T2 Biosystems, Inc.
Form 10-K
March 04, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the year ended December 31, 2014

o 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: **781-457-1200**

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

Title of Each Class:	**Name of Each Exchange on which Registered:**
Common Stock, par value $0.001 per share	**The NASDAQ Stock Market LLC**
	(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 o NO x

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 o NO x

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 x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

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

Large accelerated filer o Accelerated filer o Non-accelerated filer x Smaller reporting company o

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

As of June 30, 2014, the last business day of the registrant s most recently completed second fiscal quarter, the registrant s common stock was not listed for trading on any exchange or over-the-counter market and there was no established public market for the common stock. The common stock began trading on The NASDAQ Global Market on August 7, 2014. As of December 31, 2014, the aggregate market value of the registrant s common stock held by non-affiliates was approximately $170.7 million based on the closing price for the common stock of $19.24 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.

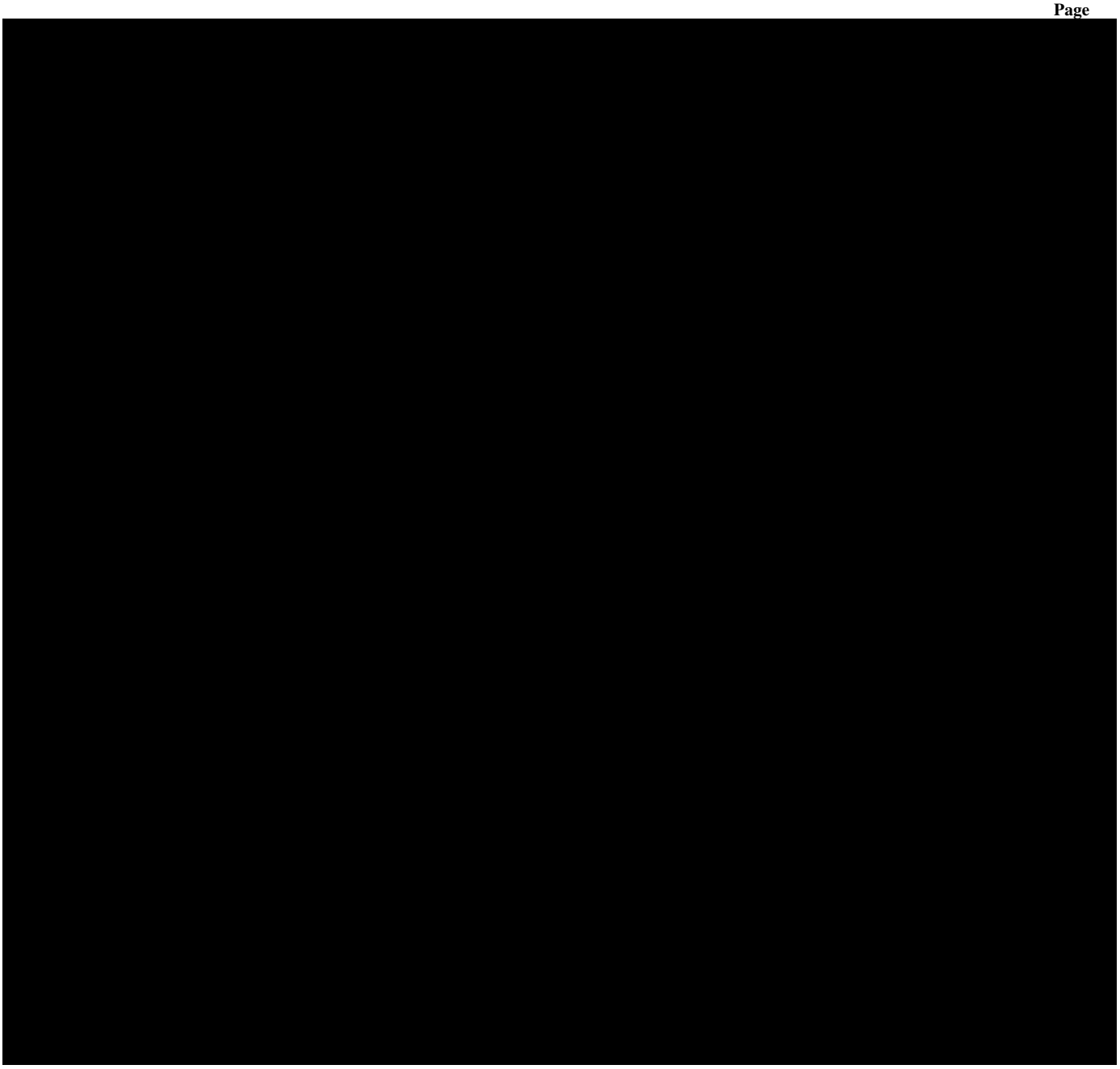
The number of outstanding shares of the registrant s common stock on March 2, 2015 was 20,125,635. The common stock is listed on the NASDAQ Global Market (trading symbol TTOO).

