect selling, general and administrative expenses to decrease as a percentage of revenue in future periods. Other selling, general and administrative expenses include facility-related costs, fees and expenses associated with obtaining and maintaining patents, clinical and economic studies and publications, marketing expenses, and travel expenses. We expense all selling, general and administrative expenses as incurred.

Interest expense, net

Interest expense, net, consists primarily of interest expense on our notes payable, changes in fair value of our derivative liability, the amortization of deferred financing costs and debt discount, and interest earned on our cash and cash equivalents.

Other income, net

Other income, net, consists of dividend and other investment income.

Results of Operations for the Years Ended December 31, 2020 and 2019

	Year ended December 31,		
	2020	2019	Change
	(in thousands)		
Revenue:			
Product revenue	$ 11,677	$ 5,327	$ 6,350
Research revenue	11	563	(552)
Contribution revenue	6,442	2,445	3,997
Total revenue	18,130	8,335	9,795
Costs and expenses:			
Cost of product revenue	21,280	16,763	4,517
Research and development	16,919	16,326	593
Selling, general and administrative	21,287	27,304	(6,017)
Total costs and expenses	59,486	60,393	(907)
Loss from operations	(41,356)	(52,058)	10,702
Other income (expense):			
Interest income	14	1	13
Interest expense	(5,518)	(7,349)	1,831
Other income, net	62	400	(338)
Total other expense	(5,442)	(6,948)	1,506
Net loss	$ (46,798)	$ (59,006)	$ 12,208

Product revenue

During the year ended December 31, 2020, product revenue totaled $11.7 million, compared to $5.3 million for the year ended December 31, 2019, an increase of $6.4 million. The increase was driven by higher consumable sales of $5.5 million primarily driven by sales of our T2SARS-CoV-2 product, higher T2Dx instrument sales of $0.7 million and higher revenue under our service agreements of $0.2 million.

Research revenue

Research revenue was $11 thousand pertaining to an immaterial agreement for the year ended December 31, 2020 compared to $0.6 million for the year ended December 31, 2019, a decrease of $0.6 million. Research revenue for the year ended December 31, 2019 primarily relates to our Co-Development Agreement with Canon U.S. Life Sciences, which completed in 2019.

Contribution revenue

Contribution revenue of $6.4 million for the year ended December 31, 2020, relates to the BARDA contract, which began in September 2019. Contribution revenue of $2.4 million for the year ended December 31, 2019 consists of $1.5 million under the BARDA contract, which began in September 2019 and has a potential value of up to $69.0 million if all contract options are awarded, and $0.9 million under our cost-sharing agreement with CARB-X, which completed in 2019.

Cost of product revenue

During the year ended December 31, 2020, cost of product revenue totaled $21.3 million, compared to $16.8 million for the year ended December 31, 2019, an increase of $4.5 million. The increase in cost was driven by $4.3 million of higher consumable sales primarily of our T2SARS-CoV-2, $1.1 million of higher instrument sales, a $0.6 million COVID-19 related impairment charge of our T2-owned instruments and components, $0.4 million of higher shipping related costs and $0.2 million of increased royalties. These increases were partially offset by $1.3 million of lower service costs primarily as a result of the impact of the COVID-19 pandemic travel restrictions and lower repair costs, $0.4 million of lower depreciation of our T2-owned instruments and components as a result of lower carrying value subsequent to the impairment charge in the first quarter of 2020, and $0.4 million of increased manufacturing efficiencies.

Research and development expenses

Research and development expenses were $16.9 million for the year ended December 31, 2020, compared to $16.3 million for the year ended December 31, 2019, an increase of $0.6 million. The increase was driven by a $1.2 million increase in consulting expenses primarily related to the BARDA contract, an increase of $0.2 million in lab and facility expenses primarily for the BARDA contract and our T2SARS-CoV-2 Panel and higher study related expenses of $0.1 million for assay development. These increases were partially offset by a $0.8 million decrease in payroll related and travel expenses due to a reduction in headcount and lower materials costs of $0.1 million.

Selling, general and administrative expenses

Selling, general and administrative expenses were $21.3 million for the year ended December 31, 2020, compared to $27.3 million for the year ended December 31, 2019, a decrease of $6.0 million. The decrease is driven by a decrease in payroll related expenses of $3.8 million and travel expenses of $1.0 million, all of which are attributable to a reduction in headcount and travel restrictions as a result of the COVID-19 pandemic. Stock compensation expense decreased by $1.0 million due to the market based restricted stock units reaching the end of the derived service periods and a reduction in headcount. Tradeshow and other marketing expenses decreased by $0.9 million, primarily due to the impact of the COVID-19 pandemic cancellations. Expenses related to systems restoration from the 2019 cyber-attack decreased by $0.7 million. There was $0.2 million less of conferences, primarily due to the COVID-19 pandemic cancellations, and $0.1 million less dues and subscriptions. The decreases are partially offset by an increase of $0.6 million in IT support and consulting primarily due to remediating the material weakness, an increase of $0.5 million in D&O insurance premiums, and a $0.5 million impairment charge from a vacated operating lease, and an increase of $0.1 million in consulting fees primarily related to temporary help related to final cyber-recovery efforts in early 2020, compliance with Section 404 of the Sarbanes-Oxley Act and a Board members search.

Interest income

Interest income was immaterial for the years ended December 31, 2020 and 2019.

Interest expense

Interest expense was $5.5 million for the year ended December 31, 2020, compared to $7.3 million for the year ended December 31, 2019. Interest expense decreased by $1.8 million primarily due to the change in fair value of the derivative associated with the CRG Term Loan Agreement.

Other income, net

Other income, net, was $0.1 million for the year ended December 31, 2020, compared to $0.4 million for the year ended December 31, 2019. Other income, net, decreased $0.3 million primarily due to decreased dividend and other investment income.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception, and as of December 31, 2020 and 2019 we had an accumulated deficit of $423.0 million and $376.2 million respectively. Having obtained clearance from the FDA and a CE mark in Europe to market the T2Dx, T2Candida, and T2Bacteria, we have incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We may seek to continue to fund our operations through public equity or private equity or debt financings, as well as other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on our business, results of operations and financial condition and our ability to develop and commercialize T2Dx, T2Candida, T2Bacteria, T2SARS-CoV-2 and other product candidates.

Historically, we have funded our operations primarily through our August 2014 initial public offering, our December 2015 public offering, our September 2016 private investment in public equity ("PIPE") financing, our September 2017 public offering, our June 2018 public offering, our July 2019 establishment of an Equity Distribution Agreement and Equity Purchase Agreement (Note 7), private placements of redeemable convertible preferred stock and debt financing arrangements.

Equity Distribution Agreement

On July 30, 2019, we entered into an Equity Distribution Agreement (the "Sales Agreement") with Canaccord Genuity LLC, as agent ("Canaccord"), pursuant to which we may offer and sell shares of common stock in an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act, for aggregate gross sale proceeds of up to $30.0 million from time to time through Canaccord. On March 9, 2020, we entered into an amendment to the Sales Agreement to increase the aggregate gross sales amount from $30.0 million to $65.0 million. On April 8, 2020, we entered into an amendment to the Sales Agreement to increase the aggregate gross sales amount from $65.0 million to $95.0 million. As of December 31, 2020, we had sold 101,606,667 shares of common stock with an aggregate gross sales amount of $95.0 million.

We had agreed to pay Canaccord for its services of acting as agent 3% of the gross proceeds from the sale of the Shares pursuant to the Sales Agreement. Legal and accounting fees were reclassified to share capital upon issuance of shares under the Sales Agreement.

Purchase Agreement

On July 29, 2019, we entered into a $30.0 million purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which we were able to sell and issue to Lincoln Park, and Lincoln Park was obligated to purchase, up to $30.0 million in value of its shares of common stock from time to time over a 36-month period starting from the effective date of the respective registration statement. On April 7, 2020, we terminated the Purchase Agreement, effective April 8, 2020.

In consideration for the execution and delivery of the Purchase Agreement, we issued 413,349 shares of common stock to Lincoln Park.

Plan of operations and future funding requirements

As of December 31, 2020 and 2019 we had unrestricted cash and cash equivalents of approximately $16.8 million and $11.0 million respectively. Currently, the majority of our cash and cash equivalents, along with our marketable securities of $35.4 million, are held in certificates of deposit and U.S. treasury securities. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, costs related to our products, clinical trials, laboratory and related supplies, supplies and materials used in manufacturing, legal and other regulatory expenses and general overhead costs.

Until such time as we can generate substantial product revenue, we expect to finance our cash needs, beyond what is currently available or on hand, through a combination of equity offerings, debt financings and revenue from existing and potential research and development and other collaboration agreements. If we raise additional funds in the future, we may need to relinquish valuable rights to our technologies, future revenue streams or grant licenses on terms that may not be favorable to us.

The COVID-19 pandemic has impacted and may continue to impact our operations. We have established protocols for continued manufacturing, distribution and servicing of our products with safe social distancing and personal protective equipment measures and for remote work for employees not essential to on-site operations. To date these measures have been mostly successful but may not continue to function should the pandemic escalate and impact our personnel. Our hospital customers have restricted our sales team's access to their facilities and as a result, we had significantly reduced our sales and general and administrative staffing levels to reduce expenses. Our customers may reduce their purchases of our products. Our customers may cease to comply with the terms of our sales agreements and this may impact our ability to recognize revenue and hinder receivables collections. We have a significant development contract with a United States government agency and should the agency reduce, cancel or not grant additional milestone projects our ability to continue our future product development may be impacted. Our shipping carriers' ability to deliver our products to customers may be disrupted, although raw materials for the manufacturing of reagents is in high demand, and interruptions in supply are difficult to predict. We have reviewed our suppliers and quantities of key materials and believe we have sufficient stocks and alternate sources of critical materials including personal protective equipment should our supply chains become disrupted. As further described in Note 5, at the onset of the pandemic, we believed that the pandemic's impact on our sales would affect the recoverability of the value of our T2-owned instruments and components. The COVID-19 pandemic also caused us to reassess our build plan and evaluate our inventories accordingly, which resulted in an additional charge to cost of product revenue for excess inventories.

Going Concern

At December 31, 2020, we had an accumulated deficit of $423.0 million. We have experienced cash outflows from operating activities over the past years and are required to maintain a minimum cash balance under our Term Loan Agreement with CRG Servicing LLC ("CRG") (Note 6). 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.

While we believe that our cash, cash equivalents, marketable securities and restricted cash of $52.7 million at December 31, 2020 will be sufficient to fund our current operating plan at least a year from issuance of these financial statements, certain elements of our operating plan cannot be considered probable. Under ASC 205-40, the future receipt of potential funding from our Co-Development partners and other resources cannot be considered probable at this time because none of the plans are entirely within our control. During the year ended December 31, 2020, management implemented a cost improvement strategy which is focused on reducing operating expenses and improving cost of goods sold.

The Term Loan Agreement with CRG (Note 6) has certain covenants which require us to achieve certain annual revenue targets, whereby we are required to pay double the amount of any shortfall as an acceleration of principal payments, and maintain a minimum cash balance of $5.0 million. As of the date of these financial statements, we achieved the revenue target for the twenty-four month period ended December 31, 2020; however there are no assurances that we will achieve the revenue target for the twenty-four month period ended December 31, 2021. Should we fail to meet the revenue target, we would seek a waiver of this provision. There can be no assurances that we would be successful in obtaining a waiver. If we are unsuccessful in obtaining a waiver, we would pay the cure amount set forth under the Term Loan Agreement. While we believe we can continue as a going concern for at least a year from issuance of these financial statements, there can be no assurances that we will continue to be in compliance with the cash covenant in future periods without additional funding. In January 2021, CRG amended the Term Loan Agreement to significantly reduce the revenue covenant for the twenty-four month period ended December 31, 2021.

These conditions raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date that the financial statements are issued. Management's plans to alleviate the conditions that raise substantial doubt include raising additional funding, earning payments pursuant to the Company's Co- Development agreements, delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels for the Company to continue as a going concern for a period of 12 months from the date the 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, the Company has concluded that substantial doubt exists about the Company's ability to continue as a going concern for a period of at least 12 months from the date of issuance of these consolidated financial statements.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

On April 7, 2020, we received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Global Market under Nasdaq Listing Rule 5450(a)(1). On June 16, 2020, we received a letter from the Nasdaq stating that we had regained compliance.

Cash flows

The following is a summary of cash flows for each of the periods set forth below:

	Year ended December 31,	
	2020	2019
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (43,215)	$ (45,361)
Investing activities	(36,261)	(761)
Financing activities	85,607	6,350
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 6,131	$ (39,772)

Net cash used in operating activities

Net cash used in operating activities was $43.2 million for the year ended December 31, 2020, and consisted primarily of a net loss of $46.8 million, an adjustment for non-cash items including stock-based compensation expense of $3.9 million, non-cash interest expense of $3.2 million, depreciation and amortization expense of $1.7 million, non-cash lease expense of $1.5 million, a change in fair value of derivative of $1.4 million, COVID-19 related impairment charge of $0.6 million of our T2-owned instruments and components, an impairment of one of our operating lease assets of $0.5 million, amortization of bond premium of $0.1 million, and a net change in operating assets and liabilities of $6.5 million. The net change in operating assets and liabilities was primarily driven by a decrease in operating lease liabilities of $2.7 million, an increase in accounts receivable of $2.2 million due to higher consumable and instrument sales shipped near quarter end, a decrease in accounts payable of $1.6 million due to timing of payments, and an increase in prepaid expenses and other assets of $1.1 million primarily related to order deposits with our contract manufacturer and increased software subscriptions, partially offset by an increase in accrued expenses of $0.4 million primarily from bonus, $0.4 million of a decrease in inventory primarily due to increased sales and an increase in deferred revenue of $0.3 million primarily due to warranty and service performance obligations associated with the recent instrument sales.

Net cash used in operating activities was $45.4 million for the year ended December 31, 2019, and consisted primarily of a net loss of $59.0 million, an adjustment for non-cash items including stock-based compensation expense of $5.5 million, non-cash interest expense of $2.4 million, depreciation and amortization expense of $2.2 million, amortization of operating lease assets of $1.4 million, and a change in fair value of derivative of $0.3 million and a net change in operating assets and liabilities of $1.9 million. The net change in operating assets and liabilities was primarily driven by a $3.7 million increase in accrued expenses primarily due to the transition of former Chief Executive Officer to Non-Executive Chairman of the Board, timing of interest payments and the final fee for CRG and an increase in accounts payable of $3.0 million due to timing of payments, partially offset by a decrease in operating lease liabilities of $2.3 million, a decrease in deferred revenue of $0.5 million as revenue under our Co-Development Agreement with Canon was fully recognized in 2019, an increase in accounts receivable of $1.0 million primarily from the BARDA contract, an increase in inventories, net, of $0.9 million to meet anticipated demand and an increase in prepaid expenses and other current assets of $0.1 million mostly related to insurance.

Net cash used in investing activities

Net cash used in investing activities was $36.3 million for the year ended December 31, 2020, and consisted of $50.7 million of purchases of marketable securities and $0.8 million of costs to acquire property and equipment, partially offset by proceeds from maturities of marketable securities of $15.3 million.

Net cash used in investing activities was $0.8 million for the year ended December 31, 2019, and consisted of costs to acquire property and equipment.

Net cash provided by financing activities

Net cash provided by financing activities was $85.6 million for the year ended December 31, 2020, and consisted primarily of net proceeds of $85.0 million under the Sales Agreement, net proceeds of $0.3 million under the Purchase Agreement and proceeds from the exercise of stock options and employee stock purchase plan of $0.3 million.

Net cash provided by financing activities was $6.4 million for the year ended December 31, 2019, and consisted primarily of net proceeds of $6.7 million under the Sales Agreement and proceeds from the exercise of stock options and employee stock purchase plan of $0.6 million which were partially offset by $0.9 million of repayments of finance leases.

Borrowing Arrangements

Term Loan Agreement

In December 2016, we entered into a Term Loan Agreement with CRG. We borrowed $40.0 million pursuant to the Term Loan Agreement, which has a six-year term with three years (through December 30, 2019) of interest-only payments, which period was extended to four years (through December 30, 2020) upon achieving the Approval Milestone, after which quarterly principal and interest payments would be due through the December 30, 2022 maturity date. Interest on the amounts borrowed under the Term Loan Agreement accrues at an annual fixed rate of (a) prior to the Approval Milestone, 12.50%, 4.0% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount and (b) following the Approval Milestone, 11.50%, 3.5% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount. In addition, if we achieve certain financial performance metrics, the loan will convert to interest-only until the December 30, 2022 maturity, at which time all unpaid principal and accrued unpaid interest will be due and payable. We are required to pay CRG a financing fee based on the loan principal amount drawn. We are also required to pay a final payment fee of 8%, subsequently amended to 10%, of the principal outstanding upon repayment. We are accruing the final payment fee as interest expense and it is included as a non-current liability at December 31, 2020 and a current liability at December 31, 2019 on the balance sheet.

The Term Loan Agreement with CRG is classified as a current liability on the balance sheet at December 31, 2019 based on our consideration of the probability of violating the 2020 revenue covenant, which in turn would trigger violation of the minimum liquidity covenant included in the Term Loan Agreement. The Term Loan Agreement with CRG is classified as a non-current liability at December 31, 2020, as we have sufficient cash, cash equivalents and marketable securities as of the date of this filing that the minimum liquidity covenant would not be triggered even upon default of the revenue covenant at December 31, 2021 as the cure would not be due until March 31, 2022. We have assessed the classification of the note payable as non-current based on facts and circumstances as of the date of this filing, specifically as it relates to achieving the minimum liquidity and revenue covenants. As of the date of this filing, we believe that should we be unable to meet such covenants as of December 31, 2021, it is probable that we would be able to pay the cure of default on March 31, 2022. Management continues to reassess at each balance sheet and filing date based on facts and circumstances and can provide no assurances regarding the probability of meeting its aforementioned covenants in future periods.

We may prepay all or a portion of the outstanding principal and accrued unpaid interest under the Term Loan Agreement at any time upon prior notice subject to a certain prepayment fee during the first five years of the term and no prepayment fee thereafter. As security for our obligations under the Term Loan Agreement, we entered into a security agreement with CRG whereby we granted a lien on substantially all of its assets, including intellectual property. The Term Loan Agreement also contains customary affirmative and negative covenants for a credit facility of this size and type, including a requirement to maintain a minimum cash balance of $5.0 million. The Term Loan Agreement also requires us to achieve certain revenue targets, whereby we are required to pay double the amount of any shortfall as an acceleration of principal payments. In March 2019, the Term Loan Agreement was amended to reduce the 2019 minimum revenue target to $9.0 million and eliminate the 2018 revenue covenant. In exchange for the amendment, we agreed to reset the strike price of the warrants to purchase 528,958 shares of our common stock, issued in connection with the Term Loan Agreement, from $8.06 per share to $4.35 per share.

In September 2019, the Term Loan Agreement was amended to extend the interest-only payment period through December 31, 2021, to extend the initial principal repayment to March 31, 2022, and to reduce the minimum product revenue target for 2019 from $9 million to $4 million, for the twenty-four month period beginning on January 1, 2019 from $95 million to $15 million and for the twenty-four month period beginning on January 1, 2020 from $140 million to $43 million. The final payment fee was increased from 8% to 10% of the principal amount outstanding upon repayment. We issued to CRG warrants to purchase 568,291 shares of our common stock (“New Warrants”) (Note 9) at an exercise price of $1.55, with typical provisions for termination upon a change of control or a sale of all or substantially all of our assets. We also reduced the exercise price for the warrants previously issued to CRG to purchase an aggregate of 528,958 shares of our common stock to $1.55. All of the New Warrants are exercisable any time prior to September 9, 2029, and all of the previously issued warrants are exercisable any time prior to December 30, 2026. We accounted for the March 2019 and September 2019 amendments as modifications to the Term Loan Agreement.

In January 2021, the Term Loan Agreement was amended to extend the interest-only payment period through December 31, 2022, to extend the initial principal repayment to December 31, 2022, and to significantly reduce the revenue covenant for the 24-month period beginning on January 1, 2020. We did not pay or provide any consideration in exchange for this amendment.

The Term Loan Agreement includes a subjective acceleration clause whereby an event of default, including a material adverse change in the business, operations, or conditions (financial or otherwise), could result in the acceleration of the obligations under the Term Loan Agreement. Under certain circumstances, a default interest rate of an additional 4.0% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default. CRG has not exercised its right under this clause.

We assessed the terms and features of the Term Loan Agreement, including the interest-only period dependent on the achievement of the Approval Milestone and the acceleration of the obligations under the Term Loan Agreement under an event of default, of the Term Loan Agreement in order to identify any potential embedded features that would require bifurcation. In addition, under certain circumstances, a default interest rate of an additional 4.0% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default, we concluded that the features of the Term Loan Agreement are not clearly and closely related to the host instrument, and represent a single compound derivative that is required to be re-measured at fair value on a quarterly basis.

The fair value of the derivative at December 31, 2020 and 2019 is $1.0 million and $2.4 million, respectively. We classified the derivative liability as a non-current liability on the balance sheet at December 31, 2020 and a current liability at December 31, 2019 to match the classification of the related Term Loan Agreement. While our fair value assessment as of December 31, 2020 assessed the likelihood of paying contingent interest as remote within the next twelve months, and as of the date of this filing, we continue to assess and believe the probability is remote that the contingent interest will commence within the next twelve months which, accordingly, provided for the non-current classification of the derivative liability. Management continues to reassess at each balance sheet and filing date based on facts and circumstances and can provide no assurances regarding the probability of payment of the contingent interest in future periods.

Equipment Lease Credit Facility

In October 2015, we signed the $10.0 million Credit Facility (the "Credit Facility") with Essex Capital Corporation ("Essex") to fund capital equipment needs. As one of the conditions of the Term Loan Agreement, the Credit Facility was capped at a maximum of $5.0 million. Under the Credit Facility, Essex funded capital equipment purchases presented by us. We repaid the amounts borrowed in 36 equal monthly installments from the date of the amount funded. At the end of the 36-month lease term, we had the option to (a) repurchase the leased equipment at the lesser of fair market value or 10% of the original equipment value, (b) extend the applicable lease for a specified period of time, which will not be less than one year, or (c) return the leased equipment to the Lessor.

In April 2016 and June 2016, we completed the first two draws under the Credit Facility of $2.1 million and $2.5 million, respectively. We made monthly payments of $67,000 under the first draw and $79,000 under the second draw. The borrowings under the Credit Facility were treated as capital leases and were included in property and equipment on the balance sheet. The amortization of the assets conveyed under the Credit Facility was included as a component of depreciation expense. During the year ended December 31, 2019, we repurchased the equipment for $0.3 million in accordance with the terms of the Credit Facility.

Contingent Liabilities and Commitments, Including Tax Matters

We have net deferred tax assets of $72.4 million as of December 31, 2020, which have been fully offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. The deferred tax assets are primarily composed of federal net operating loss ("NOL"), tax carryforwards and research and development tax credit carryforwards. As of December 31, 2020, we had federal NOL carryforwards of $222.6 million available to reduce future taxable income, if any. Out of the total NOL carryforwards of $222.6 million, $78.7 million will expire at various dates through 2037 and $143.9 million carryforward indefinitely. As of December 31, 2020, we had state NOL carryforwards of $247.9 million, of which $215.3 million expire at various dates through 2040 and $32.6 million is carried forward indefinitely. As of December 31, 2020, we had federal tax credit carryforwards of $0.8 million and state tax credit carryforwards of $0.8 million which expire at various dates through 2040 and 2035, respectively. In 2020, we completed a 382 study of our cumulative net operating loss and tax credit carryforwards. As a result, there were limitations placed on the use of our loss and credit carryforwards. The 2019 federal and state net operating loss carryforwards of $329.6 million and $292.4 million, respectively, were determined to be limited by $149.5 million and $78.9 million, respectively. The 2019 federal and state tax credit carryforwards of $5.5 million and $3.6 million, respectively, were limited by $5.4 million and $3.2 million, respectively. The decrease in the prior year tax attributes is attributable to change of control ownership shifts which were determined for the years 2013, 2016, and 2019 which caused the reduction in the value of the historical net operating loss carryforwards. Since the limitation affected the prior period, the Company has determined that its 2019 tax footnote presentation overstated the gross net operating loss deferred tax asset and corresponding valuation allowance. However, there was no net impact to the net deferred tax asset and tax expense as the decrease in the net operating loss carryforward was offset completely by a corresponding adjustment to the Company's overall valuation allowance. For comparative purposes, the Company's prior year tax footnote has been revised to reflect the adjustment to the net operating losses and valuation allowance. If we experience a Section 382 ownership change in connection as a result of future changes in our stock ownership, some of which changes are outside of our control, the tax benefits related to the NOL and tax credit carryforwards may be limited or lost.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Critical Accounting Policies and Significant Judgements

This management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue and expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements and understanding and evaluating our reported financial results. See Note 2 of the notes to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K for additional information on our accounting policies and significant judgements.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide this information.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

Stockholders and Board of Directors
T2 Biosystems, Inc.
Lexington, Massachusetts

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of T2 Biosystems, Inc. (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020**,** in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations, has an accumulated deficit, has experienced cash outflows from operating activities over the past years, has debt with both a minimum cash and product revenue covenant, and will require additional capital to fund its current operating plan, and has stated that substantial doubt exists about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation of certain inventories

As described in Note 2, the Company performs an assessment of the recoverability of capitalized inventory during each reporting period and records a charge to expense for cost basis in excess of net realizable value in the period in which the impairment is first identified, writes down any excess and obsolete inventories as appropriate, and the Company classifies instruments, including raw material and work-in-process inventories, that are Company-owned or expected to be so, as a component of property and equipment based on the Company's business model and forecast. These adjustments are based on a variety of assumptions.

We identified the estimation of the valuation of certain inventory as a critical audit matter. Management applies significant judgment in determining the net realizable value of inventories specifically related to estimated future average selling prices and future sales volumes of certain inventories. Auditing these elements required significant auditor judgment and subjectivity including the nature and extent of audit effort required to address these matters.

The primary procedures we performed to address this critical audit matter included:

- Testing management’s process for developing the net realizable value estimate of certain inventories; evaluating the appropriateness of management’s estimated net realizable value methodology; testing the completeness, accuracy, and relevance of underlying data used in the estimate of net realizable value of certain inventories.

- Evaluating management’s assumptions related to future average selling prices and future sales volumes by considering (i) current and past results, including recent sales, (ii) the consistency with current contract prices, and (iii) a comparison of the prior year estimates to actual results in the current year.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2018.

Boston, Massachusetts

March 31, 2021

T2 Biosystems, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 16,793	$ 11,033
Marketable securities	25,396	—
Accounts receivable	5,099	2,825
Inventories	3,636	3,599
Prepaid expenses and other current assets	2,660	1,438
Total current assets	53,584	18,895
Property and equipment, net	3,771	5,845
Operating lease right-of-use assets	11,034	3,360
Restricted cash	551	180
Marketable securities	10,002	—
Other assets	136	206
Total assets	$ 79,078	$ 28,486
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Notes payable	$ —	$ 42,902
Accounts payable	2,058	3,753
Accrued expenses and other current liabilities	7,512	11,207
Derivative liability	—	2,425
Deferred revenue	230	285
Total current liabilities	9,800	60,572
Notes payable, net of current portion	45,235	—
Operating lease liabilities, net of current portion	10,533	1,873
Deferred revenue, net of current portion	424	46
Derivative liability	1,010	—
Other liabilities	3,350	—
Commitments and contingencies (see Note 13)		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized; 148,078,974 and 50,651,535 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	148	51
Additional paid-in capital	431,544	342,121
Accumulated other comprehensive income	9	—
Accumulated deficit	(422,975)	(376,177)
Total stockholders' equity (deficit)	8,726	(34,005)
Total liabilities and stockholders' equity (deficit)	$ 79,078	$ 28,486

See accompanying notes to consolidated financial statements.