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year are incorporated by reference into Part III of this report.

TABLE OF CONTENTS

Page



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 authorization from the U.S. Food and Drug Administration, or 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, 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 . These forward looking statements are subject to numerous risks, including, without limitation, the following:

- *our expectation to incur losses in the future;*
- *our ability to obtain marketing authorization from the FDA or regulatory clearance for new product candidates in the United States or any other jurisdiction;*
- *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 of our anticipated sales cycle;*
- *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 future capital needs and our need to raise additional funds;*

- *the performance of our diagnostics;*

- *our ability to successfully manage our growth;*

- *our ability to compete in the highly competitive diagnostics market;*

- *our ability to protect and enforce our intellectual property rights, including our trade secret-protected proprietary rights in T2MR; and*

- *federal, state, and foreign regulatory requirements, including FDA regulation of our product candidates.*

These forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report on Form 10-K. 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. The following discussion should be read in conjunction with the financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors.

You should read the following discussion and analysis of our financial condition and results of operations together with our 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.

PART I.

Item 1. BUSINESS

Overview

We are 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. We are using our T2 Magnetic Resonance platform, or 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 and urine, and can detect cellular targets at limits of detection as low as one colony forming unit per milliliter, or CFU/mL. Our initial development efforts utilizing T2MR target sepsis, hemostasis, and Lyme disease, which are areas of significant unmet medical need in which existing therapies could be more effective with improved diagnostics.

On September 22, 2014, we received market authorization from the U.S. Food and Drug Administration, or the FDA, for our first two products, the T2Dx Instrument and the T2Candida Panel, which have the ability to rapidly identify the five clinically relevant species of *Candida*, a fungal pathogen known to cause sepsis. We began the process to commercialize these products in the fourth quarter of 2014 and anticipate our first sales in 2015.

Our next three diagnostic applications are called T2Bacteria, T2HemoStat, and T2Lyme, which are focused on bacterial sepsis infections, hemostasis, and Lyme disease, respectively. We plan to initiate clinical trials in the second half of 2015 for T2Bacteria and in 2016 for T2HemoStat. We expect that existing reimbursement codes will support our sepsis, hemostasis and Lyme disease product candidates, and that the anticipated economic savings associated with our sepsis products will be realized directly by hospitals.

Sepsis is one of the leading causes of death in the United States and 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%. According to data published by the U.S. Department of Health and Human Services for 2011, the cost of sepsis is over $20 billion in the United States, or approximately 5% of the total aggregate costs associated with domestic hospital stays. 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. This method has substantial diagnostic limitations that lead to a delay of up to several days in administration of targeted treatment and the incurrence of unnecessary hospital expense. Without the ability to rapidly identify pathogens, physicians typically start treatment of at-risk patients with broad-spectrum antibiotics, which can be ineffective and unnecessary and have contributed to the spread of antimicrobial resistance. 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%.