T2 Biosystems, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Year ended December 31,	
	2020	**2019**
Revenue:		
Product revenue	$ 11,677	$ 5,327
Research revenue	11	563
Contribution revenue	6,442	2,445
Total revenue	18,130	8,335
Costs and expenses:		
Cost of product revenue	21,280	16,763
Research and development	16,919	16,326
Selling, general and administrative	21,287	27,304
Total costs and expenses	59,486	60,393
Loss from operations	(41,356)	(52,058)
Other income (expense):		
Interest income	14	1
Interest expense	(5,518)	(7,349)
Other income, net	62	400
Total other expense	(5,442)	(6,948)
Net loss	(46,798)	(59,006)
Net loss per share — basic and diluted	$ (0.39)	$ (1.30)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	121,331,464	45,507,754
Other comprehensive loss:		
Net loss	$ (46,798)	$ (59,006)
Change in net unrealized gain on marketable securities, net of taxes:		
Net unrealized gain on marketable securities arising during the period	13	—
Less: net realized gain on marketable securities included in net loss	(4)	—
Net unrealized gain on marketable securities	9	—
Comprehensive loss	$ (46,789)	$ (59,006)

See accompanying notes to consolidated financial statements.

T2 Biosystems, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)
(In thousands, except share and per share data)

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders' Equity (Deficit)
	Shares	Amount	Capital	Deficit	Income	
Balance at December 31, 2018	44,175,441	$ 44	$ 328,514	$ (317,171)	$ —	$ 11,387
Stock-based compensation expense	—	—	5,458	—	—	5,458
Issuance of common stock from vesting of restricted stock, exercise of stock options and employee stock purchase plan	576,245	1	581	—	—	582
Issuance of common stock from secondary public offering, net of offering costs of $175	5,486,500	6	6,644	—	—	6,650
Change in fair value of warrants upon modification	—	—	264	—	—	264
Issuance of warrants	—	—	660	—	—	660
Shares issued in connection with purchase agreement	413,349	—	—	—	—	—
Net loss	—	—	—	(59,006)	-	(59,006)
Balance at December 31, 2019	50,651,535	51	342,121	(376,177)	—	(34,005)
Stock-based compensation expense	—	—	3,913	—	—	3,913
Issuance of common stock from vesting of restricted stock, exercise of stock options and employee stock purchase plan	907,272	—	296	—	—	296
Issuance of common stock from secondary public offerings, net of offering costs of $3.0 million	96,520,167	97	85,214	—	—	85,311
Unrealized gain on marketable securities	—	—	—	—	9	9
Net loss	—	—	—	(46,798)		(46,798)
Balance at December 31, 2020	148,078,974	$ 148	$ 431,544	$ (422,975)	$ 9	$ 8,726

See accompanying notes to consolidated financial statements.

T2 Biosystems, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year ended December 31,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (46,798)	$ (59,006)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,710	2,197
Amortization of bond premium	72	—
Amortization of operating lease right-of-use assets	1,446	1,445
Stock-based compensation expense	3,913	5,458
Change in fair value of derivative instrument	(1,415)	283
Gain on disposal of property and equipment	(2)	(3)
Impairment of operating lease asset	523	—
Impairment of property and equipment	636	—
Non-cash interest expense	3,238	2,407
Changes in operating assets and liabilities:		
Accounts receivable	(2,274)	(1,039)
Prepaid expenses and other assets	(1,152)	(98)
Inventories	441	(914)
Accounts payable	(1,652)	2,960
Accrued expenses and other liabilities	439	3,708
Deferred revenue	323	(499)
Operating lease liabilities	(2,663)	(2,260)
Net cash used in operating activities	(43,215)	(45,361)
Cash flows from investing activities		
Purchases of marketable securities	(50,711)	—
Proceeds from maturities of marketable securities	15,250	—
Proceeds from sale of property and equipment	4	—
Purchases and manufacture of property and equipment	(804)	(761)
Net cash used in investing activities	(36,261)	(761)
Cash flow from financing activities		
Proceeds from issuance of common stock in public offering, net of offering costs	85,311	6,650
Proceeds from issuance of shares from employee stock purchase plan and stock option exercises	296	582
Principal repayments of finance leases	—	(882)
Net cash provided by financing activities	85,607	6,350
Net increase (decrease) in cash, cash equivalents and restricted cash	6,131	(39,772)
Cash, cash equivalents and restricted cash at beginning of period	11,213	50,985
Cash, cash equivalents and restricted cash at end of period	$ 17,344	$ 11,213

See accompanying notes to consolidated financial statements.

T2 Biosystems, Inc.
Consolidated Statements of Cash Flows (Continued)
(In thousands)

	Year ended December 31,	
Reconciliation of cash, cash equivalents and restricted cash at end of period	**2020**	**2019**
Cash and cash equivalents	$ 16,793	$ 11,033
Restricted cash	551	180
Total cash, cash equivalents and restricted cash	$ 17,344	$ 11,213

	Year ended December 31,	
	2020	**2019**
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 3,692	$ 4,659
Supplemental disclosures of noncash activities		
Transfer of T2 owned instruments and components to (from) inventory	$ 478	$ (8)
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 9,602	$ 4,805
Change in fair value of warrants issued and modified	$ —	$ 924
Purchases of property and equipment included in accounts payable and accrued expenses	$ 41	$ 107

See accompanying notes to consolidated financial statements.

1. Nature of Business

T2 Biosystems, Inc. and subsidiary (the "Company," "we," or "T2") have operations based in Lexington, Massachusetts; T2 Biosystems, Inc. was incorporated on April 27, 2006 as a Delaware corporation. The Company is an *in vitro* diagnostics company that has developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. The Company is using its T2 Magnetic Resonance technology ("T2MR") to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. T2MR enables rapid detection of pathogens, biomarkers and other abnormalities in a variety of unpurified patient sample types, including whole blood, plasma, serum, saliva, sputum, cerebral spinal fluid and urine, and can detect cellular targets at limits of detection as low as one colony forming unit per milliliter ("CFU/mL"). The Company's initial development efforts target sepsis, which is an area of significant unmet medical need in which existing therapies could be more effective with improved diagnostics. On September 22, 2014, the Company received market clearance from the U.S. Food and Drug Administration ("FDA") for its first two products, the T2Dx® Instrument (the "T2Dx") and T2Candida® Panel ("T2Candida"). On May 24, 2018, the Company received market clearance from the FDA for its T2Bacteria® Panel ("T2Bacteria"). On February 6, 2019, the FDA granted the Company's T2Resistance™ Panel ("T2Resistance") designation as a Breakthrough Device. On August 2, 2019, the Center for Medicare & Medicaid Services (CMS) granted approval for a New Technology Add-on Payment (NTAP) for the T2Bacteria Panel for fiscal year 2020 and in September 2020, CMS extended the approval for 2021. On November 20, 2019, the Company's T2Resistance Panel was granted a CE-Mark. On June 30, 2020, the Company announced the U.S. launch of its COVID-19 molecular diagnostic test, the T2SARS-CoV-2 Panel, after validation of the test meeting the FDA's requirements for an Emergency Use Authorization (EUA). In August 2020, the FDA issued EUA for the Company's T2SARS-CoV-2 Panel. The test is designed to detect the presence of the SARS-CoV-2 virus in a nasopharyngeal swab sample.

The Company has devoted substantially all of its efforts to research and development, business planning, recruiting management and technical staff, acquiring operating assets, raising capital, and the commercialization and improvement of its existing products.

Liquidity and Going Concern

At December 31, 2020, the Company has cash, cash equivalents, marketable securities and restricted cash of $52.7 million, an accumulated deficit of $423.0 million and has experienced cash outflows from operating activities over the past years. The future success of the Company is dependent on its ability to successfully commercialize its products, obtain regulatory clearance for and successfully launch its future product candidates, obtain additional capital and ultimately attain profitable operations. Historically, the Company has funded its operations primarily through its August 2014 initial public offering, its December 2015 public offering, its September 2016 private investment in public equity ("PIPE") financing, its September 2017 public offering, its June 2018 public offering, its July 2019 establishment of an Equity Distribution Agreement and Equity Purchase Agreement (Note 7), private placements of redeemable convertible preferred stock and through debt financing arrangements.

The Company is subject to a number of risks similar to other early commercial stage life science companies, including, but not limited to commercially launching the Company's products, development and market acceptance of the Company's product candidates, development by its competitors of new technological innovations, protection of proprietary technology, and raising additional capital.

The COVID-19 pandemic has impacted and may continue to impact operations. The Company has established protocols for continued manufacturing, distribution and servicing of its products with safe social distancing and personal protective equipment measures and for remote work for certain employees not essential to on-site operations. To date these measures have been mostly successful but may not continue to function should the pandemic escalate and impact personnel. The Company's hospital customers have restricted the sales team's access to their facilities and as a result, the Company had significantly reduced its sales and general and administrative staffing levels to reduce expenses. Although the Company did not see any material impact to accounts receivable during the year ended December 31, 2020, the Company's exposure may increase if its customers are adversely affected by the COVID-19 pandemic. Customers may reduce their purchases of products, depending on their needs and cash flow, which could negatively impact revenue. The Company has a significant development contract with a United States government agency and should the agency reduce, cancel or not grant additional milestone projects, the Company's ability to continue its future product development may be impacted. The ability of the Company's shipping carriers to deliver products to customers may be disrupted. The Company has reviewed its suppliers and quantities of key materials and believes that it has sufficient stocks and alternate sources of critical materials including personal protective equipment should the supply chains become disrupted, although raw materials for the manufacturing of reagents is in high demand, and interruptions in supply are difficult to predict. As further described in Note 5, at the onset of the pandemic, the Company believed the pandemic's impact on its sales would affect the recoverability of the value of T2-owned instruments and components. The COVID-19 pandemic also caused the Company to reassess its build plan and evaluate its inventories accordingly, which resulted in an additional charge to cost of product revenue for excess inventories.

Since FDA authorization was obtained to market the T2Dx, T2Candida, and T2Bacteria, and EUA for T2SARS-CoV-2, the Company has incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution. The Company may seek to fund its operations through public equity, private equity or debt financings, as well as other sources. However, the Company may be unable to raise additional funds or enter into such other arrangements when needed, on favorable terms, or at all. The Company's failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on the Company's business, results of operations, financial condition and the Company's ability to develop and commercialize T2Dx, T2Candida, T2Bacteria, T2SARS-CoV-2, and other product candidates.

Pursuant to the requirements of Accounting Standards Codification ("ASC") 205-40, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued.

While the Company believes that its cash, cash equivalents, marketable securities and restricted cash of $52.7 million at December 31, 2020 will be sufficient to fund our current operating plan at least a year from issuance of these financial statements, certain elements of our operating plan cannot be considered probable. Under ASC 205-40, the future receipt of potential funding from our Co-Development partners and other resources cannot be considered probable at this time because none of the plans are entirely within our control. During the year ended December 31, 2020, management implemented a cost improvement strategy which is focused on reducing operating expenses and improving cost of goods sold.

The Term Loan Agreement with CRG Servicing LLC ("CRG") (Note 6) has certain covenants which require the Company to achieve certain annual revenue targets, whereby the Company is required to pay double the amount of any shortfall as an acceleration of principal payments, and maintain a minimum cash balance of $5.0 million. As of the date of these financial statements, the Company achieved the revenue target of $15.0 million for the twenty-four month period ended December 31, 2020; however there are no assurances that we will achieve the revenue target for the twenty-four month period ended December 31, 2021. Should we fail to meet the revenue target, we would seek a waiver of this provision. There can be no assurances that we would be successful in obtaining a waiver. If we are unsuccessful in obtaining a waiver, we would pay the cure amount set forth under the Term Loan Agreement. While we believe we can continue as a going concern for at least a year from issuance of these financial statements, there can be no assurances that we will continue to be in compliance with the cash covenant in future periods without additional funding. In January 2021, CRG amended the Term Loan Agreement to significantly reduce the revenue covenant for the twenty-four month period ended December 31, 2021.

These conditions raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date that the financial statements are issued. Management's plans to alleviate the conditions that raise substantial doubt include raising additional funding, earning payments pursuant to the Company's Co- Development agreements, delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels for the Company to continue as a going concern for a period of 12 months from the date the 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, the Company has concluded that substantial doubt exists about the Company's ability to continue as a going concern for a period of at least 12 months from the date of issuance of these consolidated financial statements.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

On April 7, 2020, the Company received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for 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 Nasdaq Global Market under Nasdaq Listing Rule 5450(a)(1). On June 16, 2020, the Company received a letter from the Nasdaq stating that the Company had regained compliance.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). The Company's consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, T2 Biosystems Securities Corporation. All intercompany balances and transactions have been eliminated.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company utilizes certain estimates in the determination of the accounts receivable allowance, the excess and obsolete inventory, the net realizable value of inventory, the fair value of its stock options, as well as restricted stock units that have market conditions, deferred tax valuation allowances, revenue recognition, expenses relating to research and development contracts, accrued expenses, the fair value of a derivative liability, the fair value of warrants and classification of the value of instrument raw material and work-in-process inventory between inventory and property and equipment. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results could differ from such estimates.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker is the Chief Executive Officer. The Company views its operations and manages its business in one operating segment, which is the business of developing and, upon regulatory clearance, launching commercially its diagnostic products aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier.

Geographic Information

The Company sells its products domestically and internationally. International sales to a single country did not exceed 10% of total revenue in any year. Total international sales were approximately $2.0 million or 11% of total revenue in 2020 and $2.8 million or 34% of total revenue in 2019.

As of December 31, 2020 and 2019, the Company had outstanding receivables of $0.5 million and $1.2 million, respectively, from customers located outside of the U.S.

Off-Balance Sheet Risk and Concentrations of Risk

The Company has no significant off-balance sheet risks, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Cash and cash equivalents are financial instruments that potentially subject the Company to concentrations of credit risk. At December 31, 2020, substantially all of the Company's cash, cash equivalents and marketable securities were deposited in accounts at two financial institutions, with the majority of marketable securities invested in certificates of deposit and U.S. treasury securities. At December 31, 2019, substantially all of the Company's cash was deposited in accounts at one financial institution, with a portion invested in money market funds that are invested in short-term U.S. government agency securities. The Company maintains its cash deposits, which at times may exceed the federally insured limits, with a large financial institution and, accordingly, the Company believes such funds are subject to minimal credit risk.

The Company derived approximately 36% of its total revenue from one customer for the year ended December 31, 2020 and 19% of its total revenue from the same customer for the year ended December 31, 2019. For the year ended December 31, 2020, the Company derived approximately 11% of its total revenue from a second customer and 6% of its total revenue from a third customer. For the year ended December 31, 2019, the Company derived approximately 11% of its total revenue from a second customer and 8% of its total revenue from a third customer.

At December 31, 2020, the Company had two customers that represented 20% and 17%, respectively, of its accounts receivable balance. At December 31, 2019, the Company had two customers that represented 27% and 10%, respectively, of its accounts receivable balance.

The Company relies on single-source suppliers for some components and materials used in its products and product candidates. The Company has entered into supply agreements with most of its suppliers to help ensure component availability and flexible purchasing terms with respect to the purchase of such components. While the Company believes replacement suppliers exist for all components and materials obtained from single sources, establishing additional or replacement suppliers for any of these components or materials, if required, may not be accomplished quickly. Even if the Company is able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. If third-party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and the Company is unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of products, the supply of products to customers and the development of any future products would be delayed, limited or prevented, which could have an adverse impact on the business.

Cash Equivalents

Cash equivalents include all highly liquid investments with original maturities of 90 days or less. Cash equivalents consist of certificates of deposit and government securities as of December 31, 2020 and money market funds invested in short-term U.S. government agency securities as of December 31, 2019.

Marketable Securities

The Company's marketable securities typically consist of certificates of deposit and U.S. treasury securities, which are classified as available-for-sale and included in current and non-current assets. Available-for-sale debt securities are carried at fair value with unrealized gains and losses reported as a component of stockholders' equity (deficit) in accumulated other comprehensive income. Realized gains and losses, if any, are included in other income in the consolidated statements of operations.

Available-for-sale securities are reviewed for possible impairment at least quarterly, or more frequently if circumstances arise that may indicate impairment. When the fair value of the securities declines below the amortized cost basis, impairment is indicated and it must be determined whether it is other than temporary. Impairment is considered to be other than temporary if the Company: (i) intends to sell the security, (ii) will more likely than not be forced to sell the security before recovering its cost, or (iii) does not expect to recover the security's amortized cost basis. If the decline in fair value is considered other than temporary, the cost basis of the security is adjusted to its fair market value and the realized loss is reported in earnings. Subsequent increases or decreases in fair value are reported as a component of stockholders' equity (deficit) in accumulated other comprehensive income. There were no other-than-temporary unrealized losses as of December 31, 2020.

The following table summarizes the Company's marketable securities at December 31, 2020 (in thousands):

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Certificates of deposit	$ 1,250	$ 1	$ —	$ 1,251
U.S. treasury securities	34,139	8	—	34,147
Total	$ 35,389	$ 9	$ —	$ 35,398

The following table summarizes the maturities of the Company's marketable securities at December 31, 2020 (in thousands):

	December 31, 2020	
	Amortized Cost	Fair Value
Due in less than 1 year	$ 25,387	$ 25,396
Due in 1-2 years	10,002	10,002
Total	$ 35,389	$ 35,398

Accounts Receivable

The Company's accounts receivable consists of amounts due from product sales to commercial customers and from research and development arrangements with partners. At each reporting period, management reviews historical loss information, characteristics of our customers, our credit practices and the economic conditions, along with all outstanding balances to determine if the facts and circumstances indicate the need for a credit loss allowance. The Company does not require collateral and did not have an allowance for doubtful accounts at December 31, 2020 or 2019.

Inventories

Inventories are stated at the lower of cost or net realizable value. The Company determines the cost of its inventories, which includes amounts related to materials, direct labor, and manufacturing overhead, on a first-in, first-out basis. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period and records a charge to expense for cost basis in excess of net realizable value in the period in which the impairment is first identified, and writes down any excess and obsolete inventories as appropriate. Shipping and handling costs incurred for inventory purchases are capitalized and recorded upon sale in cost of product revenues in the consolidated statements of operations and comprehensive loss or are included in the value of T2-owned instruments and components, a component of property and equipment, net, and depreciated.

The Company capitalizes inventories in preparation for sales of products when the related product candidates are considered to have a high likelihood of regulatory clearance, which for the T2Dx Instrument, T2Candida and T2Bacteria was upon the achievement of regulatory clearance and upon EUA for T2SARS-CoV-2, and the related costs are expected to be recoverable through sales of the inventories. In addition, the Company capitalizes inventories related to the manufacture of instruments that have a high likelihood of regulatory clearance, which for the T2Dx Instrument was upon the achievement of regulatory clearance, and will be retained as the Company's assets, upon determination that the instrument has alternative future uses. In determining whether or not to capitalize such inventories, the Company evaluates, among other factors, information regarding the product candidate's status of regulatory submissions and communications with regulatory authorities, the outlook for commercial sales and alternative future uses of the product candidate. Costs associated with development products prior to satisfying the inventory capitalization criteria are charged to research and development expense as incurred.

The Company classifies instruments that are T2-owned, as a component of property and equipment. Raw material and work-in-process inventories that are expected to be used to produce T2-owned instruments, based on the Company's business model and forecast, are also classified as property and equipment. T2-owned instruments are instruments that are manufactured and placed with customers in connection with reagent rental agreements, or are used for internal purposes.

The components of inventory consist of the following (in thousands):

	December 31, 2020	December 31, 2019
Raw materials	$ 1,496	$ 1,617
Work-in-process	1,374	1,227
Finished goods	766	755
Total inventories, net	$ 3,636	$ 3,599

Fair Value Measurements

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. ASC 820, *Fair Value Measurements and Disclosures* ("ASC 820"), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available.

Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The hierarchy defines three levels of valuation inputs:

Level 1 — Quoted unadjusted prices for identical instruments in active markets.

Level 2 — Quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-derived valuations in which all observable inputs and significant value drivers are observable in active markets.

Level 3 — Model derived valuations in which one or more significant inputs or significant value drivers are unobservable, including assumptions developed by the Company.

The fair value hierarchy prioritizes valuation inputs based on the observable nature of those inputs. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability (Note 3).

For certain financial instruments, including accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses, the carrying amounts approximate their fair values as of December 31, 2020 and 2019 because of their short-term nature. At December 31, 2020 and 2019, the fair value of the derivative liability was determined using Level 3 inputs using a valuation model that includes assumptions from the Company (Note 3).

Property and Equipment

Property and equipment are recorded at cost and depreciated over their estimated useful lives using the straight-line method. Property and equipment, net, includes assets under capital leases. Property and equipment includes raw materials and work-in-process inventory that are expected to be used or used to produce T2-owned instruments based on the Company's business model and forecast, and finished instruments that will be used for internal research and development, clinical studies or reagent rental agreements with customers. Completed T2-owned instruments are placed in service once installation procedures are completed. Construction in progress is primarily comprised of equipment that has not been placed in service. Repairs and maintenance costs are expensed as incurred, whereas major improvements are capitalized as additions to property and equipment.

Leases

Pursuant to Topic 842, *Leases* ("ASC 842"), at the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and long-term lease liabilities. The Company has elected not to recognize on the balance sheet leases with terms of one year or less. The exercise of lease renewal options is at our discretion and the renewal to extend the lease terms are not included in the Company's right-of-use assets and lease liabilities as they are not reasonably certain of exercise. The Company will evaluate the renewal options and when they are reasonably certain of exercise, the Company will include the renewal period in its lease term. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. However, certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued lease payments. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rates, which are the rates incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

In accordance with the guidance in ASC 842, components of a lease should be split into three categories: lease components (e.g. land, building, etc.), non-lease components (e.g. common area maintenance, consumables, etc.), and non-components (e.g. property taxes, insurance, etc.). Then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components.

The Company made the policy election to not separate lease and non-lease components. Each lease component and the related non-lease components are accounted for together as a single component.

Revenue Recognition

The Company generates revenue from the sale of instruments, consumable diagnostic tests, related services, reagent rental agreements and research and development agreements with third parties. Pursuant to ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company determines revenue recognition through the following steps:

- Identification of a contract with a customer
- Identification of the performance obligations in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligations
- Recognition of revenue as a performance obligation is satisfied.

The amount of revenue recognized reflects the consideration the Company expects to be entitled to receive in exchange for these goods and services.

Once a contract is determined to be within the scope of ASC 606 at contract inception, the Company reviews the contract to determine which performance obligations the Company must deliver and which of these performance obligations are distinct. The Company recognizes as revenues the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied or as it is satisfied. Generally, the Company's performance obligations are transferred to customers at a point in time, typically upon shipment, or over time, as services are performed.

Most of the Company's contracts with distributors in geographic regions outside the United States contain only a single performance obligation, whereas most of the Company's contracts with direct sales customers in the United States contain multiple performance obligations. For these contracts, the Company accounts for individual performance obligations separately if they are distinct. The transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. Excluded from the transaction price are sales tax and other similar taxes which are presented on a net basis.

Product revenue is generated by the sale of instruments and consumable diagnostic tests predominantly through the Company's direct sales force in the United States and distributors in geographic regions outside the United States. The Company does not offer product return or exchange rights (other than those relating to defective goods under warranty) or price protection allowances to its customers, including its distributors. Payment terms granted to distributors are the same as those granted to end-user customers and payments are not dependent upon the distributors' receipt of payment from their end-user customers.

The Company either sells instruments to customers and international distributors, or retains title and places the instrument at the customer site pursuant to a reagent rental agreement. When an instrument is purchased by a customer or international distributor, the Company recognizes revenue when the related performance obligation is satisfied (i.e. when the control of an instrument has passed to the customer; typically, at shipping point).

When the instrument is placed under a reagent rental agreement, the Company's customers generally agree to fixed term agreements, which can be extended, and incremental charges on each consumable diagnostic test purchased. Revenue from the sale of consumable diagnostic tests (under a reagent rental agreement) is recognized upon shipment. The transaction price from consumables purchases is allocated between the lease of the instrument (under a contingent rent methodology as provided for in ASC 842, *Leases*), and the consumables when related performance obligations are satisfied, as a component of lease and product revenue, and is included as Instrument Rentals in the below table. Revenue associated with reagent rental consumables purchases is currently classified as variable consideration and constrained until a purchase order is received and related performance obligations have been satisfied.

Revenue from the sale of consumable diagnostic tests (under instrument purchase agreements) is recognized upon shipment.

Shipping and handling costs billed to customers in connection with a product sale are recorded as a component of the transaction price and allocated to product revenue in the consolidated statements of operations and comprehensive loss as they are incurred by the Company in fulfilling its performance obligations.

Direct sales of instruments include warranty, maintenance and technical support services typically for one year following the installation of the purchased instrument ("Maintenance Services"). Maintenance Services are separate performance obligations as they are service based warranties and are recognized on a straight-line basis over the service delivery period. After the completion of the initial Maintenance Services period, customers have the option to renew or extend the Maintenance Services typically for additional one year periods in exchange for additional consideration. The extended Maintenance Services are also service based warranties that represent separate purchasing decisions. The Company recognizes revenue allocated to the extended Maintenance Services performance obligation on a straight-line basis over the service delivery period.

Fees paid to member-owned group purchasing organizations ("GPOs") are deducted from related product revenues.

The Company warrants that consumable diagnostic tests will be free from defects, when handled according to product specifications, for the stated life of the product. To fulfill valid warranty claims, the Company provides replacement product free of charge. Accordingly, the Company accrues warranty expense associated with the estimated defect rates of the consumable diagnostic tests.

Revenue earned from activities performed pursuant to research and development agreements is reported as research revenue in the consolidated statements of operations and comprehensive loss, and is recognized over time using an input method as the work is completed. The related costs are expensed as incurred as research and development expense. The timing of receipt of cash from the Company's research and development agreements generally differs from when revenue is recognized. Milestones are contingent on the occurrence of future events and are considered variable consideration being constrained until the Company believes a significant revenue reversal will not occur. Refer to Note 15 for further details regarding the Company's research and development arrangements.

Pursuant to ASU No. 2018-08, *Not-For-Profit Entities – Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made* ("ASU 2018-08"), grants received, including cost reimbursement agreements, are assessed to determine if the agreement should be accounted for as an exchange transaction or a contribution. An agreement is accounted for as a contribution if the resource provider does not receive commensurate value in return for the assets transferred. Contribution revenue is recognized when all donor-imposed conditions have been met.

The Company has a significant development contract with BARDA and should BARDA reduce, cancel or not grant additional milestone projects the Company's ability to continue our future product development may be impacted.

Disaggregation of Revenue

The Company disaggregates revenue from contracts with customers by type of products and services, as it best depicts how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors. The following table disaggregates total revenue by major source (in thousands):

	Year ended December 31,	
	2020	2019
Product Revenue		
Instruments	$ 3,139	$ 2,280
Consumables	8,423	2,863
Instrument Rentals	115	184
Total Product Revenue	11,677	5,327
Research Revenue	11	563
Contribution Revenue	6,442	2,445
Total Revenue	$ 18,130	$ 8,335

Remaining Performance Obligations

Remaining performance obligations represent the transaction price of firm orders for which work has not been performed or goods and services have not been delivered. As of December 31, 2020 and 2019, the aggregate amount of transaction price allocated to remaining performance obligations for contracts with an original duration greater than one year was $0.5 million and $0.2 million, respectively. The Company does not disclose the value of unsatisfied performance obligations for (i) contracts with an original expected length of one year or less and (ii) contracts for which it recognizes revenue at the amount to which it has the right to invoice for services performed. The Company expects to recognize revenue on the remaining performance obligations over the next 23 months.

Significant Judgments

Certain contracts with customers include promises to transfer multiple products and services to a customer. Determining whether products and services are considered distinct performance obligations that should be accounted for separately versus together may require significant judgment. Once the performance obligations are determined, the Company determines the transaction price, which includes estimating the amount of variable consideration, based on the most likely amount, to be included in the transaction price, if any. The Company then allocates the transaction price to each performance obligation in the contract based on a relative stand-alone selling price method. The corresponding revenue is recognized as the related performance obligations are satisfied as discussed in the revenue categories above.

Judgment is required to determine the standalone selling price for each distinct performance obligation. The Company determines standalone selling price based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, we estimate the standalone selling price taking into account available information such as a range of selling prices, market conditions and the expected costs and margin related to the performance obligations.

Contract Assets and Liabilities

The Company did not record any contract assets at December 31, 2020 and 2019.

The Company’s contract liabilities consist of upfront payments for research and development contracts and maintenance services on instrument sales. Contract liabilities are classified in deferred revenue as current or noncurrent based on the timing of when revenue is expected to be recognized. At December 31, 2020 and 2019, the Company had contract liabilities of $0.6 million and $0.2 million, respectively. Revenue recognized in the year-ended December 31, 2020 relating to contract liabilities at December 31, 2019 was $0.2 million, and related to straight-line revenue recognition associated with maintenance agreements.

Costs to Obtain and Fulfill a Contract

The Company capitalizes commission expenses paid to sales personnel that are recoverable and incremental to obtaining capital purchase agreements within the United States. These costs are classified as prepaid expenses and other current assets and other assets, based on their current or non-current nature, respectively. The Company capitalizes only those costs that are determined to be incremental and would not have occurred absent the customer contract. These capitalized costs are amortized as selling, general and administrative costs on a straight line basis over the expected period of benefit. These costs are reviewed periodically for impairment.

At December 31, 2020, the Company capitalized costs to fulfill contracts of $0.1 million in prepaid and other current assets and $0.1 million in other non-current assets. At December 31, 2019, no costs to obtain or fulfill contracts were capitalized.

Cost of Product Revenue

Cost of product revenue includes the cost of materials, direct labor and manufacturing overhead costs used in the manufacture of consumable diagnostic tests sold to customers, related warranty and license and royalty fees. Cost of product revenue also includes depreciation on T2-owned revenue generating T2Dx instruments that have been placed with customers under reagent rental agreements; costs of materials, direct labor and manufacturing overhead costs on the T2Dx instruments sold to customers; and other costs such as customer support costs, royalties and license fees, warranty and repair and maintenance expense on the T2Dx instruments that have been placed with customers under reagent rental agreements.

Research and Development Costs

Costs incurred in the research and development of the Company's product candidates are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including activities associated with performing services under research revenue arrangements, costs associated with the enhancements of developed products and include salaries and benefits, stock compensation, research-related facility and overhead costs, laboratory supplies, equipment and contract services.

Impairment of Long-lived Assets

The Company reviews long-lived assets, including capitalized T2 owned instruments and components and capitalized costs to fulfill a contract, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indications of impairment exist, projected future undiscounted cash flows associated with the asset or asset group are compared to the carrying amount to determine whether the asset's value is recoverable. During this review, the Company reevaluates the significant assumptions used in determining the original cost and estimated lives of long-lived assets. Although the assumptions may vary from asset to asset, they generally include operating results, changes in the use of the asset, cash flows and other indicators of value. Management then determines whether the remaining useful life continues to be appropriate or whether there has been an impairment of long-lived assets based primarily upon whether expected future undiscounted cash flows are sufficient to support the assets' recovery. If impairment exists, the Company would adjust the carrying value of the asset to fair value, generally determined by a discounted cash flow analysis. If the carrying value of the asset exceeds such projected undiscounted cash flows, the asset will be written down to its estimated fair value. The Company recorded an impairment of property and equipment of $0.6 million and an impairment of an operating lease asset of $0.5 million during the year ended December 31, 2020 and did not record any impairment expense during the year ended December 31, 2019.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss consists of net loss and other comprehensive loss, which includes certain changes in equity that are excluded from net loss. The Company had a net change in available-for-sale securities for the year ended December 31, 2020. The Company's comprehensive loss equals reported net loss for the year ended December 31, 2019.

Stock-Based Compensation

The Company issues stock-based awards to employees, generally in the form of stock options, restricted stock units and restricted stock awards. The Company accounts for stock-based awards in accordance with FASB ASC Topic 718, *Compensation-Stock Compensation*, or ASC 718. ASC 718 requires all stock-based payments to employees, including grants of employee stock options, restricted stock units, and modifications to existing stock options, to be recognized in the consolidated statements of operations and comprehensive loss based on their grant date fair values. The Company recognized the compensation cost of stock-based awards to employees on a straight-line basis over the vesting period.

The Company estimates the fair value of the stock-based awards to employees using the Black-Scholes-Merton option pricing model, which requires the input of highly subjective assumptions, including (a) the expected volatility of the stock, (b) the expected term of the award, (c) the risk-free interest rate and (d) expected dividends. The Company estimates expected volatility based on the historical volatility of the stock using the daily closing prices during the equivalent period of the calculated expected term of its stock-based awards. The Company has estimated the expected life of the employee stock options using the "simplified" method, whereby the expected life equals the average of the vesting term, and the original contractual term of the option. The risk-free interest rates for periods within the expected life of the option are based on the U.S. Treasury yield curve in effect during the period in which the options were granted. The Company has not paid, and does not anticipate paying, cash dividends on shares of common stock; therefore, the expected dividend yield is assumed to be zero.

The Company elected an accounting policy to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from the estimates. Historical data is used to estimate pre-vesting option forfeitures and stock-based compensation expense is only recorded for those awards that are expected to vest. To the extent that actual forfeitures differ from the estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised. Stock-based compensation expense recognized in the financial statements is based on awards that are ultimately expected to vest. If the actual forfeiture rate is materially different from the estimate, stock-based compensation expense could be different from what we have recorded in the current period.

The Company estimates the fair value of restricted stock units with market conditions on the date of grant using a Monte Carlo simulation. The compensation cost for restricted stock units with market conditions is being recorded over the derived service period. If a market condition is achieved prior to completion of the derived service period, the remaining compensation cost will be recognized immediately.

These assumptions used to determine stock compensation expense represent the Company's best estimates, but the estimates involve inherent uncertainties and the application of judgment. As a result, if factors change and the Company uses significantly different assumptions or estimates, stock-based compensation expense could be materially different. Refer to Note 8 for further details on the Company's stock-based compensation plan.

Income Taxes

The Company provides for income taxes using the liability method. The Company provides deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the Company's financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. A valuation allowance is provided to reduce the deferred tax assets to the amount that will more likely than not be realized.

The Company applies ASC 740 *Income Taxes* ("ASC 740") in accounting for uncertainty in income taxes. The Company does not have any material uncertain tax positions for which reserves would be required. The Company will recognize interest and penalties related to uncertain tax positions, if any, in income tax expense.

Guarantees

As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while each such officer or director is, or was, serving at the Company's request in such capacity. The term of the indemnification is the officer's or director's lifetime. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' liability insurance coverage that limits its exposure and enables the Company to recover a portion of any future amounts paid.

The Company leases office, laboratory and manufacturing space under noncancelable operating leases. The Company has standard indemnification arrangements under the leases that require it to indemnify the landlords against all costs, expenses, fines, suits, claims, demands, liabilities, and actions directly resulting from any breach, violation or nonperformance of any covenant or condition of the Company's leases.

In the ordinary course of business, the Company enters into indemnification agreements with certain suppliers and business partners where the Company has certain indemnification obligations limited to the costs, expenses, fines, suits, claims, demands, liabilities and actions directly resulting from the Company's gross negligence or willful misconduct, and in certain instances, breaches, violations or nonperformance of covenants or conditions under the agreements.

As of December 31, 2020 and December 31, 2019, the Company had not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting the weighted-average number of shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, stock options and unvested restricted stock and restricted stock contingently issuable upon achievement of certain market conditions are considered to be common stock equivalents, but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share applicable to common stockholders was the same for all periods presented.

Recent Accounting Standards

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

Accounting Standards Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). This ASU requires measurement and recognition of expected credit losses for financial assets. The Company adopted ASU 2016-13 on January 1, 2020. The adoption did not have a material impact on the Company's financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement* ("ASU 2018-13"), which eliminates, adds and modifies certain disclosure requirements for fair value measurements. The Company adopted ASU 2018-13 on January 1, 2020. The results of adoption are presented in Note 3.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements* ("ASU 2018-18"), which clarifies the interaction between ASC 808, *Collaborative Arrangements* and ASC 606, *Revenue from Contracts with Customers*. Certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, ASU 2018-18 precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue if the counterparty is not a customer for that transaction. ASU 2018-18 should be applied retrospectively to the date of initial application of ASC 606. The Company adopted ASU 2018-18 on January 1, 2020. The adoption did not have a material impact on the Company's financial statements.

Accounting Standards Issued, Not Adopted

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes: Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2020, with early adoption permitted. Adoption of the standard requires certain changes to be made prospectively, with some changes to be made retrospectively. The Company does not expect the adoption of this standard to have a material impact on its financial position, results of operations or cash flows.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)—Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"), which simplifies accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. The standard is effective for fiscal years ending after December 15, 2021, with early adoption permitted for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The Company is currently evaluating the impact that this new standard will have on its financial statements.

3. Fair Value Measurements

The Company measures the following financial assets at fair value on a recurring basis. There were no transfers between levels of the fair value hierarchy during any of the periods presented. The following tables set forth the Company's financial assets and liabilities carried at fair value categorized using the lowest level of input applicable to each financial instrument as of December 31, 2020 and 2019 (in thousands):

	Balance at December 31, 2020	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Certificates of deposit	$ 1,251	$ —	$ 1,251	$ —
US Treasury securities	34,147	34,147	—	—
Restricted cash	551	551	—	—
	$ 35,949	$ 34,698	$ 1,251	$ —
Liabilities:				
Derivative liability	$ 1,010	$ —	$ —	$ 1,010
	$ 1,010	$ —	$ —	$ 1,010

	Balance at December 31, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$ 4,301	$ 4,301	$ —	$ —
Restricted cash	180	180	—	—
	$ 4,481	$ 4,481	$ —	$ —
Liabilities:				
Derivative liability	$ 2,425	$ —	$ —	$ 2,425
	$ 2,425	$ —	$ —	$ 2,425

The Company's cash equivalents and available-for-sale marketable securities are comprised of certificates of deposit and government securities. Securities are classified as cash equivalents when the original maturities are within 90 days of the purchase dates. The Company also maintains money market accounts classified as restricted cash for $0.6 million at December 31, 2020 and certificates of deposit classified as restricted cash for $0.2 million at December 31, 2019 (Note 4).

The Company has a single compound derivative related to its Term Loan Agreement with CRG (the "Term Loan Agreement") (Note 6), which is required to be re-measured at fair value on a quarterly basis.

The fair value of the derivative at December 31, 2020 and December 31, 2019 is $1.0 million and $2.4 million, respectively, and is classified as a non-current liability on the balance sheet at December 31, 2020, and a current liability at December 31, 2019 to match the classification of the related Term Loan Agreement (Note 6). While the Company's fair value assessment as of December 31, 2020 assessed the likelihood of paying contingent interest as remote within the next twelve months and as of the date of this filing the Company continues to assess and believes the probability is remote that the contingent interest will commence within the next twelve months which, accordingly, provided for the non-current classification of the derivative liability. Management continues to reassess at each balance sheet and filing date based on facts and circumstances and can provide no assurances regarding the probability of payment of the contingent interest in future periods.

The estimated fair value of the derivative at December 31, 2020 was determined using a probability-weighted discounted cash flow model that includes contingent interest payments under the following scenarios:

	Range
4% contingent interest beginning in 2021	0%
4% contingent interest beginning in 2022	90%

The following table provides a roll-forward of the fair value of the derivative liability (in thousands):

Balance at December 31, 2018	$ 2,142
Change in fair value of derivative liability, recorded as interest expense	283
Balance at December 31, 2019	2,425
Change in fair value of derivative liability, recorded as interest expense	(1,415)
Balance at December 31, 2020	$ 1,010

4. Restricted Cash

The Company is required to maintain security deposits for its operating lease agreement for the duration of the lease agreement and for a particular credit card program as long as it is in place. At December 31, 2020, the Company had money market accounts for $0.6 million, which represented collateral as security deposits for its operating lease agreements for two facilities. At December 31, 2019, the Company had certificates of deposit for $0.2 million, which represented collateral as security deposits for its operating lease agreement for its facility and for a particular credit card program which was no longer in place as of December 31, 2020.

5. Supplemental Balance Sheet Information

Property and Equipment

Property and equipment consists of the following (dollar amounts in thousands)

	Estimated Useful Life (Years)	December 31, 2020	December 31, 2019
Office and computer equipment	3	$ 538	$ 538
Software	3	762	762
Laboratory equipment	5	5,179	4,747
Furniture	5-7	197	194
Manufacturing equipment	5	672	672
Manufacturing tooling and molds	0.5-5	255	255
T2-owned instruments and components	5	5,001	6,775
Leasehold improvements	Lesser of useful life or remaining lease term	3,691	3,497
Construction in progress	n/a	1,733	1,641
		18,028	19,081
Less accumulated depreciation and amortization		(14,257)	(13,236)
Property and equipment, net		$ 3,771	$ 5,845

Construction in progress is primarily comprised of equipment that has not been placed in service. T2-owned instruments and components is comprised of raw materials and work-in-process inventory that are expected to be used or used to produce T2-owned instruments, based on the Company's business model and forecast, and completed instruments that will be used for internal research and development, clinical studies or reagent rental agreements with customers. At December 31, 2020, there were $0.3 million of raw materials and work-in-process inventory in T2-owned instruments and components compared to $0.6 million at December 31, 2019. Completed T2-owned instruments are placed in service once installation procedures are completed and are depreciated over five years. Depreciation expense for T2-owned instruments placed at customer sites pursuant to reagent rental agreements is recorded as a component of cost of product revenue and totaled $0.3 million and $0.8 million for the year ended December 31, 2020 and 2019, respectively. Depreciation expense for T2-owned instruments used for internal research and development and clinical studies is recorded as a component of research and development expense.

Depreciation and amortization expense of $1.7 million and $2.2 million was charged to operations for the years ended December 31, 2020 and 2019, respectively.

At the beginning of the COVID-19 pandemic, the Company believed the pandemic would reduce product sales and impair the ability to recover the cost of the T2-owned instruments and components. The Company assessed the impact on the related cash flows of the T2-owned instruments and reduced the respective carrying values by $0.6 million as of December 31, 2020, which is recorded as cost of product revenue impairment expense.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2020	December 31, 2019
Accrued payroll and compensation	$ 3,629	$ 3,193
Accrued final fee	—	2,445
Accrued research and development expenses	751	267
Accrued professional services	421	511
Accrued interest	940	908
Operating lease liabilities	1,151	1,983
Other accrued expenses	620	1,900
Total accrued expenses and other current liabilities	$ 7,512	$ 11,207

At December 31, 2019, a fee associated with the Company's Term Loan Agreement (Note 6) of $2.4 million is included as accrued final fee in the table above to match the current classification of the associated debt. At December 31, 2020, the Company's Term Loan Agreement with CRG and the associated fee of $3.4 million are classified as non-current liabilities. At December 31, 2020, included within other accrued expenses in the table above is $0.2 million related to Mr. McDonough's transition payments and health benefits. Included within other accrued expenses and accrued payroll and compensation in the table above, at December 31, 2019, are $1.0 million and $0.2 million, respectively, related to the Transition Agreement (Note 13).

6. Notes Payable

Future principal payments on the notes payable as of December 31, 2020 are as follows (in thousands):

Year ended December 31,		
2021	$	—
2022		48,077
2023		—
2024		—
2025		—
Total before unamortized discount and issuance costs		48,077
Less: paid-in-kind interest		(1,669)
Less: unamortized discount and issuance costs		(1,173)
Total notes payable	$	45,235

The Term Loan Agreement with CRG is classified as a non-current liability at December 31, 2020 as the Company has sufficient cash, cash equivalents and marketable securities as of the date of this filing that the minimum liquidity covenant would not be triggered even upon default of the revenue covenant at December 31 2020, as the cure would not be due until March 31, 2022. The Term Loan Agreement with CRG is classified as a current liability on the balance sheet at December 31, 2019, based on the Company's consideration of the probability of violating the 2020 revenue covenant, which in turn would trigger violation of the minimum liquidity covenant included in the Term Loan Agreement.

The Term Loan Agreement includes a subjective acceleration clause whereby an event of default, including a material adverse change in the business, operations, or conditions (financial or otherwise), could result in the acceleration of the obligations under the Term Loan Agreement. The contractual terms of the agreement, as amended in September 2019, require quarterly principal payments of $12.0 million commencing March 31, 2022 through maturity, December 31, 2022, respectively. The January 2021 amendment extends the principal repayment to be due upon maturity, December 31, 2022.

The Company has assessed the classification of the note payable as non-current based on facts and circumstances as of the date of this filing, specifically as it relates to achieving the minimum liquidity and revenue covenants. As of the date of this filing, the Company believes that should it be unable to meet such covenants as of December 31, 2020, it is probable that it would be able to pay the cure of default on March 31, 2022. Management continues to reassess at each balance sheet and filing date based on facts and circumstances and can provide no assurances regarding the probability of meeting its aforementioned covenants in future periods.

Term Loan Agreement

In December 2016, the Company entered into a Term Loan Agreement (the "Term Loan Agreement") with CRG. The Company borrowed $40.0 million pursuant to the Term Loan Agreement, which has a six-year term with four years (through December 30, 2020) of interest-only payments, after which quarterly principal and interest payments would be due through the December 30, 2022 maturity date. Interest on the amounts borrowed under the Term Loan Agreement accrues at an annual fixed rate of 11.50%, 3.5% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount. In addition, if the Company achieves certain financial performance metrics, the loan will convert to interest-only until the December 30, 2022 maturity, at which time all unpaid principal and accrued unpaid interest will be due and payable. The Company is required to pay CRG a financing fee based on the loan principal amount drawn. The Company is also required to pay a final payment fee of 8%, subsequently amended to 10%, of the principal outstanding upon repayment. The Company is accruing the final payment fee as interest expense and it is included as a non-current liability at December 31, 2020 and a current liability at December 31, 2019 on the balance sheet to conform to the classification of the associated debt in those periods.

The Company may prepay all or a portion of the outstanding principal and accrued unpaid interest under the Term Loan Agreement at any time upon prior notice subject to a certain prepayment fee during the first five years of the term and no prepayment fee thereafter. 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. The Term Loan Agreement also contains customary affirmative and negative covenants for a credit facility of this size and type, including a requirement to maintain a minimum cash balance. The Term Loan Agreement also requires the Company to achieve certain revenue targets, whereby the Company is required to pay double the amount of any shortfall as an acceleration of principal payments. In March 2019, the Term Loan Agreement was amended to reduce the 2019 minimum revenue target to $9.0 million and eliminate the 2018 revenue covenant. In exchange for the amendment, the Company agreed to reset the strike price of the warrants to purchase 528,958 shares of the Company's common stock, issued in connection with the Term Loan Agreement, from $8.06 per share to $4.35 per share (Note 9).

In September 2019, the Term Loan Agreement was amended to extend the interest-only payment period through December 31, 2021, to extend the initial principal repayment to March 31, 2022, and to reduce the minimum product revenue target for 2019 from $9 million to $4 million, for the twenty-four month period beginning on January 1, 2019 from $95 million to $15 million and for the twenty-four month period beginning on January 1, 2020 from $140 million to $43 million. The final payment fee was increased from 8% to 10% of the principal amount outstanding upon repayment. The Company issued to CRG warrants to purchase 568,291 shares of the Company's common stock ("New Warrants") (Note 9) at an exercise price of $1.55, with typical provisions for termination upon a change of control or a sale of all or substantially all of the assets of the Company. The Company also reduced the exercise price for the warrants previously issued to CRG to purchase an aggregate of 528,958 shares of the Company's common stock to $1.55. All of the New Warrants are exercisable any time prior to September 9, 2029, and all of the previously issued warrants are exercisable any time prior to December 30, 2026. The Company accounted for the March 2019 and September 2019 amendments as modifications to the Term Loan Agreement.

In January 2021, the Term Loan Agreement was amended to extend the interest-only payment period until the December 30, 2022 maturity, to extend the initial principal repayment until the December 30, 2022 maturity, and to significantly reduce the minimum product revenue target for the twenty-four month period beginning on January 1, 2020. The Company did not pay or provide any consideration in exchange for this amendment.

The Term Loan Agreement includes a subjective acceleration clause whereby an event of default, including a material adverse change in the business, operations, or conditions (financial or otherwise), could result in the acceleration of the obligations under the Term Loan Agreement. Under certain circumstances, a default interest rate of an additional 4.0% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default.

Equipment Lease Credit Facility

In October 2015, the Company signed the $10.0 million Credit Facility (the "Credit Facility") with Essex Capital Corporation ("Essex") to fund capital equipment needs. As one of the conditions of the Term Loan Agreement, the Credit Facility is capped at a maximum of $5.0 million. Under the Credit Facility, Essex will fund capital equipment purchases presented by the Company. The Company will repay the amounts borrowed in 36 equal monthly installments from the date of the amount funded. At the end of the 36-month lease term, the Company has the option to (a) repurchase the leased equipment at the lesser of fair market value or 10% of the original equipment value, (b) extend the applicable lease for a specified period of time, which will not be less than one year, or (c) return the leased equipment to the Lessor.

In April 2016 and June 2016, the Company completed the first two draws under the Credit Facility of $2.1 million and $2.5 million, respectively. The Company made monthly payments of $67,000 under the first draw and $79,000 under the second draw. The borrowings under the Credit Facility were treated as capital leases and were included in property and equipment on the balance sheet. The amortization of the assets conveyed under the Credit Facility was included as a component of depreciation expense. During the year ended December 31, 2019, the Company repurchased the equipment for $0.3 million in accordance with the terms of the Credit Facility.

7. Stockholders' Equity (Deficit)

Common Stock

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors, subject to the prior rights of holders of all classes of stock outstanding. The Company authorized 200,000,000 shares of common stock, $0.001 par value per share, of which 148,078,974 and 50,651,535 were outstanding as of December 31, 2020 and 2019, respectively. As of December 31, 2020, a total of 8,595,929 shares, 1,643,779 shares, and 1,097,249 shares of common stock were reserved for issuance upon (i) the exercise of outstanding stock options, (ii) the issuance of stock awards, and (iii) the exercise of warrants, respectively, under the Company's 2014 Incentive Award Plan, Inducement Award Plan, and 2014 Employee Stock Purchase Plan.

Equity Distribution Agreement

On July 30, 2019, the Company entered into the Sales Agreement with Canaccord, as agent, pursuant to which the Company may offer and sell shares of common stock, for aggregate gross sale proceeds of up to $30.0 million from time to time through Canaccord. On March 9, 2020, the Company entered into an amendment to the Sales Agreement to increase the aggregate gross sales amount from $30.0 million to $65.0 million. On April 8, 2020, the Company entered into an amendment to the Sales Agreement to increase the aggregate gross sales amount from $65.0 million to $95.0 million. As of December 31, 2020, the Company had sold 101,606,667 shares of common stock with an aggregate gross sales amount of $95.0 million.

Upon delivery of a placement notice based on the Company's instructions and subject to the terms and conditions of the Sales Agreement, Canaccord was able to sell the shares by methods deemed to be an "at the market" offering, subject to shelf limitations if any, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, or by any other method permitted by law, including negotiated transactions, subject to the prior written consent of the Company. The Company was not obligated to make any sales of shares under the Sales Agreement. The Company or Canaccord were able to suspend or terminate the offering of shares upon notice to the other party, subject to certain conditions. Canaccord acted as sales agent on a commercially reasonable efforts basis consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of Nasdaq.

The Company had agreed to pay Canaccord for its services of acting as agent 3% of the gross proceeds from the sale of the shares pursuant to the Sales Agreement. The Company had also agreed to provide Canaccord with customary indemnification for certain liabilities. Legal and accounting fees associated with the Sales Agreement were immaterial. Legal and accounting fees were changed to share capital upon issuance of shares under the Sales Agreement.

During the year ended December 31, 2020, the Company sold 96,120,167 shares under the Sales Agreement for net proceeds of $85.0 million after expenses. During the year ended December 31, 2019, the Company sold 5,486,500 shares for net proceeds of $6.7 million after expenses in connection with the Sales Agreement.

Purchase Agreement

On July 29, 2019, the Company entered into a $30.0 million Purchase Agreement with Lincoln Park, pursuant to which the Company may sell and issue to Lincoln Park, and Lincoln Park is obligated to purchase, up to $30.0 million in value of its shares of common stock from time to time over a 36-month period starting from the effective date of the respective registration statement. On April 7, 2020, the Company terminated the Purchase Agreement, effective April 8, 2020.

The Company was able to direct Lincoln Park, at its sole discretion, and subject to certain conditions, to purchase up to 200,000 shares of common stock on any business day, provided that at least one business day had passed since the most recent purchase. The amount of a purchase could be increased under certain circumstances provided, however, that Lincoln Park's committed obligation under any single purchase would not exceed $2.0 million. The purchase price of shares of common stock related to the future funding was based on the then prevailing market prices of such shares at the time of sales as described in the Purchase Agreement.

In consideration for the execution and delivery of the Purchase Agreement, the Company issued 413,349 shares of common stock to Lincoln Park.

During the year ended December 31, 2020, the Company sold 400,000 shares for proceeds of $0.3 million in connection with the Purchase Agreement.

8. Stock-Based Compensation

Stock Incentive Plans

2006 Stock Incentive Plan

The Company's 2006 Stock Option Plan ("2006 Plan") was established for granting stock incentive awards to directors, officers, employees and consultants of the Company. Upon closing of the Company's IPO in August 2014, the Company ceased granting stock incentive awards under the 2006 Plan. The 2006 Plan provided for the grant of incentive and non-qualified stock options and restricted stock grants as determined by the Company's Board of Directors. Under the 2006 Plan, stock options were generally granted with exercise prices equal to or greater than the fair value of the common stock as determined by the Board of Directors, expired no later than 10 years from the date of grant, and vest over various periods not exceeding 4 years.

2014 Stock Incentive Plan

The Company's 2014 Incentive Award Plan ("2014 Plan", and together with the 2006 Plan, the "Stock Incentive Plans"), provides for the issuance of shares of common stock in the form of stock options, awards of restricted stock, awards of restricted stock units, performance awards, dividend equivalent awards, stock payment awards and stock appreciation rights to directors, officers, employees and consultants of the Company. Since the establishment of the 2014 Plan, the Company has primarily granted stock options and restricted stock units. Generally, stock options are granted with exercise prices equal to or greater than the fair value of the common stock on the date of grant, expire no later than 10 years from the date of grant, and vest over various periods not exceeding 4 years.

The number of shares reserved for future issuance under the 2014 Plan is the sum of (1) 823,529, (2) any shares that were granted under the 2006 Plan which are forfeited, lapse unexercised or are settled in cash subsequent to the effective date of the 2014 Plan and (3) an annual increase on the first day of each calendar year beginning January 1, 2015 and ending on January 1, 2026, equal to the lesser of (A) 4% of the shares outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of shares determined by the Board of Directors. As of December 31, 2020, there were 2,237,168 shares available for future grant under the Stock Incentive Plans.