We believe our sepsis products will redefine the standard of care in sepsis management while lowering healthcare costs by improving both the precision and the speed of 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, leading to the conclusion that more-rapid identification of the causative organism would be highly desirable to facilitate targeted treatment in the critical phase of septic illness. In another study published in *Clinical Infectious Diseases* in 2012, the delayed administration of appropriate anti-fungal therapy was associated with higher mortality among patients with septic shock attributed to *Candida* infection and, on that basis, the study stated that more rapid and accurate diagnostic techniques appear to be needed. Our pivotal clinical trial demonstrated that T2Candida can deliver actionable results as fast as three hours, with an average time to result during the trial of 4.2 hours, rather than the two to five or more days typically required for blood-culture-based diagnostics, which we believe will enable physicians to make treatment decisions and administer targeted treatment to patients on an accelerated basis. We believe that T2Bacteria will also deliver actionable results within these timeframes because this diagnostic panel is designed to run on the same instrument as T2Candida.

Candida has an average mortality rate of approximately 40%, and according to a study published in *Antimicrobial Agents and Chemotherapy* in 2010, this mortality rate can be reduced to 11% with the initiation of targeted therapy within 12 hours of presentation of symptoms. 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 average cost of care by approximately $30,000 per patient. We expect the anticipated economic savings associated with our sepsis products will be realized directly by hospitals, as the diagnosis and treatment of sepsis patients in the United States in a hospital inpatient setting is currently reimbursed on an inpatient basis under existing diagnosis-related group, or DRG, codes. These codes provide hospitals with a fixed-sum reimbursement for all items and services provided to the patient during a single hospitalization. Therefore, we do not believe we will need to seek new reimbursement codes for our sepsis products.

Another significant unmet clinical need that we believe can be addressed by T2MR is the timely diagnosis and management of impaired hemostasis, which is a potentially life-threatening condition in which a patient is unable to promote the formation of blood clots to stabilize excessive bleeding. For critical trauma patients with impaired hemostasis, diagnostic results are typically required in fewer than 45 minutes to aid clinicians in making the most effective treatment decisions. The need for rapid diagnosis is not met by current diagnostic methods, which typically involve multiple instruments and can take hours to process a patient specimen. As a result, physicians often make critical decisions for treatment of impaired hemostasis with limited or no diagnostic data.

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. Because of these limitations, patients are frequently misdiagnosed or are delayed in the diagnosis of this disease.

We believe our combined initial annual addressable market opportunity for sepsis, hemostasis, and Lyme disease is over $3.7 billion in the United States alone, when the market opportunity for T2Candida, T2Bacteria, T2Lyme and our initial hemostasis diagnostic panel is combined. Within the sepsis market in the United States, we estimate that there are approximately 6.75 million critical care and immunocompromised patients who present with symptoms and are at high risk for a bloodstream infection who would be appropriate to be tested by our T2Candida Panel. These patients, along with approximately two million additional patients who receive treatment in the emergency room setting, are also highly susceptible to bacterial infections, for a total of approximately 8.75 million patients who would be appropriate to be tested by our T2Bacteria Panel. Within the hemostasis market, for trauma alone, there are over ten million patients in the United States annually who present with symptoms of impaired hemostasis. These patients often require rapid and frequent hemostasis assessments to determine the presence and severity of abnormal coagulation, or blood clotting. Within the Lyme disease market in the United States, the CDC estimates that the number of patients who present with symptoms is approximately 360,000 and that there are approximately 3.4 million tests run each year in an effort to diagnose Lyme disease, each of whom we believe may be appropriate to be tested with our T2Lyme panel.

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:

- ***Drive Commercial Adoption of Our Sepsis Products by Demonstrating Their Value to Physicians, Laboratory Directors and Hospitals***. We expect our sepsis products to meaningfully improve patient outcomes while reducing costs to hospitals. We have established a targeted, direct sales force in the United States, which is initially focused on educating physicians and demonstrating 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 T2Dx, T2Candida 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.

- ***Establish a Recurring, Consumables-Based Business Model.*** We are pursuing a consumables-based business model for our products by securing placements of our T2Dx instrument at hospitals and driving utilization of our diagnostic panels starting with T2Candida. We believe this strategy will foster a sustainable and predictable business model with recurring revenue streams.