Inducement Award Plan

The Company's Amended and Restated Inducement Award Plan ("Inducement Plan"), which was adopted in March 2018 and most recently amended and restated in January 2020, provides for the granting of equity awards to new employees, including options, restricted stock awards, restricted stock units, performance awards, dividend equivalent awards, stock payment awards and stock appreciation rights. The aggregate number of shares of common stock which may be issued or transferred pursuant to awards under the Inducement Plan is 5,625,000 shares. Any awards that forfeit, expire, lapse, or are settled for cash without the delivery of shares to the holder are available for the grant of an award under the Inducement Plan. Any shares repurchased by or surrendered to the Company that are returned shall be available for the grant of an award under the Inducement Plan. The payment of dividend equivalents in cash in conjunction with any outstanding award shall not be counted against the shares available for issuance under the Inducement Plan. As of December 31, 2020, there were 2,073,281 shares available for future grant under the Inducement Plan.

Stock Options

During the years ended December 31, 2020 and 2019, the Company granted options with an aggregate fair value of $3.3 million and $3.9 million, respectively, which are being amortized into compensation expense over the vesting period of the options as the services are being provided.

The following is a summary of option activity under the Stock Incentive Plans and Inducement Plan (in thousands, except term, share and per share amounts):

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value
Outstanding at December 31, 2019	6,353,330	$ 4.95	7.29	$ 229
Granted	4,306,750	1.02		
Exercised	(49,563)	0.61		33
Forfeited	(1,232,700)	3.04		
Canceled	(781,888)	5.43		
Outstanding at December 31, 2020	8,595,929	3.24	7.75	1,011
Exercisable at December 31, 2020	4,098,314	4.98	6.57	272
Vested or expected to vest at December 31, 2020	7,650,363	$ 3.46	7.61	$ 845

There were 49,563 options exercised in the year ended December 31, 2020 and 2,119 options exercised in the year ended December 31, 2019. The total intrinsic value of options exercised in the years ended December 31, 2020 and 2019 were immaterial. The weighted-average fair values of options granted in the years ended December 31, 2020 and 2019 were $0.71 and $1.41 per share, respectively, and were calculated using the following estimated assumptions:

	Year ended December 31,	
	2020	2019
Weighted-average risk-free interest rate	1.35%	1.97%
Expected dividend yield	0.00%	0.00%
Expected volatility	92%	78%
Expected terms	5.8 years	6.0 years

The total fair values of stock options that vested during the years ended December 31, 2020 and 2019 were $3.5 million and $3.1 million, respectively.

As of December 31, 2020, there was $4.1 million of total unrecognized compensation cost related to non-vested stock options granted under the Stock Incentive Plans. Total unrecognized compensation cost will be adjusted for future changes in the estimated forfeiture rate. The Company expects to recognize that cost over a remaining weighted-average period of 2.4 years as of December 31, 2020.

Restricted Stock Units

During the year ended December 31, 2020, the Company awarded shares of restricted stock units to certain employees at no cost to them, which cannot be sold, assigned, transferred or pledged during the restriction period. The restricted stock units vest through the passage of time, assuming continued employment. Restricted stock units are not included in issued and outstanding common stock until the shares are vested and released. During the year ended December 31, 2018, an additional 73,172 restricted stock units vested but are not reflected as outstanding shares at December 31, 2019 due to a deferred release date. These restricted stock units are reflected as outstanding shares at December 31, 2020. The fair value of the restricted stock units, at the time of the grant, is expensed on a straight line basis. The granted restricted stock units had an aggregate fair value of $1.2 million, which are being amortized into compensation expense over the vesting period of the restricted stock units as the services are being provided.

Included in the nonvested restricted stock units at December 31, 2020 are 318,898 restricted stock units with market conditions, which vest upon the achievement of stock price targets. The compensation cost for restricted stock units with market conditions is being recorded over the derived service period and was immaterial for the year ended December 31, 2020 and $1.0 million for the year ended December 31, 2019.

The following is a summary of restricted stock unit activity under the 2014 Plan:

	Number of Shares	Weighted-Average Grant Date Fair Value
Nonvested at December 31, 2019	1,295,508	$ 4.19
Granted	1,380,923	0.89
Vested	(331,433)	3.45
Forfeited	(701,219)	3.37
Canceled	—	—
Nonvested at December 31, 2020	1,643,779	$ 1.91

As of December 31, 2020, there was $1.2 million of total unrecognized compensation cost related to non-vested restricted stock units granted under the 2014 Plan. Total unrecognized compensation cost will be adjusted for future changes in the estimated forfeiture rate. The Company expects to recognize that cost over a remaining weighted-average period of 1.6 years as of December 31, 2020.

Employee Stock Purchase Plan

The 2014 Employee Stock Purchase Plan (the “2014 ESPP”) period is semi-annual and allows participants to purchase the Company’s common stock at 85% of the lower of (i) the market value per share of common stock on the first day of the offering period or (ii) the market value per share of the common stock on the purchase date. Each participant can purchase up to a maximum of $25,000 per calendar year in fair market value. The first plan period began on August 7, 2014. Stock-based compensation expense from the 2014 ESPP for the years ended December 31, 2020 and 2019 was approximately $0.3 million and $0.4 million, respectively. During the year ended December 31, 2020, 453,104 shares were purchased through the 2014 ESPP.

The fair value of the purchase rights granted under this plan was estimated on the date of grant and uses the following weighted-average assumptions, which were derived in a manner similar to those discussed in Note 2 relative to stock options:

	Year ended December 31,	
	2020	2019
Weighted-average risk-free interest rate	1.59%	2.44%
Expected dividend yield	0.00%	0.00%
Expected volatility	92%	71%
Expected terms	0.5 years	0.5 years

The 2014 ESPP, which was amended and restated effective August 6, 2020, provides for the granting of up to 4,523,944 shares of the Company’s common stock to eligible employees. At December 31, 2020, there were 3,268,850 shares available under the 2014 ESPP.

Stock-Based Compensation Expense

The following table summarizes the stock-based compensation expense resulting from awards granted under Stock Incentive Plans, the Inducement Plan and 2014 ESPP, that was recorded in the Company's results of operations for the years presented (in thousands):

	Year ended December 31,	
	2020	2019
Cost of product revenue	$ 221	$ 365
Research and development	777	1,184
Selling, general and administrative	2,901	3,888
Total stock-based compensation expense	$ 3,899	$ 5,437

For the years ended December 31, 2020 and 2019, stock-based compensation expense capitalized as part of inventory or T2-owned instruments and components was immaterial.

9. Warrants

In connection with the Term Loan Agreement entered into in December 2016, the Company issued to CRG warrants to purchase a total of 528,958 shares of the Company's common stock. The warrants are exercisable any time prior to December 30, 2026 at a price of $4.35 per share, which was amended in March 2019 from an original price of $8.06 per share, with typical provisions for termination upon a change of control or a sale of all or substantially all of the assets of the Company. The warrants are classified within stockholders' equity (deficit), and the proceeds were allocated between the debt and warrants based on their relative fair value. The fair value of the warrants was determined by the Black-Scholes-Merton option pricing model. The fair value of the amended warrants was $0.9 million. The incremental fair value of the modified instrument of $0.1 million was recorded as debt discount and additional paid-in-capital.

In connection with the September 2019 amendment of the Term Loan Agreement, the Company issued to CRG warrants to purchase 568,291 shares of the Company's common stock ("New Warrants") at an exercise price of $1.55, with typical provisions for termination upon a change of control or a sale of all or substantially all of the assets of the Company. The Company also reduced the exercise price for the warrants previously issued to CRG to $1.55. All of the New Warrants are exercisable any time prior to September 9, 2029. The warrants are classified within stockholders' equity (deficit), and the proceeds were allocated between the debt and the originally issued warrants based on their relative fair value. The fair value of the new and amended warrants was determined by the Black-Scholes-Merton option pricing model. The incremental fair value of the amended warrants of $0.1 million and the fair value of the New Warrants of $0.7 million were recorded as debt discount and additional paid-in-capital.

10. Net Loss Per Share

The following table presents the calculation of basic and diluted net loss per share applicable to common stockholders (in thousands, except share and per share data):

	Year ended December 31,	
	2020	2019
Numerator:		
Net loss	$ (46,798)	$ (59,006)
Denominator:		
Weighted-average number of common shares outstanding — basic and diluted	121,331,464	45,507,754
Net loss per share applicable to common stockholders — basic and diluted	$ (0.39)	$ (1.30)

The following shares were excluded from the calculation of diluted net loss per share applicable to common stockholders, prior to the application of the treasury stock method, because their effect would have been anti-dilutive for the periods presented:

	Year ended December 31,	
	2020	2019
Options to purchase common shares	8,595,929	6,353,330
Restricted stock units	1,643,779	1,295,508
Warrants to purchase common stock	1,097,249	1,097,249
Total	11,336,957	8,746,087

11. Income Taxes

The reconciliation of the U.S. federal statutory rate to the Company's effective tax rate is as follows:

	Year Ended December 31,	
	2020	2019
Tax at statutory rates	21.0%	21.0%
State income taxes	6.4	2.6
Permanent differences	(1.9)	(1.2)
Research and development credits	1.4	1.0
Limitations on credits and net operating losses	0.1	(75.2)
Change in valuation allowance	(27.0)	51.8
Effective tax rate	0.0%	0.0%

The significant components of the Company's deferred tax asset consist of the following at December 31, 2020 and 2019 (in thousands):

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 61,551	$ 50,407
Tax credits	1,428	472
Other temporary differences	3,546	2,888
Start-up expenditures	2,672	2,716
Stock option expenses	3,382	3,450
Lease liability	3,170	987
Total deferred tax assets	75,749	60,920
Deferred tax asset valuation allowance	(72,404)	(59,764)
Net deferred tax assets	3,345	1,156
Deferred tax liabilities:		
Right of use asset	(2,994)	(859)
Prepaid expenses	(351)	(297)
Net deferred taxes	$ —	$ —

In 2020 and 2019, the Company did not record a benefit for income taxes related to its operating losses incurred. ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Based upon the level of historical U.S. losses and future projections over the period in which the net deferred tax assets are deductible, at this time, management believes it is more likely than not that the Company will not realize the benefits of these deductible differences, and as a result the Company continues to maintain a valuation allowance for the full amount of the 2020 deferred tax assets. The valuation allowance increased by $12.6 million and decreased $30.6 million for the years ended December 31, 2020 and 2019, respectively. The increase in the 2020 valuation allowance is primarily attributable to the current year loss. The decrease in 2019 was primarily attributable to the reduction of the net operating loss and tax credit carryforwards recorded as a result of the completion of the Section 382 study performed.

As of December 31, 2020, the Company had federal and state net operating losses of $222.6 million and $247.9 million, respectively, which are available to offset future taxable income, if any, of which $78.7 million of federal and $215.3 million of state carryforwards will expire in varying amounts through 2037 and 2040, respectively. Additionally, $143.9 million of federal net operating loss carryforwards and $32.6 million of state net operating loss carryforwards will carryforward indefinitely, subject to annual taxable income limitations in the year of utilization. The Company also had federal and state research and development tax credits of $0.8 million and $0.8 million, respectively, which expire at various dates through 2040 for federal purposes and 2035 for state purposes. Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. In 2020, the Company completed a study on its historic ownership changes pursuant to Internal Revenue Code Section 382 and 383 (the "382 study") of its historical net operating loss and tax credit carryforwards. As a result, there were limitations placed on the use of the Company's loss and credit carryforwards. The 2019 federal and state net operating loss carryforwards of $329.6 million and $292.4 million, respectively, were determined to be limited by $149.5 million and $78.9 million, respectively. The 2019 federal and state tax credit carryforwards of $5.5 million and $3.6 million, respectively, were limited by $5.4 million and $3.2 million, respectively. The decrease in the prior year tax attributes is attributable to change of control ownership shifts which were determined for the years 2013, 2016, and 2019 which caused the reduction in the value of the historical net operating loss carryforwards. Since the limitation affected the prior period, the Company has determined that its 2019 tax footnote presentation overstated the gross net operating loss deferred tax asset and corresponding valuation allowance. However, there was no net impact to the net deferred tax asset and tax expense as the decrease in the net operating loss carryforward was offset completely by a corresponding adjustment to the Company's overall valuation allowance. For comparative purposes, the Company's prior year tax footnote has been revised to reflect the adjustment to the net operating losses and valuation allowance. Subsequent ownership changes may further affect the limitation in future years.

The Company has no unrecognized tax benefits. Interest and penalty charges, if any, related to uncertain tax positions would be classified as income tax expenses in the accompanying consolidated statements of operations. At December 31, 2020 and 2019, the Company had no accrued interest or penalties related to uncertain tax positions.

The Company files income tax returns in the U.S. federal tax jurisdiction and various state jurisdictions. Since the Company is in a loss carryforward position, the Company is generally subject to examination by the U.S. federal, state and local income tax authorities for all tax years in which a loss carryforward is available. The Company does not have any international operations as of December 31, 2020. The statute of limitations for assessment by federal and state tax jurisdictions in which the Company has business operations is open for tax years ending December 31, 2017 and after. The tax years under examination vary by jurisdiction.

12. Leases

Operating Leases

The Company leases certain office space, laboratory space, and equipment. At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. The Company does not recognize right-of-use assets or lease liabilities for leases determined to have a term of 12 months or less. For new and amended leases beginning in 2019 and after, the Company has elected to account for the lease and non-lease components as a combined lease component.

In August 2010, the Company entered into an operating lease for office and laboratory space at its headquarters in Lexington, Massachusetts. The lease commenced in January 2011, with the Company providing a security deposit of $400,000. In accordance with the operating lease agreement, the Company reduced its security deposit to $180,000 in January 2018, which is recorded as restricted cash in the consolidated balance sheets. In March 2017, the Company entered into an amendment to extend the term to December 2021. In October 2020, the Company entered into an amendment to extend the term to December 31, 2028. In accordance with the October 2020 amendment, the Company increased its security deposit to $420,438, which is classified as restricted cash at December 31, 2020. This amendment resulted in an increase to the operating lease right-of use assets and lease liability accounts on the balance sheet of $7.6 million and $7.7 million, respectively, at December 31, 2020.

In May 2013, the Company entered into an operating lease for additional office, laboratory and manufacturing space in Wilmington, Massachusetts. In August 2018, the Company entered into an amendment to extend the term to December 2020. In October 2020, the Company entered into an amendment to extend the term to December 31, 2022. This amendment resulted in an increase to the operating lease right-of use assets and lease liability accounts on the balance sheet of $0.2 million at December 31, 2020.

In November 2014, the Company entered into an agreement to rent additional office space in Lexington, Massachusetts. In April 2015, the Company entered into an amendment to extend the term to December 31, 2017. In connection with this agreement, the Company paid a security deposit of $50,000, which is recorded as a component of other assets in the consolidated balance sheets. In May 2015, the Company entered into an amendment to expand existing manufacturing facilities in Lexington, Massachusetts. In September 2017, the Company entered into an amendment to extend the term to December 31, 2021. In June 2020, the Company vacated this office space and determined that subleasing it to a tenant was unlikely due to the impact of the COVID-19 pandemic on the local commercial real estate sub-lease market. As a result, the Company recorded an impairment charge of $0.5 million to selling, general and administrative.

In November 2014, the Company entered into a lease for additional laboratory space in Lexington, Massachusetts. The lease term commenced in April 2015 and extended for six years. The rent expense, inclusive of the escalating rent payments, is recognized on a straight-line basis over the lease term. As an incentive to enter into the lease, the landlord paid approximately $1.4 million of the $2.2 million space build-out costs. In connection with this lease agreement, the Company paid a security deposit of $281,000, which is recorded as a component of both prepaid expenses and other current assets and other assets in the consolidated balance sheets. In October 2020, the Company entered into an amendment to extend the term of the lease to October 31, 2025. In accordance with this amendment, the Company paid a replacement security deposit of $130,977, which is classified as restricted cash at December 31, 2020 and received the initial $281,000 security deposit in return. This amendment resulted in an increase to the operating lease right-of use assets and lease liability accounts on the balance sheet of $1.8 million and $1.9 million, respectively, at December 31, 2020.

Operating leases are amortized over the lease term and included in costs and expenses in the consolidated statement of operations and comprehensive loss. Variable lease costs are recognized in costs and expenses in the consolidated statement of operations and comprehensive loss as incurred.

Finance Leases

In October 2015, the Company signed a $10.0 million Credit Facility (the "Credit Facility") to fund capital equipment needs. As one of the conditions of the Term Loan Agreement, the Credit Facility was capped at a maximum of $5.0 million. Under the Credit Facility, the lender funded capital equipment purchases presented by the Company. The Company repaid the amounts borrowed in 36 equal monthly installments from the date of the amount funded. At the end of the 36-month lease term, the Company had the option to (a) repurchase the leased equipment at the lesser of fair market value or 10% of the original equipment value, (b) extend the applicable lease for a specified period of time, which would not be less than one year, or (c) return the leased equipment to the lessor.

In April 2016 and June 2016, the Company completed the first two draws under the Credit Facility of $2.1 million and $2.5 million, respectively. The Company made monthly payments of $67,000 under the first draw and $79,000 under the second draw. The property and equipment from the borrowings under the Credit Facility were treated as finance leases and were included in property and equipment on the balance sheet. The amortization of the assets conveyed under the Credit Facility was included as a component of depreciation expense. During the year ended December 31, 2019, the Company repurchased the equipment for $0.3 million in accordance with the terms of the Credit Facility.

The following table summarizes the effect of operating and finance lease costs in the Company's consolidated statement of operations and comprehensive loss (in thousands):

Lease cost	Year ended December 31, 2020	Year ended December 31, 2019
Finance lease cost:		
Amortization of right-of-use assets	$ —	$ 235
Interest on lease liabilities	—	36
Operating lease cost	1,945	1,995
Variable lease cost	754	659
Total lease cost	$ 2,699	$ 2,925

The following table summarizes supplemental information for the Company's operating leases:

Other information	Year ended December 31, 2020	Year ended December 31, 2019
Weighted-average remaining lease term - operating leases (in years)	7.1	1.9
Weighted-average discount rate - operating leases	11.9%	11.9%

The minimum lease payments for the next five years and thereafter is expected to be as follows (in thousands):

Maturity of lease liabilities	December 31, 2020 Operating Leases
2021	$ 2,440
2022	2,345
2023	2,290
2024	2,358
2025	2,331
Thereafter	5,851
Total lease payments	$ 17,615
Less: effect of discounting	(5,931)
Present value of lease liabilities	$ 11,684

The following table summarizes the presentation of the Company's operating leases in its consolidated balance sheets (in thousands):

Leases	Classification	December 31, 2020	December 31, 2019
Assets			
Operating lease assets	Operating lease assets	11,034	3,360
Total lease assets		$ 11,034	$ 3,360
Liabilities			
Current			
Operating	Accrued expenses and other current liabilities	$ 1,151	$ 1,983
Noncurrent			
Operating	Noncurrent operating lease liabilities	10,533	1,873
Total lease liabilities		$ 11,684	$ 3,856

13. Commitments and Contingencies

Guarantees

As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while each such officer or director is, or was, serving at the Company's request in such capacity. The term of the indemnification is the officer's or director's lifetime. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' liability insurance coverage that limits its exposure and enables the Company to recover a portion of any future amounts paid.

The Company leases office, laboratory and manufacturing space under noncancelable operating leases. The Company has standard indemnification arrangements under the leases that require it to indemnify the landlords against all costs, expenses, fines, suits, claims, demands, liabilities, and actions directly resulting from any breach, violation or nonperformance of any covenant or condition of the Company's leases.

In the ordinary course of business, the Company enters into indemnification agreements with certain suppliers and business partners where the Company has certain indemnification obligations limited to the costs, expenses, fines, suits, claims, demands, liabilities and actions directly resulting from the Company's gross negligence or willful misconduct, and in certain instances, breaches, violations or nonperformance of covenants or conditions under the agreements.

As of December 31, 2020 and December 31, 2019, the Company had not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

Leases

Refer to Note 12, Leases, for discussion of the commitments associated with the Company's leases.

License Agreement

In 2006, the Company entered into a license agreement with a third party, pursuant to which the third party granted the Company 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. The Company agreed to pay an annual license fee ranging from $5,000 to $25,000 for the royalty-bearing license to certain patents. For the years ended December 31, 2020 and 2019, the Company incurred immaterial amounts for regulatory milestones, license fees and reimbursed patent costs under the agreement. The Company also issued a total of 84,678 shares of common stock pursuant to the agreement in 2006 and 2007, which were recorded at fair value at the date of issuance. The Company is required to pay royalties on net sales of products and processes that are covered by patent rights licensed under the agreement at a percentage ranging between 0.5% - 3.5%, subject to reductions and offsets in certain circumstances, as well as a royalty on net sales of products that the Company sublicenses at 10% of specified gross revenue. Royalties that became due under this agreement for the year ended December 31, 2020 were $0.1 million and for the year ended December 31, 2019 were immaterial.

Transition Agreement

On July 30, 2019, the Company announced that founding CEO John McDonough was named Executive Chairman of the Board until a successor is named at which time Mr. McDonough will become non-executive Chairman of the Board. John Sperzel was named CEO in January 2020. In connection with John McDonough's transition to Non-Executive Chairman of the Board from CEO, the Company agreed to transition payments and health benefits to be paid over the 15 month period following Mr. Sperzel's start date. Accrued expenses include amounts related to Mr. McDonough's transition payments and health benefits of $0.2 million and $1.2 million at December 31, 2020 and 2019, respectively.

14. 401(k) Savings Plan

In March, 2008, the Company established a retirement savings plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers substantially all employees of the Company who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax basis. Company contributions to the 401(k) Plan may be made at the discretion of the Board of Directors. Company contributions to the 401(k) Plan were $163,000 and $195,000 for the years ended December 31, 2020 and 2019, respectively.

15. Co-Development Agreements

Canon US Life Sciences

On February 3, 2015, the Company entered into a Co-Development Partnership Agreement (the "Co-Development Agreement") with Canon U.S. Life Sciences, Inc. ("Canon US Life Sciences") to develop a diagnostic test panel to rapidly detect Lyme disease. On September 21, 2016, Canon became a related party when the Company sold the Canon Shares for an aggregate cash purchase price of $39.7 million, which represented 19.9% of the outstanding shares of common stock of the Company. Under the terms of the Co-Development Agreement, the Company received an upfront payment of $2.0 million from Canon US Life Sciences and the agreement includes an additional $6.5 million of consideration upon achieving certain development and regulatory milestones for total aggregate payments of up to $8.5 million. In October 2015, the Company achieved a specified technical requirement and received $1.5 million related to the achievement of the milestone. In May 2018, the Company achieved the next milestone and received $2.0 million. As of December 31, 2019, the Company had determined that it will not achieve the final regulatory milestone of $3.0 million prior to the termination of this agreement and therefore, as of December 31, 2019, all revenue related to the Co-Development Agreement had been recognized. All payments under the Co-Development Agreement were non-refundable once received. The Company will retain exclusive worldwide commercialization rights of any products developed under the Co-Development Agreement, including sales, marketing and distribution and Canon US Life Sciences will not receive any commercial right and will be entitled to only receive royalty payments on the sales of all products developed under the Co-Development Agreement. Either party may terminate the Co-Development Agreement upon the occurrence of a material breach by the other party (subject to a cure period).

The Company evaluated the promised goods and services under the Co-Development Agreement and determined that the Co-Development Agreement included one performance obligation, the research and development services. The Company recognized revenue for research and development services as a component of research revenue in the consolidated financial statements over time, as the services were delivered. The Company used the input method by allocating and recognizing revenue over time based on the total full-time equivalent effort incurred to date as a percentage of total full-time equivalent time expected, limited to payments earned. Costs incurred to deliver the services under the Co-Development Agreement were recorded as research and development expense in the consolidated financial statements.

The Co-Development Agreement was completed in 2019 and the Company did not record any revenue for the year ended December 31, 2020 and recorded revenue of $0.5 million for the year ended December 31, 2019, respectively.

CARB-X

In March 2018, the Company was awarded a grant of up to $2.0 million from CARB-X. The collaboration with CARB-X will be used to accelerate the development of new tests to identify bacterial pathogens and resistance markers directly in whole blood more rapidly than is possible using today's diagnostic tools. The new tests aim to expand the T2Dx instrument product line by detecting 20 additional bacterial species and resistance targets, with a focus on blood borne pathogens on the United States Centers for Disease Control and Prevention ("CDC") antibiotic resistance threat list.

Under this cost-sharing agreement, the Company may be reimbursed up to $1.1 million, with the possibility of up to an additional $0.9 million based on the achievement of certain project milestones. In January 2019, the Company was awarded the $0.9 million reimbursement option.

CARB-X was completed in 2019 and as such, the Company did not record any revenue for the year ended December 31, 2020. The Company recorded revenue of $0.9 million for the year ended December 31, 2019 under the CARB-X Agreement.

US Government Contract

In September 2019, the Biomedical Advanced Research and Development Authority ("BARDA") awarded the Company a milestone-based contract, with an initial value of $6.0 million, and a potential value of up to $69.0 million, if BARDA awards all contract options. BARDA operates within the Office of the Assistant Secretary for Preparedness and Response ("ASPR") at the U.S. Department of Health and Human Services' ("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, the Company completed the initial award and BARDA exercised the first contract option valued at $10.5 million.

The Company recorded contribution revenue of $6.4 million and $1.5 million for the years ended December 31, 2020 and 2019, respectively, under the BARDA contract.

16. Subsequent Events

Term Loan Agreement

In January 2021, the Term Loan Agreement was amended to extend the interest-only payment period until the December 30, 2022 maturity, to extend the initial principal repayment until the December 30, 2022 maturity, and to significantly reduce the minimum product revenue target for the twenty-four month period beginning on January 1, 2020. The Company did not pay or provide any consideration in exchange for this amendment.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Management conducted an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of December 31, 2020. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2020, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, the Company's disclosure controls and procedures were effective.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets;
(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles and that receipts and expenditures of the issuer are being made only in accordance with authorizations of management and directors; and
(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the Company's consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Remediation of Prior Material Weakness

In our December 31, 2019 Annual Report on Internal Control over Financial Reporting, management identified a material weakness in our internal control over financial reporting relating to an IT tape backup system. The Company historically backed up IT data monthly to a tape system and stored the tapes offsite in a secure location for use in data recovery. However, management determined that the monthly frequency of the backup presented a potential loss of data that takes an inordinate amount of time to recover. This prevented the Company from timely filing its report on Form 10-Q for the quarterly period ended September 30, 2019 without filing an extension. Furthermore, management determined that semi-annual data recovery testing to a secure environment to ensure the integrity and recoverability of the data was not performed. Because these tests were not performed, the Company did not detect flaws in the backup data timely and this flawed data required a lengthy data recovery process which delayed the Company's ability to prepare timely and accurate financial statements. Management concluded that the material weakness existed as of December 31, 2019.

Management undertook actions to remediate the material weakness, including:

- Upgrading our tape backup system during the third quarter of 2019. Backups to tapes occur monthly.
- Implementing redundant cloud-based backup processes during 2020. Redundant cloud-based backups occur daily.
- Implementing a semi-annual data recovery process to a secure environment to ensure data integrity and timely recoverability.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2020. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control—Integrated Framework (2013). Based on our assessment, our management concluded that the material weakness was remediated and internal control over financial reporting was effective as of December 31, 2020.

Changes in Internal Control Over Financial Reporting

Except as noted above regarding the implementation of a remediation plan for the material weakness identified in 2019, there have been no changes in our internal control over financial reporting during the year ended December 31, 2020, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

None.

PART III.

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Board of Directors

Our Board of Directors currently consists of eight directors. Set forth below is certain information regarding our current directors as of the date hereof.

Name	Positions and Offices Held with T2 Biosystems	Director Since	Class and Year in Which Term Will Expire	Age
John McDonough	Chairman of the Board	2007	Class I - 2021	61
Robin Toft	Director	2020	Class I - 2021	60
Seymour Liebman	Director	2016	Class I - 2021	71
Ninfa Saunders	Director	2020	Class II - 2022	69
Thierry Bernard	Director	2020	Class II - 2022	56
John Sperzel	Chief Executive Officer, President and Director	2020	Class II - 2022	57
John Cumming	Director	2014	Class III - 2023	75
David Elsbree	Director	2014	Class III - 2023	73

Set forth below are the biographies of each director, as well as a discussion of the particular experience, qualifications, attributes, and skills that led our Board of Directors to conclude that each person nominated to serve or currently serving on our Board of Directors should serve as a director. In addition to the information presented below, we believe that each director meets the minimum qualifications established by the nominating and corporate governance committee of our Board of Directors.

John Sperzel has served as our President and Chief Executive Officer and a member of our Board of Directors since January 2020. From March 2014 to January 2020, Mr. Sperzel was the Chief Executive Officer, President and a member of the Board of Directors of Chembio Diagnostics, Inc., a point-of-care diagnostics company focused on infectious diseases. From September 2011 to December 2013, Mr. Sperzel was the Chief Executive Officer and President of International Technidyne Corporation, a developer of point-of-care cardiovascular diagnostic testing solutions. Mr. Sperzel received his Bachelor of Science degree in Business Administration/Management from Plymouth State College. Mr. Sperzel's extensive management experience as a senior executive and his diagnostic company experience contributed to our Board of Directors' conclusion that he should serve as a director of our company.

John McDonough has served as the Non-Executive Chairman of our Board of Directors since January 2020. He served as a director, and our President and CEO from 2007 to January 2020 and served as Executive Chairman from July 2019 to July 2020. From 2003 to 2007, Mr. McDonough held various positions at Cytyc Corporation, a company engaged in the design, development, manufacturing and marketing of clinical products that focus on women's health, where he ultimately served as President of Cytyc Development Corporation. Mr. McDonough received his B.S.B.A. from Stonehill College. Mr. McDonough's extensive diagnostic company experience contributed to our Board of Directors' conclusion that he should serve as a director of our company.

Robin Toft has served as a member of our Board of Directors since June 2020. Ms. Toft has been employed by the Toft Group Executive Search (a ZRG Company), an executive search firm that focuses on biotechnology, pharmaceutical, diagnostics, medical device, life science tools and healthcare high tech companies since July 2010 and currently serves as President. Prior to the Toft Group Executive Search, Ms. Toft was employed by Sanford Rose Associates – Toft Group from 2006 to 2010. Prior to that, Ms. Toft was employed by Roche Diagnostics, a diagnostics company that manufactures equipment and reagents for research and medical diagnostic applications from January 2003 to November 2005, as Senior Vice President of Commercial Operations. Ms. Toft holds a B.S. in Medical Technology (Clinical Laboratory Science) from Michigan State University. Ms. Toft's leadership and industry experience contributed to our Board of Directors' conclusion that she should serve as a director of our company.

Seymour Liebman has served as a member of our Board of Directors since September 2016. Mr. Liebman has been employed by Canon USA, Inc., a leading provider of consumer, business-to-business, and industrial imaging solutions to the United States and to the Latin American and the Caribbean markets, since 1974 and currently serves as the Executive Vice President, Chief Administrative Officer and General Counsel and Senior Managing Executive Officer of Canon Inc., Japan. Mr. Liebman received his J.D. from Touro Law School, his M.S. in mathematics from Rutgers University, his M.S. in accounting from Long Island University and his B.A. in mathematics from Hofstra University. Mr. Liebman's management and board experience contributed to our Board of Directors' conclusion that he should serve as a director of our company.

Ninfa Saunders has served as a member of our Board of Directors since June 2020. Ms. Saunders has been employed by Navicent Health, the second largest hospital in Georgia, since October 2012, where she is currently the President and Chief Executive Officer. Prior to joining Navicent Health, Ms. Saunders served as President and COO of Virtua Health, the largest health system in southern New Jersey, from 2003 to

2012. Dr. Saunders has a Doctorate in Healthcare Administration from the Medical University of South Carolina, a Master's of Business Administration from Emory University, a Master of Science in Nursing from Rutgers University and a Bachelor of Science in Nursing from Concordia College. Ms. Saunders' leadership and industry experience contributed to our Board of Directors' conclusion that she should serve as a director of our company.

Thierry Bernard has served as a member of our Board of Directors since June 2020. Mr. Bernard has been employed by Qiagen NV, a provider of sample and assay technologies for molecular diagnostics, applied testing, and academic and pharmaceutical research since February 2015 and was named Chief Executive Officer in March 2020. From August 2014 to February 2015, Mr. Bernard was employed by Daktari Diagnostics, a point of care diagnostics company, where he served as Chief Executive Officer. From April 1998 to August 2014, Mr. Bernard was employed by bioMérieux, an in vitro diagnostics company, where he served in roles of increasing responsibility, most recently as Corporate Vice President, Global Commercial Operations, Investor Relations and the Greater China Region. He has earned a BS International Economics & Finance from Sciences Po Paris, an MSc Administration & Economics from the College of Europe, an MSc International Economics from the London School of Economics, a DESS Comercio Exterior from Universidad de Barcelona and a degree from the Advanced Management Program (AMP) 177 at Harvard Business School. Mr. Bernard's extensive knowledge of and experience with diagnostic product companies contributed to our Board of Directors' conclusion that he should serve as a director of our company.

John W. Cumming has served as a member of our Board of Directors since July 2014 and Lead Independent Director since June 2020. He also serves as a member of the Board of Directors of TransMed7, LLC. Mr. Cumming currently serves as Chief Executive Officer and Managing Director of Cumming & Associates LLC, a strategic advisory firm serving the healthcare industry. From August 2000 until December 2013, Mr. Cumming served in a number of leadership roles at Hologic Inc., a diagnostics company, including as Chief Executive Officer from 2001 through 2009 and again from July 2013 through December 2013, as President from 2001 until 2003, as Chairman of the Board from 2002 until 2007 and again from 2008 through 2011, and as Global Strategic Advisor from 2011 through July 2013. Mr. Cumming attended the University of South Carolina. Mr. Cumming's extensive knowledge of and experience with diagnostic product companies and expertise as a strategic advisor focused on the healthcare industry contributed to our Board of Directors' conclusion that he should serve as a director of our company.

David Elsbree has served as a member of our Board of Directors since July 2014. From 1970 until 2004, Mr. Elsbree was employed by Deloitte & Touche, most recently as a senior partner. Mr. Elsbree served in a number of leadership roles in the firm's high technology practice, including partner-in-charge of the New England High Technology Practice. Mr. Elsbree served on the Board of Directors of Art Technology Group, Inc. from June 2004 until January 2011 and on the board of directors of Acme Packet, Inc. from November 2006 until March 2013. Mr. Elsbree received his B.A. from Northeastern University. Mr. Elsbree's extensive knowledge of and experience with technology companies and financial expertise contributed to our Board of Directors' conclusion that he should serve as a director of our company.

Information about our Executive Officers

The following table identifies our executive officers and sets forth their current position(s) at T2 Biosystems and their ages as of the date hereof.

Name	Age	Position
John Sperzel	57	President, Chief Executive Officer and Director
John Sprague	62	Chief Financial Officer
Michael Gibbs, Esq.	50	Vice President and General Counsel
Alec Barclay	40	Chief Operations Officer
Anthony Pare	58	Chief Commercial Officer

Information concerning John Sperzel, our Chief Executive Officer, may be found above under "*Board of Directors*".

John Sprague has served as our Chief Financial Officer since January 2018. Prior to joining our company, Mr. Sprague was Chief Financial Officer at Caliber Imaging & Diagnostics, Inc., a medical technologies company that designs, develops and markets innovative digital imaging solutions that show tissue at the cellular level using in-vivo confocal microscopes designed specifically for imaging skin and other tissues for pathology and life sciences, from February 2017 to January 2018. From 2011 to 2017, Mr. Sprague held various positions at GE Healthcare, with his last assignment serving as Finance Manager of GE's North American Core Imaging business. Mr. Sprague is a certified public accountant and received his B.S. in accounting from Boston College.

Michael Gibbs, Esq. has served as our Vice President and General Counsel since January 2016. Mr. Gibbs joined our company in December 2014 as Senior Corporate Counsel. From 2011 until he joined our company, Mr. Gibbs was General Counsel for Keystone Dental, Inc., a medical device company focused on dental implants and biomaterials. From 2003 to 2011, Mr. Gibbs was a corporate attorney with the law firm Bingham McCutchen LLP (now Morgan Lewis & Bockius). Prior to joining Bingham McCutchen LLP, he was an officer in the United States Marine Corps, departing with the rank of Major. Mr. Gibbs received his J.D. from Boston College Law School and his B.S. in Political Science from Syracuse University.

Alec Barclay has served as our Senior Vice President, Operations since March 2018. Mr. Barclay joined our company in April 2016 as Vice President of Product Development and Product Management. Prior to joining the Company, Mr. Barclay served as the Director of Hardware and Systems Engineering at Becton Dickinson, a medical technology company that manufactures and sells medical devices, instrument systems, and reagents, within their Genomics division from January 2015 to April 2016. Prior to joining Becton Dickinson, he held various positions within Siemens Healthcare from July 2006 to December 2014, with his last assignment serving as Senior Manager, Lead Systems Integrator. Mr. Barclay received his BSME from Rochester Institute of Technology.

Anthony Pare has served as our Chief Commercial Officer since January 8, 2020. Mr. Pare joined our company in 2019 as Vice President and General Manager of International. Prior to joining T2, Mr. Pare was the Chief Commercial Officer for Hemanext, a pre-revenue company developing a new technology that improves the quality, consistency and efficacy of red cell transfusion therapy from July 2016 to April 2019. Prior to joining Hemanext, Mr. Pare was the Vice President of Business Development. Mergers and Acquisitions for Haemonetics Corporation, a blood device and diagnostic company from January 1997 to May 2015. Mr. Pare received a B.S. in Engineering from Maine Maritime Academy and a Masters in Engineering Administration from George Washington University.

Dr. Aparna Ahuja, MD. has served as our Chief Medical Officer since January of 2021. Prior to joining our company, she served in a variety of roles of increasing responsibilities with Becton Dickinson, a medical technology company that manufactures and sells medical devices, instrument systems, and reagents, from December 2012 to December 2020, most recently as Worldwide Vice President, Medical Affairs. Prior to joining Becton Dickinson, Dr. Ahuja was the Director of Clinical Reference Laboratories, Clinical Research Services Laboratory; Health and Wellness Centers, in India, at Super Religare Laboratories Limited, a leading diagnostic company providing pathology and radiology services with networks in India and internationally, from February 2008 to November 2012. She earned a Bachelor of Medicine, Bachelor of Surgery, completed her MD Residencies, and received her Postgraduate Diploma in Family Welfare, Child Health, and Hospital Management from Delhi University.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our officers and directors and persons who beneficially own more than 10% of any class of our equity securities registered pursuant to Section 12 of the Exchange Act (collectively, “Reporting Persons”) to file reports of beneficial ownership and changes in beneficial ownership with the SEC. Based on a review of copies of Forms 3, 4 or 5 filed by the Company on behalf of its directors and officers and upon any written representations of the Reporting Persons received by us, the Company believes that during and with respect to the fiscal year ended December 31, 2020, there has been compliance with all Section 16(a) filing requirements applicable to such Reporting Persons, except that one Form 3 for Mr. Pare and one Form 4 for each of Mr. Lowery, Mr. Sprague, Mr. Pare, Mr. Gibbs and Mr. Barclay were inadvertently filed late.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics for our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, which is available on our website at www.t2biosystems.com in the Investor Relations section under “Corporate Governance.” If we make any amendments to the code of business conduct and ethics or grant any waiver from a provision of the code of business conduct and ethics to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website to the extent required by law or the listing standards of The Nasdaq Stock Market LLC (“Nasdaq”). The information on, or that can be accessed from, our website is not incorporated by reference into this Annual Report.

Procedures for the Recommendation of Director Nominees by Stockholders

There have been no changes to the procedures by which stockholders can recommend nominees to the Board of Directors since such procedures were previously disclosed in the Company’s Proxy Statement for its 2020 Annual Meeting of Stockholders.

Audit Committee and Audit Committee Financial Expert

David Elsbree, Ninfa Saunders and Thierry Bernard currently serve on the audit committee, which is chaired by David Elsbree. Prior to their June 12, 2020 resignation, Michael Cima and Stanley Lapidus served on the audit committee with David Elsbree. Our Board of Directors has determined that each member of the audit committee is currently, and was during 2020, “independent” for audit committee purposes as that term is defined in the rules of the SEC and the applicable Nasdaq Rules. Our Board of Directors has designated David Elsbree as an “audit committee financial expert,” as defined under the applicable rules of the SEC. The audit committee’s responsibilities include:

- appointing, overseeing the independence of, and setting the compensation of our independent auditor;

- overseeing the work of the independent auditor, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and our independent auditor our annual and quarterly financial statements and related disclosures;
- coordinating the Board's oversight of our internal control over financial reporting, disclosure controls and procedures;
- discussing our risk management and risk assessment policies;
- establishing procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls or auditing matters;
- reviewing the company's policies and procedures for reviewing and approving or ratifying any related person transactions;
- meeting independently with our internal auditing staff, if any, independent auditors and management; and
- preparing the audit committee report.

Item 11. EXECUTIVE COMPENSATION

EXECUTIVE COMPENSATION

This section discusses the material components of the executive compensation program offered to our named executive officers identified below. For 2020, our named executive officers and their positions as of December 31, 2020 were:

- John Sperzel, President and Chief Executive Officer;
- John McDonough, Former President and Chief Executive Officer;
- Alec Barclay, Chief Operations Officer; and
- Anthony Pare, Chief Commercial Officer.

In July 2019, Mr. McDonough notified the Company of his resignation as President and Chief Executive Officer effective as of the date his successor commenced employment or such earlier date as determined by the Board of Directors, and we entered into a second amendment to his employment agreement setting forth the terms of his transition. Mr. Sperzel was appointed as our President and Chief Executive Officer effective January 8, 2020, and Mr. McDonough's resignation became effective on that date. Following Mr. McDonough's resignation, he continued to serve as Chairman of our Board of Directors and received compensation under our non-employee director compensation policy pursuant to its terms.

Overview

Our compensation programs are designed to:

- attract and retain individuals with superior ability and managerial experience;
- align executive officers' incentives with our corporate strategies, business objectives and the long-term interests of our stockholders; and
- increase the incentive to achieve key strategic performance measures by linking incentive award opportunities to the achievement of performance objectives and by providing a portion of total compensation for executive officers in the form of ownership in the company.

Our compensation committee is primarily responsible for establishing and approving, or recommending for approval by the Board of Directors, the compensation for all of our executive officers. The compensation committee oversees our compensation and benefit plans and policies, administers our equity incentive plans and reviews and approves, or recommends for approval by the Board of Directors, all compensation decisions relating to all of our executive officers, including our chief executive officer. The compensation committee typically considers, and during 2020 did consider, recommendations from our chief executive officer regarding the compensation of our executive officers other than himself. Our compensation committee has the authority under its charter to engage the services of a consulting firm or other outside advisor to assist it in designing our compensation programs and in making compensation decisions and has engaged Arnosti Consulting to provide these services. The compensation committee reviewed compensation assessments provided by Arnosti Consulting comparing our

executive compensation program to that of a group of peer companies within our industry and met with Arnosti Consulting to discuss compensation of our executive officers, including the chief executive officer, and to receive input and advice. The compensation committee had considered the adviser independence factors required under SEC rules as they relate to Arnosti Consulting and does not believe Arnosti Consulting's work in 2020 raised a conflict of interest.

Executive Compensation Components

Our executive compensation program consists of base salary, cash incentive bonuses, long-term incentive compensation in the form of stock options and restricted stock units, and a broad-based benefits program. We have not adopted any formal guidelines for allocating total compensation between long-term and short-term compensation, cash compensation and non-cash compensation, or among different forms of non-cash compensation. The compensation committee considers a number of factors in setting compensation for its executive officers, including company performance, as well as the executive's performance, experience, responsibilities and the compensation of executive officers in similar positions at comparable companies.

Base Salary

Our named executive officers receive base salaries to compensate them for the satisfactory performance of duties to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. Base salaries for our named executive officers have generally been set at levels deemed necessary to attract and retain individuals with superior talent. For 2020, Mr. Sperzel's annual base salary was $500,000, Mr. Barclay's annual base salary was $340,000, which remained unchanged from 2019, and Mr. Pare's base salary was $325,000, increased from $275,000 effective January 8, 2020 in conjunction with his promotion to Chief Commercial Officer. Mr. McDonough served as Chief Executive Officer until Mr. Sperzel's start date of January 8, 2020, and his base salary remained at the rate in effect for 2019 of $550,000.

Cash Incentive Compensation

Each of our named executive officers is eligible to participate in an annual cash incentive compensation program which provides participants with an opportunity to earn variable cash incentive compensation based on individual and company performance. For 2020, Mr. Sperzel's target bonus was 75% of his base salary and Mr. Barclay's and Mr. Pare's target bonuses were 60% of their base salaries. Mr. McDonough's target bonus for 2020 was 85% of his base salary and he was eligible to receive a prorated bonus for 2020 pursuant to the second amendment to his employment agreement.

Objectives for the 2020 annual cash incentive compensation program were established in January 2020 by our compensation committee and generally related to attaining clinical, business development and financing milestones and publication, commercialization and operational goals. The determination of 2020 bonus amounts was based on a non-formulaic assessment of these factors, as well as our compensation committee's subjective evaluation of our company's overall performance and each named executive officer's individual performance and contribution to our company. The compensation committee did not assign specific weights to any elements of our bonus program in determining 2020 bonuses.

After considering these factors, the Board of Directors, based upon the recommendation of our compensation committee, approved bonuses for our named executive officers for 2020 as set forth in the "Non-Equity Incentive Plan Compensation" column of our 2020 Summary Compensation Table.

Equity-Based Compensation

We generally grant stock options and restricted stock unit awards to our employees, including our named executive officers, as the long-term incentive component of our compensation program. We typically grant stock options to employees when they commence employment with us and may thereafter grant additional options and restricted stock unit awards in the discretion of our Board of Directors. Our stock options granted upon commencement of employment typically vest as to 25% of the shares subject to the option on the first anniversary of the date of grant and in substantially equal monthly installments over the ensuing 36 months, subject to the holder's continued employment with us. Additional stock options granted after the commencement of employment typically vest in substantially equal monthly installments over 48 months. Our restricted stock unit awards typically vest in substantially equal annual installments over 24 to 36 months, subject to the holder's continued employment with us. Each restricted stock unit entitles the holder to receive one share of our common stock or its cash value upon vesting or a later settlement date. From time to time, our Board of Directors may also construct alternate vesting schedules as it determines are appropriate to motivate particular employees.

We awarded stock options and restricted stock unit awards to our named executive officers in 2020 in the following amounts:

Named Executive Officer	January 2020 Options Granted (#) (1)(2)	March 2020 Options Granted (#) (1)(3)	March 2020 RSUs Granted (#) (4)	August 2020 RSUs Granted (#) (5)
John Sperzel	3,000,000			
John McDonough				45,454
Alec Barclay		130,000	65,000	
Anthony Pare	150,000	105,000	52,500	

(1) Stock options were granted with exercise prices equal to the fair market value of our common stock on the date of grant.
(2) The options vest in 48 substantially equal monthly installments from January 8, 2020.
(3) The options vest in 48 substantially equal monthly installments from March 14, 2020 for Messrs. Pare and Barclay.
(4) The RSUs vest in three substantially equal annual installments commencing March 14, 2020 for Messrs. Pare and Barclay.
(5) Represents RSUs granted under our non-employee director compensation policy in consideration of Mr. McDonough's service on our Board of Directors.

Retirement, Health, Welfare and Additional Benefits

Our named executive officers are eligible to participate in our employee benefit plans and programs, including medical and dental benefits, flexible spending accounts and short-and long-term disability and life insurance, to the same extent as our other full-time employees, subject to the terms and eligibility requirements of those plans. Our named executive officers are also eligible to participate in a tax-qualified 401(k) defined contribution plan to the same extent as all of our other full-time employees. We make company contributions for participants in the 401(k) plan equal to 50% of the participant's contribution, up to 2% of the participant's eligible compensation or $3,000 per year, whichever is lesser.

2020 Summary Compensation Table

Name and Principal Position	Year	Salary ($)(1)	Bonus ($)	Stock Awards ($)(2)	Option Awards ($)(3)	Non-Equity Incentive Plan Compensation ($)(4)	All Other Compensation ($)(5)	Total ($)
John Sperzel,	2020	490,705			2,571,384	393,750	3,000	3,458,839
President and Chief Executive Officer								
John McDonough,	2020	72,906(6)		74,999(7)			1,022,182(8)	1,170,087
Former President and Chief Executive Officer	2019	550,000		372,000	478,728	233,750	3,000	1,637,478
Alec Barclay,	2020	340,000		25,675	38,621	234,600	952	639,848
Chief Operations Officer	2019	337,500	35,000	111,600	348,834	102,000	2,900	937,834
Anthony Pare,	2020	325,000		20,738	159,763	185,250	3,000	693,751
Chief Commercial Officer								

(1) Amounts in this column represent base salaries earned for 2020 and 2019 rather than 2020 and 2019 annual base salary rates.
(2) Represents the aggregate grant date fair value of the restricted stock unit awards granted during the given year computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. For a description of the assumptions used in valuing these awards, see Note 8 to the audited consolidated financial statements included in this Annual Report on Form 10-K.
(3) Represents the aggregate grant date fair value of the option awards granted during the given year computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. For a description of the assumptions used in valuing these awards, see Note 8 to the audited consolidated financial statements included in this Annual Report on Form 10-K.
(4) Represents awards earned under our annual cash incentive compensation program. For additional information regarding these amounts, see the section titled "Executive Compensation Components—Cash Incentive Compensation" above.
(5) Except as otherwise indicated, represents Company matching contributions under our 401(k) plan.
(6) Represents Mr. McDonough's salary and accrued vacation through January 8, 2020.
(7) Represents the grant date fair value of RSUs granted to Mr. McDonough in August 2020 under our non-employee director compensation policy for his service as a non-employee director following his resignation as our Chief Executive Officer.
(8) Includes (i) $938 in Company matching contributions under our 401(k) plan; (ii) $50,995 in director fees paid to Mr. McDonough under our non-employee director compensation policy for his service as a non-employee director following his resignation as our Chief Executive Officer; (iii) $687,500 in cash severance payable to Mr. McDonough pursuant to the second amendment to his employment agreement; (iv) $233,750 in prorata bonus for 2020 performance pursuant to the second amendment to his employment agreement; and (v) $48,999 in premium payments for 15 months of continued medical coverage under COBRA pursuant to the second amendment to his employment agreement.

Outstanding Equity Awards at Fiscal Year-End Table—2020

	Option Awards					Stock Awards			
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)(1)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares of Units of Stock That Have Not Vested (#)(2)	Equity Incentive Plan Awards: Number of Unearned Shares or Units of Stock That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares or Units of Stock That Have Not Vested (#)(3)(4)
John Sperzel									
	01/08/2020	687,500	2,312,500	1.15	01/08/2030				
John McDonough									
	02/21/2019	91,667	108,333	3.72	02/21/2029				
	03/01/2018	206,250	93,750	5.08	03/01/2028				
	02/09/2017	95,833	4,167	5.67	02/09/2027				
	01/20/2016	133,334	—	9.02	01/20/2026				
	02/13/2015	134,124	—	19.95	02/13/2025				
	07/02/2014	66,411	—	10.69	07/02/2024				
	01/22/2014	33,205	—	3.21	01/22/2024				
	—	166,029	—	3.21	10/24/2023				
	—	194,558	—	2.45	01/17/2022				
	08/06/2020					45,454(5)	56,363		
Alec Barclay									
	03/14/2020	24,375	105,625	0.40	03/14/2030				
	09/10/2019	83,333	116,667	1.43	09/10/2029				
	02/21/2019	27,500	32,500	3.72	02/21/2029				
	03/01/2018	61,875	28,125	5.08	03/01/2028				
	01/05/2017	14,688	312	5.19	01/05/2027				
	09/12/2016	10,000	—	6.79	09/12/2026				
	04/25/2016	15,000	—	9.32	04/25/2026				
	03/14/2020					65,000	80,600		
	02/21/2019					20,000	24,800		
	03/15/2018							72,258	89,600
Anthony Pare									
	03/14/2020	19,688	85,312	0.40	03/14/2030				
	01/08/2020	34,375	115,625	1.15	01/08/2030				
	09/10/2019	41,667	58,333	1.43	09/10/2029				
	04/08/2019	41,667	58,333	3.10	04/08/2029				
	03/14/2020					52,500	65,100		

(1) All unvested options for Mr. Sperzel and Mr. McDonough vest in substantially equal monthly installments over the 48 month vesting period from the vesting commencement date based on continued employment or, in the case of Mr. McDonough, service, with us through the applicable vesting date. The unvested options for Mr. Barclay (a) granted on September 10, 2019 vest in substantially equal monthly installments over the 36 month period from the vesting commencement date, and (b) granted on all other dates vest in substantially equal monthly installments over the 48 month period from the vesting commencement date; in each case, subject to Mr. Barclay's continued employment with us through the applicable vesting date. The unvested options for Mr. Pare (a) granted on April 8, 2019 vest as to 25% of the shares subject to the option on the first anniversary of the vesting commencement date and as to the remaining shares subject to the option in substantially equal monthly installments over the ensuing 36 months, (b) granted on September 10, 2019 vest in substantially equal monthly installments over the 36 month period from the vesting commencement date, and (c) granted on all other dates vest in substantially equal monthly installments over the 48 month period from the vesting commencement date; in each case, subject to Mr. Pare's continued employment with us through the applicable vesting date. The options are subject to potential accelerated vesting as described in the sections titled "Employment Letter Agreements with Our Named Executive Officers" and "Potential Payments upon a Change in Control" below.

(2) All unvested restricted stock units for Mr. Barclay and Mr. Pare granted on March 14, 2020 vest in three substantially equal annual installments beginning on March 14, 2021, each subject to the holder's continued employment with us through the applicable vesting date and potential accelerated vesting as described in the sections titled "Employment Letter Agreements with Our Named Executive Officers" and "Potential Payments upon a Change in Control" below. The unvested restricted stock units for Mr. Barclay granted on February 21, 2019 vest in substantially equal annual installments beginning on February 21, 2020, subject to Mr. Barclay's continued employment with us through the applicable vesting date and potential accelerated vesting as described in the sections titled "Employment Letter Agreements with Our Named Executive Officers" and "Potential Payments upon a Change in Control" below.

(3) Based on the closing price of our common stock on December 31, 2020 of $1.24.

(4) The performance-based restricted stock units vest upon achievement of pre-established 90-day average stock price targets, if achieved between March 15, 2018 and March 18, 2021, subject to the holder's continued employment with us through the applicable vesting date and potential accelerated vesting as described in the sections titled "Employment Letter Agreements with Our Named Executive Officers" and "Potential Payments upon a Change in Control" below.

(5) The 45,454 unvested restricted stock units for Mr. McDonough were granted under our non-employee director compensation policy for his service as a non-employee director following his resignation as our Chief Executive Officer.