- ***Broaden Our Addressable Markets in Infectious Disease and Hemostasis.*** Our product development pipeline includes additional instruments and diagnostic panels that provide near-term and complementary market expansion opportunities. Our next sepsis product candidate will focus on bacterial infections, will run on T2Dx and is expected to address the same high-risk patients as T2Candida, while also expanding our reach to a new patient population at increased risk for bacterial sepsis infections. We also are utilizing T2MR to address the challenges of providing rapid hemostasis monitoring, along with rapid and sensitive diagnosis of Lyme disease. We expect to initiate pivotal clinical trials for our bacterial diagnostic panel, T2Bacteria in 2015 and our hemostasis instrument and diagnostic panel, T2Stat and T2HemoStat, in 2016, respectively. We are targeting to commercialize these product candidates after obtaining marketing authorization or regulatory clearance.

- ***Broaden Our Addressable Markets Beyond Infectious Disease and Hemostasis.*** We intend to expand our product offerings by applying T2MR to new applications beyond sepsis, hemostasis and Lyme disease. We plan to conduct internal development and 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, will have potential applications within and outside of the *in vitro* diagnostics market, including environmental, food safety, industrial and veterinary applications. For example, we have recently entered into a joint collaboration with Canon U.S. Life Sciences to develop a novel test panel to rapidly detect Lyme disease. The test panel will be developed using our T2MR technology applied for the direct detection of bacteria associated with Lyme disease.

- ***Drive International Expansion.*** We plan to commercialize our current products and product candidates in European and other international markets, and we have initiated a clinical study in Europe for the T2Candida Panel and T2Dx Instrument. We are in the process of developing distribution and commercialization strategies for these markets, and we have recently received CE marking for our T2Candida Panel and T2Dx Instrument.

Our Technology Platform

T2 Magnetic Resonance Platform 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, such as proteins; and

- a broad range of hemostasis measurements.

For molecular and immunodiagnostics targets, T2MR utilizes advances in the field of nanotechnology 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.

For hemostasis measurements, particles are not required because T2MR is highly sensitive to changes in viscosity in a blood sample, such as clot formation, stabilization or dissipation, which changes the T2 relaxation signal. This enables the rapid identification of clinically relevant hemostasis changes.

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. Over 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 the potential applications for T2MR extend 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 authorization for the T2Dx, a bench-top instrument for sepsis, Lyme disease, and other applications, and we are developing T2Stat, a compact, fully integrated instrument for hemostasis applications.

T2Dx

T2Dx 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 work flow steps such as pipetting that can introduce risks of cross-contamination. To perform a diagnostic test, the patient sample tube is snapped onto our disposable test cartridge, which is pre-loaded with all necessary reagents. The cartridge is then inserted into T2Dx, which automatically processes the sample and then delivers a diagnostic test result.

The initial panels designed to run on T2Dx are T2Candida and T2Bacteria, which are focused on identifying life-threatening pathogens associated with sepsis. In 2014 we received FDA marketing authorization for T2Dx and T2Candida, and expect to initiate pivotal clinical trials for T2Bacteria in the second half of 2015. T2Lyme, which is in development, will also run on T2Dx.

T2Stat

We are also applying T2MR to develop T2Stat, which we believe will be the first compact, fully integrated instrument capable of rapidly providing comprehensive hemostasis measurements. T2Stat will run our T2HemoStat panel, which includes a broad set of hemostasis measurements, including platelet function, clotting time and clot degradation, also known as fibrinolysis. We expect to initiate a pivotal clinical trial for T2Stat and T2HemoStat in 2016.

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.

In 2013, the U.S. Department of Health and Human Services reported that sepsis is the most expensive hospital-treated condition in the United States, with an economic burden to hospitals exceeding $20 billion annually, almost double that of acute myocardial infarction. 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 two to five days to generate results.

The following table reflects key statistics from the 2013 U.S. Department of Health and Human Services study regarding the five most expensive hospital-treated conditions:

Rank	Condition	U.S. hospital costs (in billions)	Percentage of total inpatient costs
1	Sepsis	$ 20.3	5.2%
2	Osteoarthritis	14.8	3.8
3	Complication of device, implant or graft	12.9	3.3
4	Liveborn	12.4	3.2
5	Acute myocardial infarction (heart attack)	11.5	3.0

Over 1.6 million individuals are diagnosed with sepsis each year, 1.35 million of whom are at high risk for infection due to their suppressed immune system or their presence in critical care units. 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 as more targeted drugs are required.