Employment Arrangements with Our Named Executive Officers

We have entered into employment and/or severance letter agreements with each of the named executive officers. Certain key terms of these agreements are described below.

John Sperzel. We have entered into an employment agreement with Mr. Sperzel, which provides that if Mr. Sperzel's employment is terminated by us without cause or by Mr. Sperzel for good reason, in each case, other than on or within 12 months following the date of a change of control, subject to his signing and not revoking a general release of claims in our favor, he will be entitled to receive 12 months of base salary continuation, plus a pro-rata portion of his target annual cash bonus for the calendar year in which the termination occurs, payable at such time as such year's annual bonus would have been paid had his employment not terminated, and reimbursement for a portion (based on active employee cost sharing rates) of COBRA healthcare premiums for up to 12 months following termination. In the event that Mr. Sperzel's employment is terminated by us without cause or by Mr. Sperzel for good reason, in each, case on or within 12 months following the date of a change in control, subject to signing and not revoking a release of claims in our favor, he will be entitled to receive 18 months of base salary continuation, plus a pro-rata portion of his target annual cash bonus for the calendar year in which the termination occurs, payable at such time as such year's annual bonus would have been paid had his employment not terminated, reimbursement for a portion (based on active employee cost sharing rates) of COBRA healthcare premiums for up to 18 months following termination and full accelerated vesting of all equity or equity-based awards held by Mr. Sperzel.

Mr. Sperzel has also entered into a non-compete, non-disclosure and invention assignment agreement with us pursuant to which he has agreed to refrain from disclosing our confidential information indefinitely and from competing with us or soliciting our employees or consultants for 12 months following termination of his employment.

John McDonough. In July 2019, we entered into a second amendment to the employment letter agreement with Mr. McDonough which provided that, in consideration for his agreement to resign his position as President and Chief Executive Officer and to continue to serve through the date his successor commences employment or earlier termination without cause and his execution and non-revocation of a general release of claims, upon his resignation he would be entitled to receive (i) continued base salary for 15 months following the termination date, which equals an aggregate amount of $687,500, (ii) an amount equal to $233,750, which represents 50% of his last target annual bonus, payable in a single lump sum on March 15 of the year following the year in which the termination date occurs, (iii) if such termination occurred prior to his receipt of an annual bonus in respect of 2019, the amount of any annual bonus that would have been earned had Mr. McDonough remained employed, based on actual performance and pro-rated for the portion of 2019 that Mr. McDonough remained employed (or, if his termination occurred in a subsequent year, the amount of any annual bonus that would have been earned had Mr. McDonough remained employed, based on actual performance and pro-rated for the portion of such year that Mr. McDonough remained employed), payable in a lump sum on March 15 of the year following the year in his termination date occurred, (iv) all premium payments for up to 15 months of continued medical coverage under COBRA; and (v) accelerated vesting of the time-vesting restricted stock unit awards granted to Mr. McDonough in February 2017 and February 2019.

Following Mr. McDonough's resignation as our President and Chief Executive Officer, his equity awards continue to vest based on his continued service in accordance with their terms, provided that the performance-based restricted stock units granted in March 2018 were forfeited pursuant to the terms of the second amendment to Mr. McDonough's employment agreement.

Mr. McDonough's employment letter agreement also contains restrictive covenants pursuant to which he has agreed to refrain from competing with us or soliciting our customers, prospective customers, employees or consultants for one year following his termination of employment.

Alec Barclay. We have entered into a severance letter agreement with Mr. Barclay, which provides that if Mr. Barclay's employment is terminated by us without cause within the three months preceding or the 12 months following a change in control, or if Mr. Barclay resigns his employment for good reason within the 12 months following a change in control, and he timely executes a release of claims in our favor, he will be entitled to receive 12 months of base salary continuation, accelerated vesting of all outstanding unvested equity awards and reimbursement for a portion (based on active employee cost sharing rates) of healthcare premiums for up to 12 months.

Mr. Barclay has also entered into a non-compete, non-disclosure and invention assignment agreement with us pursuant to which he has agreed to refrain from disclosing our confidential information indefinitely and from competing with us or soliciting our employees or consultants for 12 months following termination of his employment.

Anthony Pare. We have entered into a severance letter agreement with Mr. Pare, which provides that if Mr. Pare's employment is terminated by us without cause within the three months preceding or the 12 months following a change in control, or if Mr. Pare resigns his employment for good reason within the 12 months following a change in control, and he timely executes a release of claims in our favor, he will be entitled to receive six months of base salary continuation, accelerated vesting of all outstanding unvested equity awards and reimbursement for a portion (based on active employee cost sharing rates) of healthcare premiums for up to 12 months.

Mr. Pare has also entered into a non-compete, non-disclosure and invention assignment agreement with us pursuant to which he has agreed to refrain from disclosing our confidential information indefinitely and from competing with us or soliciting our employees or consultants for 12 months following termination of his employment.

Potential Payments Upon a Change in Control

As described above, under the terms of their individual agreements with the Company, Mr. Sperzel, Mr. Barclay and Mr. Pare may become entitled to payments or benefits in connection with certain terminations of employment that occur at specified times around a change in control.

In addition, the agreements governing Mr. Sperzel's, Mr. Barclay's and Mr. Pare's unvested stock options and restricted stock units provide for full accelerated vesting if their employment is terminated by us without cause within the three months preceding or the 12 months following a change of control or if they resign for good reason within 12 months following a change in control.

Mr. McDonough became entitled to the benefits and payments described above in connection with his resignation effective January 8, 2020.

DIRECTOR COMPENSATION

The following table presents the total compensation for each person who served as a non-employee member of our Board of Directors during 2020, other than Mr. McDonough. Because Mr. McDonough served as our President and Chief Executive Officer for a portion of 2020, his compensation as a non-employee director is included in the 2020 Summary Compensation Table set forth above.

Director Compensation Table—2020

	Fees Earned or Paid in Cash ($)(1)	Stock Awards ($)(2)(3)(4)	All Other Compensation ($)(5)	Total ($)
John W. Cumming	68,372	74,999	—	143,371
David B. Elsbree	58,000	74,999	—	132,999
Seymour Liebman	40,000	74,999	—	114,999
Thierry Bernard (6)	25,861	112,499	—	138,360
Dr. Ninfa M. Saunders (6)	2,286	112,499	—	114,785
Robin Toft (6)	31,306	112,499	—	143,805
Adrian Jones (7)	42,250	17,094	250	59,594
Michael J. Cima, Ph.D. (7)	28,125	—	3,125	31,250
Stanley N. Lapidus (7)	41,175	—	4,575	45,750

(1) Messrs. Elsbree, Jones and Liebman each elected to receive his $40,000 2020 annual retainer for board service in the form of restricted stock units and, as a result, were each issued 34,188 restricted stock units on January 1, 2020 that vested in a single installment on January 1, 2021. Amounts in this column include the value of the $40,000 2020 annual retainer forgone in lieu of restricted stock units for each of Messrs. Elsbree, Jones and Liebman.
(2) Messrs. Cumming, Elsbree and Liebman were granted $75,000 in the form of restricted stock units, and, as a result, were each issued 45,454 restricted stock units on August 6, 2020 that vest in a single installment on the earlier of the first anniversary of the grant date or the date of the next annual meeting of stockholders.
(3) As Directors elected or appointed to the Board in 2020, Messrs. Bernard, Saunders and Toft were granted 1.5 times the number of restricted stock units granted to the Directors listed in (2) and, as a result, were each issued 68,181 restricted stock units on August 6, 2020 that vest in substantially equal installments on each of the first three anniversaries of the date of grant.
(4) Amounts for Messrs. Lapidus, Cima and Jones includes the incremental fair value of the accelerated vesting of unvested restricted stock units and the extended exercise period for each director's outstanding vested options approved by the Board in connection with their resignation.
(5) Represents the payment of the board retainers for Messrs. Lapidus, Cima and Jones from the date of their resignation through the second quarter of 2020, which was approved by the Board in conjunction with their resignations.
(6) Messrs. Bernard, Saunders and Toft were elected to the Board on June 14, 2020.
(7) Messrs. Lapidus, Cima and Jones resigned from the Board of Directors effective June 12, 2020.

The table below shows the aggregated numbers of outstanding option awards (exercisable and unexercisable) and unvested stock awards held as of December 31, 2020 by each non-employee director.

	Option Awards Outstanding at 2020 Fiscal Year End	Unvested Stock Awards Outstanding at 2020 Fiscal Year End
John W. Cumming	123,470	45,454
David B. Elsbree	123,470	79,642
Seymour Liebman	88,176	79,642
Thierry Bernard	—	68,181
Dr. Ninfa M. Saunders	—	68,181
Robin Toft	—	68,181
Adrian Jones	—	—
Michael J. Cima, Ph.D.	—	—
Stanley N. Lapidus	—	—

We maintain a non-employee director compensation policy pursuant to which all non-employee directors were paid cash compensation as set forth below for 2020:

	Annual Retainer ($)
Board of Directors:	
All non-employee members	40,000
Additional retainer for Lead Independent Director	30,000
Audit Committee:	
Chairperson	18,000
Membership	7,500
Compensation Committee:	
Chairperson	14,000
Membership	5,000
Nominating and Corporate Governance Committee:	
Chairperson	10,000
Membership	3,500
Technology Committee:	
Chairperson	15,000

Annual retainers are earned on a quarterly basis and paid in arrears following the end of each calendar quarter. Retainers are prorated for partial quarters of service. Each director also has the opportunity to elect to be paid the director's $40,000 annual retainer for board service in the form of restricted stock units that vest in a single installment on January 1 of the following year.

Under the non-employee director compensation policy in effect at the beginning of 2020, each non-employee director initially appointed or elected to the Board of Directors was granted an option to purchase 66,176 shares of our common stock on the date he or she first became a non-employee director. The option vests and becomes exercisable in substantially equal installments on each of the first three anniversaries of the date of grant, subject to the director's continued service on the Board of Directors. The Board of Directors was also able to elect, prior to the date of the annual stockholder meeting, to make annual equity awards under the program in the form of (i) an option to purchase 22,000 shares of our common stock, (ii) 11,000 restricted stock units on the date of such annual meeting, or (iii) a combination thereof. These awards would vest (i) if an option, in 12 substantially equal monthly installments following the date of grant and (ii) if a restricted stock unit, in a single installment on the first anniversary of the grant date, subject to the director's continued service on the Board of Directors.

In June 2020, following its review of the results of a competitive market analysis performed by Arnosti Consulting, our independent compensation consultant, our Board of Directors approved the amendment of the non-employee director compensation program to provide that the annual equity grant to continuing non-employee directors made on the date of the annual meeting of stockholders will be an award of restricted stock units having an aggregate value of $75,000, based on the closing price of the Company's common stock on the date of grant. However, the maximum number of restricted units subject to such grant will not exceed 100,000 restricted stock units (as may be adjusted for stock splits, recapitalizations and the like). The restricted stock units subject to the annual grant will vest in a single installment on the earlier of (i) the first anniversary of the grant date and (ii) the date of the next annual meeting of stockholders, subject to the director's continued service on the Board of Directors. The non-employee director compensation program was also amended to provide that the initial non-employee director grant will be an award of restricted stock units covering a number of shares equal to one and a half times the number of restricted stock units subject to the last (or concurrent) annual grant for continuing directors. The initial grant vests in substantially equal installments on each of the first three anniversaries of the date of grant, subject to the director's continued service on the Board of Directors. Any new directors appointed to the Board of Directors prior to the 2020 annual meeting of the stockholders shall receive their initial grant on the date of the 2020 annual meeting of stockholders, and the number of shares subject to such initial grant will be determined based on the annual grants made at the 2020 annual meeting of stockholders. Prior to the amendment of the non-employee director compensation program in June 2020, the annual equity grants to our non-employee directors were positioned below the 10th percentile of the Company's peer group, and such amendments are intended to position the annual grant closer to the median of our peer group and align the initial grant with peer practice.

Effective June 12, 2020, Stanley Lapidus, Michael Cima and Adrian Jones resigned from the Board of Directors. In connection with their resignation, the Board of Directors approved the (i) acceleration of unvested restricted stock units, if any, held by each individual at the time of his resignation, (ii) payment of each of their Board retainer fees through the second quarter of 2020 and (iii) extension of the time period each of them has to exercise any vested options held by them on their resignation date until December 31, 2020.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

EQUITY COMPENSATION PLAN INFORMATION

The following table provides information on our equity compensation plans as of December 31, 2020.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, and Rights		Weighted Average Exercise Price of Outstanding Options, and Rights		Number of Securities Available for Future Issuance Under Equity Compensation Plans	
Equity compensation plans approved by security holders (1)	6,687,989	(2)	$ 4.42	(3)	5,506,018	(4)
Equity compensation plans not approved by security holders (5)	3,551,719		1.57		2,073,281	
Total	10,239,708		$ 3.24		7,579,299	

(1) Consists of the 2006 Employee, Director and Consultant Stock Plan, or the 2006 Plan, the 2014 Incentive Award Plan, as amended and restated, or the 2014 Plan, and the Employee Stock Purchase Plan, or ESPP. We ceased issuing new awards under the 2006 Plan when the 2014 Plan became effective.

(2) Consists of 700,781 outstanding options to purchase shares of our common stock under the 2006 Plan, 4,343,429 outstanding options to purchase shares of our common stock under the 2014 Plan, and 1,643,779 outstanding restricted stock units under the 2014 Plan.

(3) Represents the weighted-average exercise price of options under the 2014 Plan and 2006 Plan as of December 31, 2020. Amounts shown do not take into account any restricted stock units awarded under the 2014 Plan, which do not have an exercise price.

(4) Pursuant to the terms of the 2014 Plan, the number of shares of common stock available for issuance under the 2014 Plan automatically increases on January 1 of each year during the current ten year term of the 2014 Plan, beginning on January 1, 2015. The annual increase in the number of shares is currently equal to the lesser of: (a) 4% of our shares of common stock outstanding (on an as-converted basis) on the final day of the immediately preceding calendar year; and (b) such smaller number of shares of common stock determined by the Board of Directors. Pursuant to the terms of the ESPP, as amended in August 2020, the aggregate number of shares that may be issued pursuant to rights granted under the ESPP shall be 4,523,944 shares. As of December 31, 2020, a total of 3,268,850 shares of stock were available for issuance under the ESPP, 1,300,000 of which were subject to purchase with respect to the purchase period in effect as of December 31, 2020, which purchase period ends on May 15, 2021.

(5) Consists of the Inducement Award Plan. See Note 8 to the audited consolidated financial statements included in this Annual Report on Form 10-K for a description of the material features of the plan.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding beneficial ownership of our common stock as of December 31, 2020, for: each person known to us to be the beneficial owner of more than five percent of our outstanding common stock; each of our named executive officers; each of our directors and nominees; and all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Except as noted by footnote, and subject to community property laws where applicable, we believe based on the information provided to us that the persons and entities named in the table below have sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by them.

The table lists applicable percentage ownership based on 148,078,974 shares of our common stock outstanding as of December 31, 2020. The number of shares beneficially owned includes shares of our common stock that each person has the right to acquire within 60 days of December 31, 2020, except as noted in the footnotes below, including upon the exercise of stock options and vesting of restricted stock units. These stock options and restricted stock units shall be deemed to be outstanding for the purpose of computing the percentage of outstanding shares of our common stock owned by such person but shall not be deemed to be outstanding for the purpose of computing the percentage of outstanding shares of our common stock owned by any other person.

Name of Beneficial Owner	Amount and Nature of Ownership	Percentage of Class
5% or Greater Stockholders		
None		
Named Executive Officers and Directors		
John Sperzel (1)	812,500	*
John McDonough (2)	1,641,775	1.1%
Alec Barclay (4)	334,263	*
Anthony Pare (3)	176,898	*
John W. Cumming (5)	147,050	*
David B Elsbree (6)	248,739	*
Seymour Liebman (7)	6,227,702	4.2%
Thierry Bernard	—	*
Dr. Ninfa M. Saunders	—	*
Robin Toft	—	*
All executive officers and directors as a group (13 persons) (8)	10,213,366	6.9%

* Less than 1%.

(1) Consists of options to purchase 812,500 shares of common stock which Mr. Sperzel has the right to acquire pursuant to outstanding stock options which are, or will be, immediately exercisable within 60 days of December 31, 2020.

(2) Consists of (a) 489,114 shares of common stock and (b) options to purchase 1,152,661 shares of common stock which Mr. McDonough has the right to acquire pursuant to outstanding stock options which are, or will be, immediately exercisable within 60 days of December 31, 2020.

(3) Consists of (a) 19,155 shares of common stock and (b) options to purchase 157,743 shares of common stock which Mr. Pare has the right to acquire pursuant to outstanding stock options which are, or will be, immediately exercisable within 60 days of December 31, 2020.

(4) Consists of (a) 62,527 shares of common stock, (b) options to purchase 261,736 shares of common stock which Mr. Barclay has the right to acquire pursuant to outstanding stock options which are, or will be, immediately exercisable within 60 days of December 31, 2020 and (c) 10,000 restricted stock units vesting within 60 days of December 31, 2020.

(5) Consists of (a) 23,580 shares of common stock and (b) options to purchase 123,470 shares of common stock which Mr. Cumming has the right to acquire pursuant to outstanding stock options which are, or will be, immediately exercisable within 60 days of December 31, 2020.

(6) Consists of (a) 91,081 shares of common stock, (b) options to purchase 123,470 shares of common stock which Mr. Elsbree has the right to acquire pursuant to outstanding stock options which are, or will be, immediately exercisable within 60 days of December 31, 2020 and (c) 34,188 restricted stock units vesting within 60 days of December 31, 2020.

(7) Based on information set forth in a Schedule 13D filed with the SEC by Canon U.S.A., Inc. on September 21, 2016, this includes 6,055,341 shares held by Canon U.S.A., Inc. Mr. Seymour Liebman is the Executive Vice President, Chief Administrative Officer and General Counsel of Canon U.S.A., Inc. and the Senior Managing Executive Officer of Canon Inc., Japan, and Chairman of the Board of BriefCam, a Canon Inc. company and may be deemed to have beneficial ownership of the shares held by Canon U.S.A., Inc. Canon U.S.A., Inc. and Mr. Liebman each disclaim beneficial ownership of the shares held directly or indirectly by Canon U.S.A., Inc., except to the extent of its pecuniary interest therein, if any. On September 21, 2016, 66,176 options were granted to Mr. Liebman, in connection with Mr. Liebman becoming a member of our Board of Directors, on June 2, 2017, 18,000 restricted stock units were granted to Mr. Liebman, on January 1, 2018, 9,708 restricted stock units were granted to Mr. Liebman, on June 8, 2018, 9,000 restricted stock units were granted to Mr. Liebman, on January 1, 2019, 13,289 restricted stock units were granted to Mr. Liebman, on June 7, 2019, 22,000 options were granted to Mr. Liebman, of which all are immediately exercisable and on January 1, 2020, 34,188 restricted stock units were granted to Mr. Liebman, of which 34,188 are vesting within 60 days of December 31, 2020. The mailing address of the beneficial owner is One Canon Park, Melville, New York 11747.

(8) Consists of (a) 6,884,157 shares of common stock, (b) 3,230,833 shares of common stock which our directors and executive officers as a group have the right to acquire pursuant to outstanding stock options which are, or will be, immediately exercisable within 60 days of December 31, 2020 and (c) 98,376 restricted stock units vesting within 60 days of December 31, 2020.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Policies for Approval of Related Person Transactions

We have adopted a written policy that transactions with directors, officers and holders of 5% or more of our voting securities and their affiliates, or each, a related party, must be approved by our audit committee or another independent body of our Board of Directors. All related party transactions shall be disclosed in our applicable filings with the SEC as required under SEC rules.

Transactions with Related Persons

Based on a review of the transactions and arrangements between us and any related person or related person's affiliate, we describe below the transactions or arrangements since January 1, 2019 in which any related person or related person affiliate has a direct or indirect material interest and the amount involved exceeds $120,000.

Co-Development Agreement. On February 3, 2015, we entered into a Co-Development Partnership Agreement with Canon U.S. Life Sciences, Inc. ("Canon US Life Sciences") to develop a diagnostic test panel to rapidly detect Lyme disease. Canon US Life Sciences is an affiliate of Canon U.S.A., Inc., which acquired greater than 5% of our voting securities on September 21, 2016. Under the terms of the agreement, we received an upfront payment of $2.0 million from Canon US Life Sciences and the agreement included an additional $6.5 million of consideration upon achieving certain development and regulatory milestones for total aggregate payments of up to $8.5 million. Of the additional $6.5 million of consideration, we received $3.5 million related to the achievement of two milestones. We recorded revenue of $0.5 million for the year ended December 31, 2019. As of December 31, 2019, all revenue related to the Co-Development Agreement had been recognized.

Indemnification Agreements with Executive Officers and Directors. We have entered into an indemnification agreement with each of our directors and executive officers. These indemnification agreements and our certificate of incorporation and our bylaws indemnify each of our directors and officers to the fullest extent permitted by the DGCL. See the "*Limitation of Liability and Indemnification Agreements"* section for further details.

Limitation of Liability and Indemnification Agreements We have adopted provisions in our certificate of incorporation and bylaws that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended.

Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;

- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our Board of Directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our Board of Directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have entered into indemnification agreements with each of our directors and executive officers. These agreements provide that we will indemnify each of our directors, such executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us and/or in furtherance of our rights. Additionally, each of our directors may have certain rights to indemnification, advancement of expenses and/or insurance provided by their affiliates, which indemnification relates to and might apply to the same proceedings arising out of such director's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that our obligations to those same directors are primary and any obligation of the affiliates of those directors to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, or persons controlling the registrant under the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Independence of the Board of Directors

Board Leadership and Independence. Our Board of Directors has determined that all members of the Board of Directors, (including Ninfa Saunders, Thierry Bernard and Robin Toft), except John McDonough, John Sperzel and Seymour Liebman, are independent, as determined in accordance with Nasdaq rules. The Board had previously determined that Stanley Lapidus, Michael Cima and Adrian Jones were independent in accordance with Nasdaq rules. In making such independence determination, the Board of Directors considered the relationships that each such non-employee director has with us and all other facts and circumstances that the Board of Directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of the directors listed above, our Board of Directors considered the association of our directors with the holders of more than 5% of our common stock. There are no family relationships among any of our directors or executive officers.

The positions of our Chairman of the Board, or Lead Independent Director, and Chief Executive Officer are presently separated. Separating these positions allows our Chief Executive Officer to focus on our day-to-day business, while allowing the Chairman of the Board, or Lead Independent Director, to lead the Board of Directors in its fundamental role of providing advice to and independent oversight of management. Our Board of Directors recognizes the time, effort and energy that the Chief Executive Officer must devote to his position in the current business environment, as well as the commitment required to serve as our Chairman or Lead Independent Director, particularly as the Board of Directors' oversight responsibilities continue to grow. Our Board of Directors also believes that this structure ensures a greater role for the non-management directors in the oversight of our company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of our Board of Directors. Our Board of Directors believes its administration of its risk oversight function has not affected its leadership structure. Although our bylaws do not require our Chairman, or Lead Independent Director, and Chief Executive Officer positions to be separate, our Board of Directors believes that having separate positions is the appropriate leadership structure for us at this time. John W. Cumming was appointed Lead Independent Director on June 14, 2020, replacing Stanley Lapidus.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth fees billed for professional audit services and other services rendered to us by BDO USA, LLP ("BDO"), our independent registered public accounting firm, and its affiliates for the fiscal years ended December 31, 2020 and 2019.

	Fiscal 2020	Fiscal 2019
Audit Fees	$ 721,708	$ 865,084
Tax Fees	49,350	43,400
Total	$ 771,058	$ 908,484

Audit Fees. Audit fees consist of fees billed for professional services performed by BDO for the audit of our annual consolidated financial statements, the review of interim consolidated financial statements, and related services that are normally provided in connection with registration statements.

Tax Fees. Tax fees consist of fees for professional services, including tax consulting and compliance performed by BDO.

Audit Committee Pre-Approval of Audit and Non-Audit Services

The Audit Committee has adopted a policy (the "Pre-Approval Policy") that sets forth the procedures and conditions pursuant to which audit and non-audit services proposed to be performed by the independent auditor may be pre-approved. The Pre-Approval Policy generally provides that we will not engage BDO USA, LLP to render any audit, audit-related, tax or permissible non-audit service unless the service is either (i) explicitly approved by the Audit Committee ("specific pre-approval") or (ii) entered into pursuant to the pre-approval policies and procedures described in the Pre-Approval Policy ("general pre-approval"). Unless a type of service to be provided by BDO USA, LLP has received general pre-approval under the Pre-Approval Policy, it requires specific pre-approval by the Audit Committee or by a designated member of the Audit Committee to whom the committee has delegated the authority to grant pre-approvals. Any proposed services exceeding pre-approved cost levels or budgeted amounts will also require specific pre-approval. For both types of pre-approval, the Audit Committee will consider whether such services are consistent with the SEC's rules on auditor independence. The Audit Committee will also consider whether the independent auditor is best positioned to provide the most effective and efficient service, for reasons such as its familiarity with the Company's business, people, culture, accounting systems, risk profile and other factors, and whether the service might enhance the Company's ability to manage or control risk or improve audit quality. All such factors will be considered as a whole, and no one factor should necessarily be determinative. The Audit Committee periodically reviews and generally pre-approves any services (and related fee levels or budgeted amounts) that may be provided by BDO USA, LLP without first obtaining specific pre-approvals from the Audit Committee or the Chair of the Audit Committee. The Audit Committee may revise the list of general pre-approved services from time to time, based on subsequent determinations.

All BDO services and fees in the fiscal years ended December 31, 2020 and 2019 were pre-approved by the audit committee.

Item 15. EXHIBITS, FINANCIAL STATEMENTS AND SCHEDULES

a. *Documents filed as part of this Annual Report.*

1. The following financial statements of T2 Biosystems, Inc. and Report of Independent Registered Public Accounting Firm, are included in this report:

Report of BDO USA LLP, Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2020 and 2019

Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2020 and 2019

Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2020 and 2019

Consolidated Statements of Cash Flows for the years ended December 31, 2020 and 2019

Notes to Consolidated Financial Statements

2. List of financial statement schedules. All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3.

INDEX TO EXHIBITS

Exhibit Number		Description of Exhibit
3.1		Restated Certificate of Incorporation of the Company, as amended (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36571) filed on August 12, 2014)
3.2		Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 of the Company's Form 8-K (File No. 001-36571) filed on August 12, 2014)
4.1		Form of Common Stock Certificate of the Company (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A (File No. 333-197193) filed on July 28, 2014)
4.2		Fourth Amended and Restated Investors' Rights Agreement, dated as of March 22, 2013, as amended (incorporated by reference to Exhibit 4.2 of the Company's Registration Statement on Form S-1/A (File No. 333-197193) filed on July 28, 2014
4.3		Registration Rights Agreement dated as of July 29, 2019 by and between T2 Biosystems Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 4.1 of the Company's Form 8-K (File No. 001-36571) filed on July 30, 2019)
4.4	*	Description of Securities
10.1	#	Amended and Restated 2006 Employee, Director and Consultant Stock Plan, as amended, and form of option agreements thereunder (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-197193 filed on July 2, 2014)
10.2	#	Amended and Restated 2014 Incentive Award Plan and form of option agreements thereunder (incorporated by reference to Exhibit 10.2 of the Company's Form 10-K (File No. 001-36571) filed on March 19, 2018)
10.3	*#	Non-Employee Director Compensation Program, effective as of February 24, 2021
10.4	#	Form of Indemnification Agreement for Directors and Officers (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1/A (File No. 333-197193 filed on July 28, 2014)
10.5	#	Employment Letter Agreement, dated as of March 14, 2008, by and between the Company and John McDonough, as amended (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1/A (File No. 333-197193) filed on July 28, 2014)
10.6	†	Exclusive License Agreement, dated as of November 7, 2006, as amended on December 2, 2008 and February 21, 2011, by and between The General Hospital Corporation d/b/a Massachusetts General Hospital and the Company (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 (File No. 333-197193) filed on July 2, 2014)
10.7		Commercial Lease, dated as of May 6, 2013, as amended on September 24, 2013, by and between the Company and Columbus Day Realty, Inc. (incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1 (File No. 333-197193) filed on July 2, 2014)
10.8		Lease, dated as of August 6, 2010, by and between the Company and King 101 Hartwell LLC, as amended by the First Amendment to Lease on November 30, 2011 and the Second Amendment to Lease on July 11, 2014 (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1/A (File No. 333-197193) filed on July 16, 2014)
10.9		2014 Employee Stock Purchase Plan, effective as of June 14, 2020 (incorporated by reference to Exhibit 10.4 of the Company's Form 10-Q (File No. 001-36571) filed on August 12, 2020)
10.10	†	Supply Agreement by and between the Company and SMC Ltd., effective as of October 10, 2014 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K/A (File No. 001-36571) filed on January 21, 2015)

10.11	†	Co-Development Partnership Agreement by and between the Company and Canon U.S. Life Sciences, Inc., dated as of February 3, 2015 (incorporated by reference to Exhibit 10.22 of the Company's Form 10-K (File No. 001-36571) filed on March 4, 2015)
10.12		Third Amendment to Lease with King 101 Hartwell LLC on May 27, 2015 (incorporated by referenced to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on May 29, 2015)
10.13	†	Master Lease Agreement and between the Company and Essex Capital Corporation, dated as of October 31, 2015 (incorporated by reference to Exhibit 10.27 of the Company's Form 10-K (File No. 001-36571) filed on March 9, 2016)
10.14		Stock Purchase Agreement, dated September 21, 2016, by and among Canon U.S.A., Inc. and the Company (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on September 22, 2016)
10.15		Voting and Standstill Agreement, dated September 21, 2016, by and among Canon U.S.A., Inc. and the Company (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K (File No. 001-36571) filed on September 22, 2016)
10.16		Registration Rights Agreement, dated September 21, 2016, by and among Canon U.S.A., Inc. and the Company (incorporated by reference to Exhibit 10.3 of the Company's Form 8-K (File No. 001-36571) filed on September 22, 2016)
10.17	†	Co-Development, Collaboration and Co-Marketing Agreement, dated November 1, 2016, by and between the Company and Allergan Sales, LLC (incorporated by reference to Exhibit 10.28 of the Company's Form 10-K (File No. 001-36571) filed on March 15, 2017)
10.18	†	Term Loan Agreement, dated December 30, 2016, by and among the Company, CRG Servicing LLC, as administrative and collateral agent, and the lenders from time to time party thereto and the subsidiary guarantors from time to time party thereto (incorporated by reference to Exhibit 10.29 of the Company's Form 10-K (File No. 001-36571) filed on March 15, 2017)
10.19		Security Agreement, dated December 30, 2016, by and among the Company, the other grantors from time to time party thereto and CRG Servicing LLC, as administrative and collateral agent (incorporated by reference to Exhibit 10.30 of the Company's Form 10-K (File No. 001-36571) filed on March 15, 2017)
10.20		Warrant to Purchase Shares of Common Stock of T2 Biosystems, Inc., dated December 30, 2016, by and between the Company and CRG Partners III - Parallel Fund "A" L.P. (incorporated by reference to Exhibit 10.32 of the Company's Form 10-K (File No. 001-36571) filed on March 15, 2017)
10.21		Warrant to Purchase Shares of Common Stock of T2 Biosystems, Inc., dated December 30, 2016, by and between the Company and CRG Partners III L.P. (incorporated by reference to Exhibit 10.33 of the Company's Form 10-K (File No. 001-36571) filed on March 15, 2017)
10.22		Warrant to Purchase Shares of Common Stock of T2 Biosystems, Inc., dated December 30, 2016, by and between the Company and CRG Partners III Parallel Fund "B" (Cayman) L.P. (incorporated by reference to Exhibit 10.34 of the Company's Form 10-K (File No. 001-36571) filed on March 15, 2017)
10.23		Fourth Amendment to Lease, dated March 2, 2017, by and between the Company and King 101 Harwell LLC (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on March 3, 2017)
10.24		Amendment No. 1 to Term Loan Agreement, dated March 1, 2017, by and among the Company, CRG Servicing LLC, as administrative and collateral agent, and the lenders party thereto (incorporated by reference to Exhibit 10.3 of the Company's Form 10-Q (File No. 001-36571) filed on May 8, 2017)
10.25		Amendment to Co-Development, Collaboration and Co-Marketing Agreement, by and between the Company and Allergan Sales, LLC, dated June 1, 2017 (incorporated by reference to Exhibit 10.3 of the Company's Form 10-Q (File No. 001-36571) filed on August 4, 2017)
10.26	†	Amendment to Supply Agreement, by and between the Company and SMC Ltd., dated August 29, 2017 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on August 29, 2017)
10.27		Second Amendment to Supply Agreement, by and between the Company and SMC Ltd., dated December 22, 2017 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on December 27, 2017)
10.28		Lease Indenture Agreement, dated September 21, 2017, by and between 91 Hartwell Ave. Trust and the Company (incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q (File No. 001-36571) filed on November 3, 2017)
10.29	#	Employment Offer Letter, dated as of March 7, 2016, by and between the Company and Alec Barclay (incorporated by reference to Exhibit 10.35 of the Company's Form 10-K (File No. 001-36571) filed on March 19, 2018)

10.30	#	Change of Control Severance Agreement, dated February 1, 2017, as amended on March 6, 2018, by and between the Company and Alec Barclay (incorporated by reference to Exhibit 10.36 of the Company's Form 10-K (File No. 001-36571) filed on March 19, 2018)
10.31	#	Amendment to Change of Control Severance Agreement, by and between the Company and Alec Barclay, dated March 6, 2018 (incorporated by reference to Exhibit 10.37 of the Company's Form 10-K (File No. 001-36571) filed on March 19, 2018)
10.32	#	Employment Offer Letter, dated as of January 30, 2018, by and between the Company and John M. Sprague (incorporated by reference to Exhibit 10.38 of the Company's Form 10-K (File No. 001-36571) filed on March 19, 2018)
10.33	#	Change of Control Severance Agreement, dated January 30, 2018, by and between the Company and John M. Sprague (incorporated by reference to Exhibit 10.39 of the Company's Form 10-K (File No. 001-36571) filed on March 19, 2018)
10.34		Amendment No. 2 to Commercial Lease, dated as of September 21, 2015, by and between the Company and Columbus Day Realty, Inc. (incorporated by reference to Exhibit 10.40 of the Company's Form 10-K (File No. 001-36571) filed on March 19, 2018)
10.35		Amendment No. 3 to Commercial Lease, dated as of August 10, 2017, by and between the Company and Columbus Day Realty, Inc. (incorporated by reference to Exhibit 10.41 of the Company's Form 10-K (File No. 001-36571) filed on March 19, 2018)
10.36		Amendment No. 2 to Term Loan Agreement, dated December 18, 2017, by and among the Company, CRG Servicing LLC, as administrative and collateral agent, and the lenders party thereto (incorporated by reference to Exhibit 10.42 of the Company's Form 10-K (File No. 001-36571) filed on March 19, 2018)
10.37		Amendment No. 3 to Term Loan Agreement, dated March 16, 2018, by and among the Company, CRG Servicing LLC, as administrative and collateral agent, and the lenders party thereto (incorporated by reference to Exhibit 10.43 of the Company's Form 10-K (File No. 001-36571) filed on March 19, 2018)
10.38	#	T2 Biosystems, Inc. Inducement Award Plan (as amended and restated, effective January 8, 2020) and form of option agreement, restricted stock agreement, and restricted stock unit agreement thereunder (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K (File No. 001-36571) filed on January 9, 2020)
10.39		Third Amendment to Supply Agreement, by and between the Company and SMC Ltd., dated May 16, 2018 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on May 17, 2018)
10.40		Amendment No. 4 to Commercial Lease, dated as of August 31, 2018, by and between the Company and Columbus Day Realty, Inc. (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on September 7, 2018)
10.41		Fifth Amendment to Lease, dated December 6, 2018, by and between the Company and King 101 Harwell LLC (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on December 12, 2018)
10.42	#	Employment Offer Letter, dated as of October 29, 2014, by and between the Company and Michael Gibbs (incorporated by reference to Exhibit 10.45 of the Company's Form 10-K (File No. 001-36571) filed on March 14, 2019)
10.43	#	Change of Control Severance Agreement, dated October 29, 2014, by and between the Company and Michael Gibbs (incorporated by reference to Exhibit 10.46 of the Company's Form 10-K (File No. 001-36571) filed on March 14, 2019)
10.44	#	Amendment to Change of Control Severance Agreement, by and between the Company and Michael Gibbs, dated June 6, 2017 (incorporated by reference to Exhibit 10.47 of the Company's Form 10-K (File No. 001-36571) filed on March 14, 2019)
10.45		Amendment No. 4 to Term Loan Agreement, dated March 13, 2019, between the Company and CRG Servicing LLC (incorporated by reference to Exhibit 10.50 of the Company's Form 10-K (File No. 001-36571) filed on March 14, 2019)
10.46		Amendment to Warrant to Purchase Shares of Common Stock, dated March 13, 2019, between the Company and CRG Partners III L.P. (incorporated by reference to Exhibit 10.51 of the Company's Form 10-K (File No. 001-36571) filed on March 14, 2019)

10.47		Amendment to Warrant to Purchase Shares of Common Stock, dated March 13, 2019, between the Company and CRG Partners III – Parallel Fund "A" L.P. (incorporated by reference to Exhibit 10.52 of the Company's Form 10-K (File No. 001-36571) filed on March 14, 2019)
10.48		Amendment to Warrant to Purchase Shares of Common Stock, dated March 13, 2019, between the Company and CRG Partners III Parallel Fund "B" (CAYMAN) L.P. (incorporated by reference to Exhibit 10.53 of the Company's Form 10-K (File No. 001-36571) filed on March 14, 2019)
10.49		Replacement Warrant to Purchase Shares of Common Stock of T2 Biosystems, Inc., dated March 13, 2019, between the Company and CRG PARTNERS III (CAYMAN) LEV AIV L.P. (incorporated by reference to Exhibit 10.54 of the Company's Form 10-K (File No. 001-36571) filed on March 14, 2019)
10.50		Replacement Warrant to Purchase Shares of Common Stock of T2 Biosystems, Inc., dated March 13, 2019, between the Company and CRG PARTNERS III (CAYMAN) UNLEV AIV 1 L.P. (incorporated by reference to Exhibit 10.55 of the Company's Form 10-K (File No. 001-36571) filed on March 14, 2019)
10.51	†	Amendment No. 5 to Term Loan Agreement dated as of September 10, 2019 by and between T2 Biosystems, Inc., CRG Servicing LLC and the lenders listed on the signature pages thereto (incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q (File No. 001-36571) filed on November 18, 2019)
10.52	†	Contract, dated as of September 6, 2019, by and between the Company and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services (incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q/A (File No. 001-36571) filed on November 18, 2019)
10.53	#	Second Amendment to Employment Agreement, dated July 30, 2019, between the Company and John McDonough (incorporated by reference to Exhibit 10.3 of the Company's Form 8-K (File No. 001-36571) filed on July 30, 2019)
10.54	†	Supply Agreement, dated as of March 1, 2019, by and between the Company and GE Healthcare (incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q (File No. 001-36571) filed on May 10, 2019)
10.55	#	Employment Agreement, dated as of January 8, 2020, by and between the Company and John Sperzel (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on January 9, 2020)
10.56	#	Offer Letter, dated as of March 11, 2019, by and between the Company and Anthony Pare (incorporated by reference to Exhibit 10.62 of the Company's Form 10-K (File No. 001-36571) filed on March 16, 2020)
10.57	#	Promotion Letter, dated as of January 3, 2020, by and between the Company and Anthony Pare (incorporated by reference to Exhibit 10.63 of the Company's Form 10-K (File No. 001-36571) filed on March 16, 2020)
10.58	#	Change in Control Severance Agreement, dated as of March 11, 2019, by and between the Company and Anthony Pare (incorporated by reference to Exhibit 10.64 of the Company's Form 10-K (File No. 001-36571) filed on March 16, 2020)
10.59	†	Amendment of Solicitation/Modification of Contract, dated as of September 30, 2020 by and between the Company and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services (incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q (File No. 001-36571) filed on November 5, 2020)
10.60		Sixth Amendment to Lease by and between the Company and LS King Hartwell Innovation Campus LLC, dated as of October 19, 2020 (incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q (File No. 001-36571) filed on November 5, 2020)
10.61		First Amendment to Lease by and between the Company and LS King Hartwell Innovation Campus LLC, dated as of October 19, 2020 (incorporated by reference to Exhibit 10.3 of the Company's Form 10-Q (File No. 001-36571) filed on November 5, 2020)
10.62		Amendment No. 5 to Commercial Lease between Columbus Day Realty, Inc. and the Company, dated as of October 20, 2020 (incorporated by reference to Exhibit 10.4 of the Company's Form 10-Q (File No. 001-36571) filed on November 5, 2020)
10.63	†*	Amendment No. 6 to Term Loan Agreement, dated January 25, 2021, between T2 Biosystems, Inc. and CRG Servicing LLC

10.64	#*	Employment Offer Letter, dated as of December 31, 2020, by and between the Company and Dr. Aparna Ahuja
10.65	#*	Change of Control Severance Agreement, dated December 31 ,2020, by and between the Company and Dr. Aparna Ahuja
21.1	*	Subsidiaries of the Registrant
23.1	*	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm
31.1	*	Certification of principal executive officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	*	Certification of principal financial officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	**	Certification of the principal executive officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350.
32.2	**	Certification of the principal financial officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350.
101.INS	*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	*	Inline XBRL Taxonomy Extension Schema Document
101.CAL	*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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* Filed herewith.

** Furnished herewith.

# Indicates management contract or compensatory plan.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, or the Securities Act.

Item 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 31, 2021.

T2 BIOSYSTEMS, INC.

By: /S/ JOHN SPERZEL
Name: John Sperzel
Title: President, Chief Executive Officer and Director (principal executive officer)

March 31, 2021

By: /S/ JOHN M. SPRAGUE
Name: John M. Sprague
Title: Chief Financial Officer (principal financial officer and principal accounting officer)

March 31, 2021

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Signature	Title	Date
/ S / JOHN SPERZEL **John Sperzel**	President, Chief Executive Officer and Director (principal executive officer)	March 31, 2021
/ S / JOHN M. SPRAGUE **John M. Sprague**	Chief Financial Officer (principal accounting officer)	March 31, 2021
/ S / JOHN MCDONOUGH **John McDonough**	Non-executive Chairman and Director	March 31, 2021
/ S / THIERRY BERNARD **Thierry Bernard**	Director	March 31, 2021
/ S / DR. NINFA M. SAUNDERS **Dr. Ninfa M. Saunders**	Director	March 31, 2021
/ S / ROBIN TOFT **Robin Toft**	Director	March 31, 2021
/ S / JOHN W. CUMMING **John W. Cumming**	Director	March 31, 2021
/ S / DAVID B. ELSBREE **David B. Elsbree**	Director	March 31, 2021
/ S / SEYMOUR LIEBMAN **Seymour Liebman**	Director	March 31, 2021

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED UNDER SECTION 12 OF THE EXCHANGE ACT

General

As of December 31, 2020, T2 Biosystems, Inc. had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). References herein to "we," "us," "our" and the "Company" refer to T2 Biosystems, Inc. and not to any of its subsidiaries.

The following description of our common stock and certain provisions of our amended and restated certificate of incorporation (our "charter") and amended and restated bylaws ("bylaws") are summaries and are qualified in their entirety by reference to the full text of our amended and restated certificate of incorporation and our amended and restated bylaws, each of which have been publicly filed with the Securities and Exchange Commission (the "SEC"). We encourage you to read our amended and restated certificate of incorporation and our amended and restated bylaws and the applicable provisions of the Delaware General Corporation Law (the "DGCL") for additional information.

Common Stock

Our board of directors is authorized to direct us to issue up to 200,000,000 shares of common stock, $0.001 par value. Holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of shareholders and do not have any cumulative voting rights. An election of directors by our stockholders is determined by a plurality of the votes cast by the stockholders entitled to vote in the election. Subject to the supermajority votes for some matters, other matters are decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our restated certificate of incorporation.

Dividend

Holders of our common stock are entitled to receive proportionately any dividends as may be declared by the board of directors, subject to any preferential dividend rights of any outstanding preferred stock that we may designate and issue in the future. The Company has not paid cash dividends on any of its shares of capital stock.

Other Rights and Preferences

Our common stock has no preemptive, subscription, redemption or conversion rights or sinking fund provisions.

Liquidation

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock.

Fully Paid and Non-Assessable

All outstanding shares of common stock are fully paid and non-assessable.

Preferred Stock

Our board of directors is authorized to direct us to issue up to 10,000,000 shares of preferred stock in one or more series without shareholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock.

Staggered Board

Our board of directors is divided into three classes. The directors in each class serve for a three year term, one class being elected each year by our stockholders. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Anti-Takeover Effects of Delaware Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. Under Section 203, we would generally be prohibited from engaging in any business combination with any interested stockholder for a period of three years following the time that this stockholder became an interested stockholder unless:

- prior to this time, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers, and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to such time, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Under Section 203, a “business combination” includes:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder, subject to limited exceptions;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

T2 BIOSYSTEMS, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM
(effective as of February 24, 2021)

Non-employee members of the board of directors (the "***Board***") of T2 Biosystems, Inc. (the "***Company***") shall be eligible to receive cash and equity compensation as set forth in this Non-Employee Director Compensation Program (this "***Program***"). The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a "***Non-Employee Director***") who may be eligible to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Program shall, as of its effective date set forth above (the "***Effective Date***"), supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors. No Non-Employee Director shall have any rights hereunder, except with respect to stock options and restricted stock units granted pursuant to the Program.

1. Annual Compensation.

(a) Annual Retainers. Each Non-Employee Director shall be eligible to receive an annual retainer of $40,000 for service on the Board (the "Annual Retainer").

(b) Additional Annual Retainers. In addition, each Non-Employee Director shall be eligible to receive the following annual retainers (each, a "Committee Member Retainer"):

(i) Chairman of the Board or Lead Independent Director. A Non-Employee Director serving as Chairman of the Board or Lead Independent Director shall receive an additional annual retainer of $40,000 for such service.

(ii) Audit Committee. A Non-Employee Director serving as Chairperson of the Audit Committee shall receive an additional annual retainer of $20,000 for such service. A Non-Employee Director serving as a member of the Audit Committee shall receive an additional annual retainer of $10,000.

(iii) Compensation Committee. A Non-Employee Director serving as Chairperson of the Compensation Committee shall receive an additional annual retainer of $15,000 for such service. A Non-Employee Director serving as a member of the Compensation Committee shall receive an additional annual retainer of $6,000.

(vi) Nominating and Corporate Governance Committee. A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of $10,000 for such service. A Non-

Employee Director serving as a member of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of $5,000.

(c)Payment of Retainers. The Annual Retainer and Committee Member Retainer shall be earned on a quarterly basis based on a calendar quarter and shall be paid by the Company in cash in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section 1(b), for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable. Any changes to the retainers set forth above shall be pro-rated based on the effective date of such change.

(d) Annual Retainer Election. For each calendar year of the Non-Employee Director's service, the Non-Employee Director will have the opportunity to elect in writing in a form provided by the Company and delivered to the Company, prior to January 1 of the applicable year, payment of the Annual Retainer in cash or an equivalent number of Restricted Stock Units (as defined in the Company's 2014 Incentive Award Plan or any other applicable Company equity incentive plan then-maintained by the Company (the "***Equity Plan***")), determined by dividing (1) the Annual Retainer by (2) the Fair Market Value (as defined in the Plan) of one share of the Company's common stock on the last trading day prior to January 1 of the year to which the Annual Retainer relates. Restricted Stock Units will be issued under, and subject to the terms of, the Equity Plan and a separate restricted stock unit agreement and will vest, subject to the Non-Employee Director's continued service, in one single installment on January 1 of the year following the year to which the Annual Retainer relates. Unless otherwise determined by the Board, unvested Restricted Stock Units will be forfeited upon the Non-Employee Director's termination of service.

2. Equity Compensation. Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Equity Plan and shall be granted subject to award agreements, including attached exhibits, in substantially the forms previously approved by the Board. All applicable terms of the Equity Plan apply to this Program as if fully set forth herein, and all grants of stock options hereby are subject in all respects to the terms of the Equity Plan. For the avoidance of doubt, the share numbers in Sections 2(a) and 2(b) shall be subject to adjustment as provided in the Equity Plan.

(a)Initial Awards. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall be eligible to receive such number of Restricted Stock Units equal to 1.5 times the number of Restricted Stock Units subject to the Subsequent Award (as defined below) most recently granted pursuant to Section 2(b) below, including any Subsequent Award made on the date of election or appointment of the Non-Employee Director receiving the award. The awards described in this Section 2(a) shall be referred to as "***Initial Awards***." No Non-Employee Director shall be granted more than one Initial Award.

(b)Subsequent Awards. A Non-Employee Director who (i) has been serving as a Non-Employee Director on the Board for at least six months as of the date of any Annual Meeting and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall be automatically granted on the date of the Annual Meeting a number of Restricted

Stock Units equal to (A) (i)$150,000 in the case of the Chairman or Lead Independent Director, and (ii) $134,000 for all other Non-Employee Directors, divided by (B) the average daily closing price per share of the Company's Common Stock on the NASDAQ Global Market (the "Average Stock Price") measured over a measurement period of 90 consecutive calendar days that ends on the date of grant, rounded down to the nearest whole share; provided, however, that the total number of shares subject to any such Subsequent Award shall not exceed 100,000 (which number shall be subject to adjustment in accordance with the Equity Plan in the event of any stock splits, dividends, recapitalizations and the like effected after the Effective Date) The awards described in this Section 2(b) shall be referred to as "***Subsequent Awards***." For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an Annual Meeting shall only receive an Initial Award in connection with such election, and shall not receive any Subsequent Award on the date of such meeting as well.

(c) Termination of Service of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their service with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section 2(a) above, but to the extent that they are otherwise eligible, will be eligible to receive, after termination from service with the Company and any parent or subsidiary of the Company, Subsequent Awards as described in Section 2(b) above.

(d) Vesting of Awards Granted to Non-Employee Directors. Each Initial Award shall vest in substantially equal installments on each of the first three anniversaries of the date of grant, subject to the Non-Employee Director continuing in service on the Board through each such vesting date. Each Subsequent Award shall vest in one installment on the earlier of (i) the first anniversary of the grant date and (ii) the date of the next annual meeting of stockholders, subject to the Non-Employee Director continuing in service on the Board through such vesting date. Unless the Board otherwise determines, any portion of an Initial Award or Subsequent Award which is unvested at the time of a Non-Employee Director's termination of service on the Board shall be immediately forfeited upon such termination of service and shall not thereafter become vested. All of a Non-Employee Director's Restricted Stock Units granted in respect of the Annual Retainer, Initial Awards and Subsequent Awards shall vest in full immediately prior to the occurrence of a Change in Control (as defined in the Equity Plan), to the extent outstanding at such time.

* * * * *

Exhibit 10.63

EXECUTION VERSION

AMENDMENT NO. 6 TO TERM LOAN AGREEMENT

THIS AMENDMENT NO. 6 TO TERM LOAN AGREEMENT, dated as of January 25, 2021 (this "***Amendment***") is made among T2 BIOSYSTEMS, INC., a Delaware corporation ("***Borrower***"), the other Obligors party hereto, CRG SERVICING LLC, as administrative agent and collateral agent (in such capacities, "***Administrative Agent***") and the lenders listed on the signature pages hereof under the heading "LENDERS" (each, a "***Lender***" and, collectively, the "***Lenders***"), with respect to the Loan Agreement described below.

RECITALS

WHEREAS, Borrower, Administrative Agent and the Lenders are parties to the Term Loan Agreement, dated as of December 30, 2016, with the Subsidiary Guarantors from time to time party thereto (as amended by Amendment No. 1 to Term Loan Agreement, dated as of March 1, 2017, among Borrower, Administrative Agent and the lenders party thereto, as further amended by Amendment No. 2 to Term Loan Agreement, dated as of December 18, 2017, among Borrower, Administrative Agent and the lenders party thereto, as further amended by Amendment No. 3 to Term Loan Agreement, dated as of March 16, 2018, as further amended by Amendment No. 4 to Term Loan Agreement, dated as of March 13, 2019, among Borrower, Administrative Agent and the lenders party thereto, and as further amended by Amendment No. 5 to Term Loan Agreement, dated as of September 10, 2019, among Borrower, Administrative Agent and the lenders party thereto, and as further amended, supplemented or modified to date, the "***Loan Agreement***"); and

WHEREAS, Borrower has requested that Administrative Agent and the Lenders (which Lenders constitute the Majority Lenders), and Administrative Agent and the Lenders (which Lenders constitute the Majority Lenders) have agreed to, amend the Minimum Required Revenue covenant in **Section 10.02(e)** of the Loan Agreement and make certain other changes as more fully set forth herein.

NOW, THEREFORE, in consideration of the mutual agreements, provisions and covenants contained herein, the parties agree as follows:

SECTION 1. Definitions; Interpretation.

(a) **Terms Defined in Loan Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement.

(b) **Interpretation**. The rules of interpretation set forth in **Section 1.03** of the Loan Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2. Amendments to Loan Agreement. Subject to **Section 3** of this Amendment, the Loan Agreement is hereby amended as follows:

[****] = = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(a) The following definition in **Section 1.01** of the Loan Agreement is hereby amended and restated in their entirety:

"***Interest-Only Period***" means the period from and including the first Borrowing Date to the Stated Maturity Date."

(b) **Section 3.01** is hereby amended and restated in its entirety as follows:

"(a) **Repayment**. During the Interest-Only Period, no scheduled payments of principal of the Loans shall be due.

(b) **Application**. To the extent not previously paid, the principal amount of the Loans, together with all other outstanding Obligations, shall be due and payable on the Maturity Date."

(c) **Section 10.02(e)** is hereby amended and restated in its entirety as follows:

"(e) during the twenty-four month period beginning on January 1, 2020, of at least $[*****]."

(d) **Annex B** of **Exhibit D** of the Loan Agreement is hereby amended and restated in its entirety by **Annex B to Compliance Certificate** attached hereto as **Exhibit A.**

SECTION 3. Conditions of Effectiveness. The effectiveness of **Section 2** of this Amendment shall be subject to the following conditions precedent:

(a) Borrower, Administrative Agent and the Lenders, which constitute the Majority Lenders, shall have duly executed and delivered this Amendment pursuant to **Section 13.04** of the Loan Agreement; *provided*, *however*, that this Amendment shall have no binding force or effect unless all conditions set forth in this **Section 3** have been satisfied;

(b) no Default or Event of Default (in each case subject to any cure period provided under the Loan Agreement) under the Loan Agreement shall have occurred and be continuing; and

(c) Borrower shall have paid or reimbursed Administrative Agent and the Lenders for their reasonable out of pocket costs and expenses (including the reasonable fees and expenses of Administrative Agent's and the Lenders' legal counsel) incurred in connection with this Amendment pursuant to **Section 13.03(a)(i)(z)** of the Loan Agreement.