We estimate that approximately 15 million patients are tested for blood stream infections in the United States annually. Of these, approximately 6.75 million are at high risk for a *Candida* infection and an additional two million, or approximately 8.75 million, in total are at high risk for a bacterial infection. 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.

There is also a significant market opportunity outside the United States for improved sepsis diagnosis, as this disease burdens other countries with similarly high mortality rates and high costs. Each year, over 18 million cases of sepsis are diagnosed worldwide, with estimated mortalities exceeding five million patients, making it 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 two to five 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 PCR-based diagnostics, there is a requirement for extraction of target cells from the sample into a clear solution, where 90% or more of the cells can be lost. Extraction into a clear solution is needed because existing diagnostic detection methods cannot detect the targeted pathogen due to the complex background of the sample itself. 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 two and as many as five 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 two- to five-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 the driving force behind the spread of antimicrobial-resistant pathogens, which the U.S. Centers for Disease Control and Prevention, or 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 Solution

T2MR delivers what we believe no other technology currently available can: a rapid, sensitive and simple diagnostic platform that enables sepsis applications, including T2Candida and T2Bacteria, 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. We believe T2MR sepsis applications provide a pathway for more rapid and targeted treatment of infections, potentially reducing the mortality rate by as much as 75% if a patient is treated within 12 hours of suspicion of infection and significantly reducing the cost burden of sepsis. Each year, approximately 500,000 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%; the survival rate for septic patients who remained untreated for greater than 36 hours was approximately 5%.

We believe T2MR sepsis applications address 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 As Fast 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 actionable results as fast as 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 FDA authorized products, 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%, and 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, which will significantly improve patient outcomes and reduce hospital costs. We further believe that the adoption of 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.

We surveyed 111 decision-makers involved with laboratory purchasing, including laboratory directors, hospital administrators and infectious disease physicians, in a web-based survey to seek their views on acceptable pricing for T2Candida in exchange for an honorarium. Based on the survey, we believe that with 90% sensitivity, 95% specificity and a cost savings of $650 per tested patient, T2Candida would be adopted by nearly 50% of physicians at a selling price of $200 per test. However, we expect that cost savings will be $800 per patient and we observed overall sensitivity of 91.1% and specificity of 99.4% in our direcT2 clinical trial described below. Additionally, in this survey, 95% of laboratory directors and hospital administrators, along with 89% of infectious disease physicians, either strongly agreed or agreed that initiating appropriate antifungal therapy within 12 hours of the patient presenting with symptoms would be likely to provide the following benefits:

- reduction in the mortality rate from an average of 40% to approximately 10% for candidemia patients;

- direct cost-savings as a result of an average of nine fewer days of hospitalization for each candidemia patient, including two fewer days of stay in the intensive care unit; and

- a meaningful decrease in antifungal therapy utilization in a hospital due to cessation of therapy based on a negative test result.

The surveyed physicians also indicated that, on average, they would order T2Candida for approximately 75% of their patients considered at-risk for *Candida* infections. In the United States, we are focusing our sales efforts on the 450 hospitals that have the highest concentration of patients at risk for *Candida* infections. In each of these institutions, over 5,000 patients present with symptoms of candidemia annually. We believe that with appropriate sales efforts and medical education, all of these patients will eventually be tested, representing a total recurring revenue opportunity of $1 million in each of our target accounts.

We are also developing T2Bacteria, a multiplex diagnostic panel that detects the major bacterial pathogens associated with sepsis that are frequently not covered by first-line antibiotics. T2Bacteria will also run on T2Dx and is expected to address the same approximately 6.75 million symptomatic high-risk patients as T2Candida while also expanding our reach to a new population of patients who are at increased risk for bacterial infections, including an additional two million people presenting with symptoms of infection in the emergency room setting. We expect that T2Bacteria will achieve similar performance capabilities and provide similar benefits as T2Candida.