SECTION 4. Representations and Warranties; Reaffirmation.

(a) Borrower hereby represents and warrants to each Lender as follows:

(i) Borrower has full power, authority and legal right to make and perform this Amendment. This Amendment is within Borrower's corporate powers and has been duly authorized by all necessary corporate action and, if required, by all necessary shareholder action. This Amendment has been duly executed and delivered by Borrower and constitutes a legal, valid and binding obligation of Borrower, enforceable against Borrower in accordance with its terms,

[****] = = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

except as such enforceability may be limited by (a) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors' rights and (b) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law). This Amendment (x) does not require any consent or approval of, registration or filing with, or any other action by, any Governmental Authority or any third party, except for such as have been obtained or made and are in full force and effect, (y) will not violate (i) the charter, bylaws or other organizational documents of Borrower and its Subsidiaries or (ii) any applicable law or regulation or any order of any Governmental Authority, other than any such violations in the case of this clause (ii) that, individually or in the aggregate, could not reasonably be expected to have a Material Adverse Effect and (z) will not violate or result in a default under any Material Agreement or agreement creating or evidencing any Material Indebtedness, or give rise to a right thereunder to require any payment to be made by any such Person.

(ii) No Default has occurred or is continuing or will result after giving effect to this Amendment.

(iii) The representations and warranties in **Section 7** of the Loan Agreement are true and correct in all material respects (taking into account any changes made to schedules updated in accordance with **Section 7.20** of the Loan Agreement) (unless qualified by materiality or Material Adverse Effect, in which case they are true in all respects (taking into account any changes made to schedules updated in accordance with **Section 7.20** of the Loan Agreement)) on and as of the date hereof, with the same force as if made on and as of the date hereof (except that the representation regarding representations and warranties that refer to a specific earlier date is that they were true and correct in all material respects (taking into account any changes made to schedules updated in accordance with **Section 7.20** of the Loan Agreement) (unless qualified by materiality or Material Adverse Effect, in which case they are true in and correct in all respects (taking into account any changes made to schedules updated in accordance with **Section 7.20** of the Loan Agreement)) on such earlier date).

(iv) There has been no Material Adverse Effect since the date of the Loan Agreement.

(b) Each Obligor hereby ratifies, confirms, reaffirms, and acknowledges its obligations under the Loan Documents to which it is a party and agrees that the Loan Documents remain in full force and effect, undiminished by this Amendment, except as expressly provided herein. By executing this Amendment, Borrower acknowledges that it has read, consulted with its attorneys regarding, and understands, this Amendment.

SECTION 5. Release. In consideration of the agreements of Administrative Agent and the Lenders contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Borrower, on behalf of itself and its successors, assigns and other legal representatives, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Administrative Agent and each Lender, and their respective successors and assigns, and their respective present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Administrative Agent, each Lender and all such other persons being hereinafter

[****] = = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

referred to collectively as the "***Releasees***" and individually as a "***Releasee***"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower or any of its successors, assigns or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment, including, without limitation, for or on account of, or in relation to, or in any way in connection with the Loan Agreement or any of the other Loan Documents or transactions thereunder or related thereto (collectively, the "***Released Claims***"). Borrower understands, acknowledges and agrees that the release set forth above (the "***Release***") may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of the Release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the Release. Borrower acknowledges that the Release constitutes a material inducement to Administrative Agent and the Lenders to enter into this Amendment and that Administrative Agent and the Lenders would not have done so but for Administrative Agent's and each Lender's expectation that the Release is valid and enforceable in all events.

SECTION 6. Governing Law; Submission to Jurisdiction; WAIVER OF JURY TRIAL.

(a) **Governing Law**. This Amendment and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction; *provided that* Section 5-1401 of the New York General Obligations Law shall apply.

(b) **Submission to Jurisdiction**. Borrower agrees that any suit, action or proceeding with respect to this Amendment or any judgment entered by any court in respect thereof may be brought initially in the federal or state courts in Houston, Texas or in the courts of its own corporate domicile and irrevocably submits to the non-exclusive jurisdiction of each such court for the purpose of any such suit, action, proceeding or judgment. This **Section 6** is for the benefit of Administrative Agent and the Lenders only and, as a result, none of Administrative Agent or any Lender shall be prevented from taking proceedings in any other courts with jurisdiction. To the extent allowed by applicable Laws, Administrative Agent and the Lenders may take concurrent proceedings in any number of jurisdictions.

(c) **WAIVER OF JURY TRIAL**. BORROWER, ADMINISTRATIVE AGENT AND EACH LENDER HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AMENDMENT.

SECTION 7. Miscellaneous.

[****] = = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(a) **No Waiver**. Except as expressly stated herein, nothing contained herein shall be deemed to constitute a waiver of compliance with any term or condition contained in the Loan Agreement or any of the other Loan Documents or constitute a course of conduct or dealing among the parties. Except as expressly stated herein, Administrative Agent and the Lenders reserve all rights, privileges and remedies under the Loan Documents. Except as amended hereby, the Loan Agreement and other Loan Documents remain unmodified and in full force and effect. All references in the Loan Documents to the Loan Agreement shall be deemed to be references to the Loan Agreement as amended hereby.

(b) **Severability**. In case any provision of or obligation under this Amendment shall be invalid, illegal or unenforceable in any jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

(c) **Headings**. Headings and captions used in this Amendment (including the Exhibits, Schedules and Annexes hereto, if any) are included for convenience of reference only and shall not be given any substantive effect.

(d) **Integration**. This Amendment constitutes a Loan Document and, together with the other Loan Documents, incorporates all negotiations of the parties hereto with respect to the subject matter hereof and is the final expression and agreement of the parties hereto with respect to the subject matter hereof.

(e) **Counterparts**. This Amendment may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Amendment by signing any such counterpart. Executed counterparts delivered by facsimile or other electronic transmission (e.g., "PDF" or "TIF") shall be effective as delivery of a manually executed counterpart.

(f) **Controlling Provisions**. In the event of any inconsistencies between the provisions of this Amendment and the provisions of any other Loan Document, the provisions of this Amendment shall govern and prevail. Except as expressly modified by this Amendment, the Loan Documents shall not be modified and shall remain in full force and effect.

[Remainder of page intentionally left blank]

[****] = = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment as of the date first above written.

BORROWER:

T2 BIOSYSTEMS, INC.

By: /s/ John Sprague
Name: John Sprague
Title: CFO

[Signature Page to Amendment No. 6 to Term Loan Agreement]

ADMINISTRATIVE AGENT:

CRG SERVICING LLC

By /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

LENDERS:

CRG PARTNERS III L.P.
By CRG PARTNERS III GP L.P., its General Partner
By CRG PARTNERS III GP LLC, its General Partner

By /s/ Nathan Hukill

Name: Nathan Hukill
Title: Authorized Signatory

CRG PARTNERS III – PARALLEL FUND "A" L.P.
By CRG PARTNERS III – PARALLEL FUND "A" GP L.P., its General Partner
By CRG PARTNERS III – PARALLEL FUND "A" GP LLC, its General Partner

By /s/ Nathan Hukill

Name: Nathan Hukill
Title: Authorized Signatory

CRG PARTNERS III (CAYMAN) UNLEV AIV I L.P.

By CRG PARTNERS III (CAYMAN) GP L.P., its General Partner
By CRG PARTNERS III (CAYMAN) GP LLC, its General Partner

By /s/ Nathan Hukill

Name: Nathan Hukill
Title: Authorized Signatory

Witness: /s/ Nicole Nesson
Name: Nicole Nesson

CRG PARTNERS III (CAYMAN) LEV AIV L.P.
By CRG PARTNERS III (CAYMAN) GP L.P., its General Partner
By CRG PARTNERS III (CAYMAN) GP LLC, its General Partner

By /s/ Nathan Hukill

Name: Nathan Hukill
Title: Authorized Signatory

Witness: /s/ Nicole Nesson
Name: Nicole Nesson

CRG PARTNERS III PARALLEL FUND "B" (CAYMAN) L.P.
By CRG PARTNERS III (CAYMAN) GP L.P., its General Partner
By CRG PARTNERS III (CAYMAN) GP LLC, its General Partner

By /s/ Nathan Hukill

Name: Nathan Hukill
Title: Authorized Signatory

Witness: /s/ Nicole Nesson
Name: Nicole Nesson

EXHIBIT A

Annex B to Compliance Certificate

CALCULATIONS OF FINANCIAL COVENANT COMPLIANCE

	Section 10.01: Minimum Liquidity	
	Amount of unencumbered (other than Liens securing the Obligations and Liens permitted pursuant to **Section 9.02(c)** and **Section 9.02(j)**); *provided* that with respect to case subject to a Lien in connection with Permitted Priority Debt, there is no default under the documentation governing the Permitted Priority Debt) cash and Permitted Cash Equivalent Investments (which for greater certainty shall not include any undrawn credit lines), in each case, to the extent held in an account over which the Lenders have a perfected security interest:	$_____
	The greater of:	$_____
	$5,000,000 and	
	to the extent Borrower has incurred Permitted Priority Debt, the minimum cash balance required of Borrower by Borrower's Permitted Priority Debt creditors	
	Is Line IA equal to or greater than Line IB?:	*Yes: In compliance; No: Not in compliance*
	Section 10.02(a)-(e): Minimum Revenue—Subsequent Periods	
	Revenues during the twelve month period beginning on January 1, 2017	$_____
	[Is line II.A equal to or greater than $[*****]*?*	*Yes: In compliance; No: Not in compliance]*[1]
	Revenues during the twelve month period beginning on January 1, 2019	$_____
	[Is line II.C equal to or greater than $[*****]*?*	*Yes: In compliance; No: Not in compliance]*[2]
	Revenues during the twenty-four month period beginning on January 1, 2019	$_____
	[Is line II.D equal to or greater than $[*****]*?*	*Yes: In compliance; No: Not in compliance]*[3]
	Revenues during the twenty-four month period beginning on January 1, 2020	$_____
	[Is line II.E equal to or greater than $[*****]*?*	*Yes: In compliance; No: Not in compliance]*[4]

1 Include bracketed entry only on the Compliance Certificate to be delivered within 90 days of the end of 2017 pursuant to Section 8.01(b) of the Loan Agreement.

2 Include bracketed entry only on the Compliance Certificate to be delivered within 90 days of the end of 2019 pursuant to Section 8.01(b) of the Loan Agreement.

3 Include bracketed entry only on the Compliance Certificate to be delivered within 90 days of the end of 2020 pursuant to Section 8.01(b) of the Loan Agreement.

4 Include bracketed entry only on the Compliance Certificate to be delivered within 90 days of the end of 2021 pursuant to Section 8.01(b) of the Loan Agreement.

[****] = = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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Exhibit 10.64

December 31, 2020

Aparna Jha Ahuja, M.D.
****
****

Dear Aparna:

On behalf of T2 Biosystems, Inc., (the "Company") I am delighted to make this offer of employment to you to join us in the role of Chief Medical Officer for the Company beginning on January 5, 2021.

At T2 Biosystems, a leader in the detection of sepsis causing pathogens, our mission is to save lives and improve healthcare by empowering clinicians to get patients on the right therapy faster than ever. We have developed game-changing detection technology, T2 Magnetic Resonance (T2MR®), that enables the rapid detection of clinically relevant targets and helps clinicians to optimize outcomes for their patients. We come to work every day to solve critical and unmet needs in healthcare diagnostics that make a significant impact on patient care.

We are positively impacting the lives of patients and saving hospitals millions of dollars each year. Our products are being used in more than 180 hospitals around the world. We have a strong pipeline of products in development, including a next-generation, high-throughput instrument to further round out our sepsis portfolio, as well as products for the detection of viruses such as SARS-CoV-2 which is responsible for COVID-19 infections, in addition to a panel for the detection of biothreat pathogens. There is a lot of growth ahead and you are joining us at a very exciting time!

Aparna, we are thrilled to extend this offer of employment to you. We think you can help us fulfill our mission and we believe you'd be a great fit for our team. To kick things off, you will find all of the pertinent information related to our offer of employment in the attached pages. Please read the offer carefully and, if it is acceptable, sign and return one copy to my attention (PDF copy is fine).

If you have any questions, please do not hesitate to contact me at (781) 457-1283 or email at kmorgan@t2biosystems.com. We are looking forward to having you on our team!

Sincerely,

/s/ Kelley Morgan

Kelley Morgan
Chief People Officer

OFFER OF EMPLOYMENT

Date of employment: Should you accept the terms of this offer, your employment with the Company will commence on January 11, 2021 (the "Start Date").

Background check: Your employment is contingent upon your successful completion of a background check, which is required for all employees of the Company. The Company will forward you the appropriate documents, and such documents shall be required to be submitted to the Company by no later than one week prior to the Start Date.

Position: You have been offered the position of Chief Medical Officer. In this capacity, you will report to John Sperzel, Chief Executive Officer. Your duties and responsibilities will include all those customarily attendant to such a position, and any other such duties or responsibilities that John Sperzel or the Company may, from time to time, assign to you. You agree that you shall not enter into any employment endeavors which may conflict with your ability to devote the necessary time and energies to the Company's business interest while engaged by the Company. You further agree to comply with all applicable laws and with all Company rules and policies established by the Company from time to time.

Compensation and Tax Matters: Your salary shall be $16,041.67 (the equivalent of $385,000 when annualized), payable semi-monthly and subject to pro-ration for any partial initial or terminal week during which you are employed, in accordance with normal payroll practices and schedule of the Company.

You will be eligible to receive an annual bonus (the "Annual Bonus") based upon the achievement of specific company and individual milestones as determined by the Board of Directors (the "Board"). The target amount of your Annual Bonus will be 60% of your Base Salary, subject to adjustment by the Board. Payment of the Annual Bonus will be subject to your continued employment with the Company through the date of payment.

You will also be eligible to receive a sign-on bonus (the "Sign-On Bonus") of $20,000.00, contingent upon your employment with the Company commencing on January 11, 2021. The Sign-On Bonus will be paid to you within the first thirty (30) days of your employment.

All compensation amounts stated are before any deductions for FICA taxes, state and federal withholding taxes and other payroll deductions required to be made by the Company under applicable law.

Restricted Stock: Subject to your execution of the enclosed Non Competition/Non-Disclosure/Invention Assignment Agreement and the execution of a Restricted Stock Award Agreement, you will receive an equity grant equal to the value of $650,000.00 in the form of restricted shares ("RSUs") of T2 Biosystems common stock under the Company's Inducement Award Plan (the "Inducement Plan"). The actual number of RSUs awarded will be based on the closing price on your Start Date. The RSUs will have a 3-year vesting schedule with 1/3 of the shares vesting annually in equal installments on the anniversary of the Start Date. The terms and conditions of the restricted stock award will be more fully described in the Company's Inducement Plan document and the applicable Restricted Stock Award Agreement.

Severance Compensation: Also subject to your execution of the enclosed Non Competition/Non-Disclosure/Invention Assignment Agreement and Change of Control Severance Agreement (the "Change in Control Agreement"), you will receive certain benefits in the event of a change in control of the Company, as set forth in more detail and defined in the Change in Control Agreement, including severance

compensation and the acceleration of certain equity awards, each such benefit to be subject to the terms of the Change in Control Agreement.

Fringe Benefits: You will have the opportunity to participate in the Company's fringe benefits program. Currently, these fringe benefits are as follows:

- The Company currently provides contributions toward a medical and dental plan for yourself and immediate family members
- Three (3) weeks paid vacation, Company designated holidays, personal holidays and sick days (see Benefits Summary for more information).
- The Company provides 100% contribution towards Term Life Insurance, Accidental Death and Dismemberment Insurance, and Short and Long-Term Disability Insurance;
- The opportunity to enroll in the Company's 401(k) Investment and Section 125 Plans based on plan eligibility requirements; and
- Pay or reimburse you in accordance with the Company's reimbursement policies from time to time in connection with the performance of your duties for the Company subject to your submission of satisfactory documentation with respect thereto.

The Company reserves the right to amend, delete or change any of its employment policies and/or benefits at any time in its sole discretion.

Non-Competition/Non-Disclosure/Invention Assignment Agreement: No later than on the first day of your employment with the Company you will be required to sign the enclosed Non-Competition/Non-Disclosure/Inventions Assignment Agreement ("Obligations Agreement") which includes non-competition, nondisclosure, inventions ownership, and other provisions that are necessary to protect the Company's confidential information, intellectual; property, trade secrets, and customer relationships. As you may be given access to such protectable interests, your employment is contingent upon your signing the Obligations Agreement. The terms of the Obligations Agreement will survive termination, for whatever reason, of the employment relationship.

Prior Agreements: You acknowledge and confirm that you have provided/disclosed to the Company all restrictive covenants and agreements, including nondisclosure and confidentiality agreements, to which you are a party. You agree that you shall not disclose to the Company or use while an employee of the Company any confidential or trade secret information obtained by you from other persons or employers and shall not bring any property upon the Company premises which has been misappropriated by others. You also acknowledge that the Company expects you to honor any prior obligations to former employers to which you remain bound.

Employment At Will: Although you are being hired as an employee commencing on January 11, 2021, your employment with the Company shall be at will. This means that your employment is not guaranteed for any definite period of time, and you or the Company may terminate your employment relationship with or without notice at any time and for any or no reason or cause. The Company is not bound to follow any policy, procedure, or process in connection with employee discipline, employment termination or otherwise.

Entire Agreement: This letter (together with the attached Obligations Agreement and Change in Control

Agreement) sets forth the entire understanding between the Company and yourself with respect to your employment by the Company. All prior discussions, negotiations, correspondence and other understandings between you and the Company are superseded, and there are no representations, warranties or undertakings by the Company or you with respect to your employment by the Company, which are not set forth in this letter.

If you agree with the terms of this offer, please acknowledge your understanding and acceptance of this offer by signing where indicated below and return to me by 5:00pm ET on January 2, 2021. We look forward to working with you.

Sincerely,

T2 Biosystems, Inc.

By: /s/ Kelley Morgan 12/31/2020
Kelley Morgan Date
Chief People Officer

I have read agree with and accept the items contained in this letter.

By: /s/ Aparna Ahuja 1/04/2021
Aparna Jha Ahuja, M.D. Date

The Immigration Control and Reform Act of 1986 requires that all new employees complete the I-9 form and submit proof of employment eligibility to work in the United States within the first three days of their start date. If accepting employment the Company will provide you the I-9 form and requests that you present appropriate documents when you report to the Company and a representative of the Company will complete the I-9 form with you. Accordingly, you will have three days from your start date to submit proof of your eligibility to work in the United States.

Active: 2020

Exhibit 10.65

December 31, 2020

Aparna Jha Ahuja, M.D.
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Dear Aparna,

This letter sets forth the agreement between you and T2 Biosystems, Inc. (the "Company") regarding certain terms and conditions of your employment. You are entitled to receive the following:

1. Severance Compensation. If your employment is terminated either by you with Good Reason within 12 months following a Change of Control, or by the Company without Cause within 3 months preceding or within 12 months following a Change of Control, subject to your executing and delivering to the Company, and not revoking, a release of claims in a form acceptable to the Company (the "Release") within the 30-day period following your termination of employment:

(a) the Company will pay you severance in an amount equal to 12 months of your then current annual base salary, payable in equal installments over a period of 12 months (the "Severance Period") in accordance with the Company's payroll practices, commencing on your termination of employment;

(b) if you have been continuously employed by the Company for at least one year as of the date your employment terminates, all of the outstanding unvested equity awards of the Company held by you shall become fully vested and, if applicable, exercisable as of the date of your termination, provided that with respect to any such awards intended to constitute "qualified performance based compensation" under Section 162(m) of the Code, whether a Change of Control has occurred shall be determined without regard to clause (iv) of the definition of Change of Control below; and

(c) If you timely elect continued group medical insurance coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company will reimburse you for a portion of the applicable premiums, based on the then-current cost-sharing rates for active employees, for you and your eligible dependents during the period commencing on the date of your termination of employment and ending on the earliest to occur of (a) the final day of the Severance Period, (b) the date you and/or your eligible dependents are no longer eligible for COBRA, and (c) the date you become eligible to receive medical insurance coverage from a subsequent employer (and you agree to notify the Company of such eligibility). Notwithstanding the foregoing, if the Company determines that it cannot provide such reimbursement of premiums to you without potentially violating applicable law, the Company shall in lieu thereof provide to you a taxable monthly payment in an amount equal to a portion of the applicable premiums, based on then-current cost-sharing rates for active employees, which payment will be made regardless of whether you elect COBRA continuation coverage and will commence in the month following the month in which your termination of employment occurs and end on the earliest to occur of (x) the final day of the Severance Period, (y) the date you and/or your eligible dependents are no longer

eligible for COBRA, and (z) the date you become eligible to receive medical insurance coverage from a subsequent employer (and you agree to notify the Company of such eligibility).

Notwithstanding anything herein to the contrary, in the event that any compensation or benefit that constitutes "nonqualified deferred compensation" within the meaning of Section 409A (as defined below) becomes payable upon the occurrence of a Change of Control, such compensation or benefit shall not be paid unless such Change of Control constitutes a "change in control event" within the meaning of Section 409A.

2. Definitions. For purposes of this letter, the terms "Change of Control," "Cause," and "Good Reason" shall have the following meanings.

(a) "Change of Control" means that any of the following events has occurred:

(i) Any person (as such term is used in Section 13(d) of the Securities Exchange Act of 1934 (the "Exchange Act")), other than the Company, any employee benefit plan of the Company, or any entity organized, appointed, or established by the Company for or pursuant to the terms of any such plan, together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Exchange Act) becomes the beneficial owner or owners (as defined in Rule 13d-3 and 13d-5 promulgated under the Exchange Act), directly or indirectly (the "Control Group"), of more than 50% of the outstanding equity securities of the Company, or otherwise becomes entitled, directly or indirectly, to vote more than 50% of the voting power entitled to be cast at elections for directors ("Voting Power") of the Company, provided that a Change of Control will not have occurred if such Control Group acquired securities or Voting Power solely by purchasing securities from the Company, including, without limitation, acquisition of securities by one or more third party investors;

(ii) A consolidation or merger (in one transaction or a series of related transactions) of the Company pursuant to which the holders of the Company's equity securities immediately prior to such transaction or series of related transactions cease to be the holders, directly or indirectly, immediately after such transaction or series of related transactions of more than 50% of the Voting Power of the entity surviving such transaction or series of related transactions;

(iii) The sale, lease, exchange, or other transfer (in one transaction or series of related transactions) of all or substantially all of the assets of the Company; or

(iv) The liquidation or dissolution of the Company or the Company ceasing to do business.

(b) "Cause" means:

(i) Your conviction of a felony, either in connection with the performance of your obligations to the Company or which otherwise materially and adversely affects your ability to perform such obligations;

(ii) Your willful disloyalty to the Company or deliberate material dishonesty to the Company;

(iii) The commission by you of an act of fraud or embezzlement against the Company;

(iv) Your willful, substantial failure to perform any of your duties hereunder or your deliberate failure to follow reasonable, lawful directions of the Company's Board of Directors or your direct supervisor, which failure, if capable of being cured, is not cured within 30 days after delivery to you by the Company of written notice of such failure; or

(v) A material breach by you of any material provision of this letter which breach is not cured within 30 days after delivery to you by the Company of written notice of such breach.

(c) "Good Reason" means one or more of the following:

(i) A material change in the principal location at which you provide services to the Company, without your prior written consent;

(ii) A material and continuing diminution by the Company in the duties, authority or responsibilities of your position which causes such position to become of less responsibility or authority than immediately prior to such material and continuing diminution, provided that such change is not in connection with a termination of your employment hereunder by the Company;

(iii) A material reduction in your base salary or other benefits except if such a reduction is in connection with a general reduction in compensation or other benefits of all similarly situated employees of the Company;

(iv) Failure by the Company to obtain the assumption of this Agreement by any successor to the Company.

Notwithstanding the foregoing, Good Reason shall only exist if you have given written notice to the Company within 90 days of the initial existence of the Good Reason condition(s), and the Company has failed to cure such event(s) within 30 days of its receipt of said notice.

3. Section 409A.

(a) *Separation from Service*. Notwithstanding anything in this letter to the contrary, any compensation or benefit payable under this letter that is designated as payable upon your termination of employment shall be payable only upon your "separation from service" with the Company (a "Separation from Service") within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder (collectively, "Section 409A"), and except as provided below, any such compensation or benefits shall not be paid, or, in the case of installments, shall not commence payment, until the 30th day following your Separation from Service. Any installment payments that would have been made to you during the 30 day period immediately following your Separation from Service but for the preceding sentence shall be paid to you on the 30th day following your Separation from Service and the remaining payments shall be made as provided in this letter.

(b) *Specified Employee*. Notwithstanding anything in this letter to the contrary, if you are deemed by the Company at the time of your Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which you are entitled under this letter is required in order to avoid a prohibited distribution under Section 409A,

such portion of your benefits shall not be provided to you prior to the earlier of (i) the expiration of the six-month period measured from the date of your Separation from Service with the Company or (ii) the date of your death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump-sum to you (or your estate or beneficiaries), and any remaining payments due to you under this letter shall be paid as otherwise provided herein.

(c) *Installments*. Your right to receive any installment payments under this letter shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

4. General

(a) No provision of this letter shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by you and by an authorized officer of the Company (other than you). No waiver by either party of any breach of, or of compliance with, any condition or provision of this letter by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time. The validity, interpretation, construction and performance of this letter shall be governed by the laws of the Commonwealth of Massachusetts without regard to conflicts of law. The invalidity or unenforceability of any provision or provisions of this letter shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect. This letter may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

(b) This letter contains the entire and exclusive agreement between the parties with respect to the subject matter hereof and is intended to supersede and replace all previous agreements, negotiations, and representations between the parties, whether written or oral, including any provision of the employment offer letter agreement between you and the Company, dated as of December 18, 2020, to the extent such letter addresses the subject matter hereof.

Sincerely,

T2 BIOSYSTEMS, INC.

By:/s/ Michael Gibbs
Name:Michael Gibbs
Title: General Counsel

Acknowledged and Agreed

/s/ Aparna Ahuja
Aparna Jha Ahuja, M.D.

Exhibit 21.1

Subsidiaries of T2 Biosystems, Inc.:

Name	Jurisdiction of Organization
T2 Biosystems Securities Corporation	Massachusetts

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

T2 Biosystems, Inc.
Lexington, Massachusetts

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-206707, No. 333-216833, No. 333-225275, and No. 333-227847) and Form S-8 (No. 333-197946, No. 333-227850, and No. 333-238727) of T2 Biosystems, Inc. of our report dated March 31, 2021, relating to the consolidated financial statements, which appear in this Annual Report on Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/BDO USA, LLP

Boston, Massachusetts

March 31, 2021

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John Sperzel, certify that:

1. I have reviewed this Annual Report on Form 10-K of T2 Biosystems, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

DDate: March 31, 2021

By: /s/ John Sperzel
John Sperzel
President, Chief Executive Officer and Director

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John Sprague, certify that:

1. I have reviewed this Annual Report on Form 10-K of T2 Biosystems, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2021

By: /s/ John M. Sprague
John M. Sprague
Principal Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of T2 Biosystems, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2020 (the "Report"), as filed with the Securities and Exchange Commission on or about the date hereof, I, John Sperzel, President, Chief Executive Officer and Director of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(i) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2021

By: /s/ John Sperzel
John Sperzel
President, Chief Executive Officer and Director

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of T2 Biosystems, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of T2 Biosystems, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2020 (the "Report"), as filed with the Securities and Exchange Commission on or about the date hereof, I, John M. Sprague, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(i) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2021

By: /s/ John M. Sprague
John M. Sprague
Principal Financial Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of T2 Biosystems, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.