Clinical Utility

direcT2 Clinical Trial Clinical Infectious Disease

In 2013 and 2014, we conducted a pivotal clinical trial for our T2Dx Instrument and our T2Candida Panel, or the direcT2 trial. Our direcT2 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 direcT2 trial was designed to evaluate the sensitivity and specificity of T2Candida on the T2Dx instrument.

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 direcT2 trial was reviewed by the FDA as part of pre-submission communications. The purpose of the direcT2 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 Panel. 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 direcT2 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 direcT2 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 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 4.2 hours compared to blood culture average time to result of 129 hours;

- T2Candida demonstrated an average time to negative result of 4.4 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 an 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 T2Dx and blood culture-based diagnostics. In this study, contrived blood samples were split between T2Candida using 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	
	C. albicans	= 100%	*C. albicans*	= 100%
	C. tropicalis	= 100%	*C. tropicalis*	= 100%

Sensitivity	100%
Specificity	98%

Hemostasis

Another significant unmet clinical need is the diagnosis and management of impaired hemostasis, which is a life-threatening condition in which a patient is unable to promote the formation of blood clots to stabilize excessive bleeding. Within the broader population of patients with symptoms of impaired hemostasis, there are over ten million trauma patients in the United States annually. These trauma patients typically face life-threatening injuries or invasive surgical procedures. Approximately 25% of trauma patients have impaired hemostasis, which frequently goes undetected during the initial hospitalization. According to a study in the *Journal of the American College of Surgeons*, for trauma patients with symptoms of impaired hemostasis, mortality was reduced from 45% to 19% with more rapid delivery of therapy. Today, there is no hemostasis diagnostic method that can rapidly provide comprehensive results. We estimate that rapid, targeted treatment for trauma patients with impaired hemostasis can reduce healthcare costs in the United States by nearly $2 billion each year due to more efficient utilization of scarce and expensive blood products and more rapid patient stabilization, reducing length of hospital stays by approximately 20%.

Because the hemostasis status of trauma patients changes frequently, patients are on average tested three times per episode, which we estimate results in approximately 13 million hemostasis tests performed annually on trauma patients in the United States alone. We believe this unmet need represents a nearly $1 billion annual market opportunity, which will be the initial focus for T2Stat and T2HemoStat.

Existing hemostasis screening methods have a range of limitations. Such screening can require:

- up to 24 hours to provide a diagnosis;
- large volumes of blood from patients;
- as many as five separate instruments to provide comprehensive results;
- highly skilled technicians; and
- specialty laboratories.

T2Stat and T2HemoStat utilize T2MR and are designed to provide hemostasis measurements in less than 45 minutes. T2HemoStat is a comprehensive panel of diagnostic tests that can provide data across the hemostasis spectrum, including measurements of clotting time, platelet activity, clot contraction and clot lysis. We believe that T2HemoStat will be the first panel capable of rapidly identifying key coagulation, platelet and other hematologic factors directly from whole blood on a single, easy to operate, compact instrument that will provide all of the following benefits:

- comprehensive results in 45 minutes or less;
- results from clinical samples as small as a finger stick of blood;
- replacement of up to five instruments with one compact instrument;
- easy-to-use system, not requiring highly skilled technicians to operate; and
- small, tabletop instrument that can be used at the point of care.

We expect that existing DRG and Current Procedural Terminology, or CPT codes, will be used to facilitate reimbursement of our hemostasis diagnostic products.

While the panel of HemoStat diagnostic tests currently in development is focused on addressing the unmet need for trauma patients, T2HemoStat can be expanded to add diagnostic tests that can address the needs of the broader population of patients with impaired hemostasis.

We also believe T2MR will be able to identify novel biomarkers with important clinical utility. For example, in a 2014 peer-reviewed article featured on the cover of the journal, *Blood*, T2MR was used to identify a new clot structure that has potential as a novel biomarker which could provide additional actionable information to manage patients with impaired hemostasis after trauma.

Lyme Disease

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 subject to high false negative rates 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, polymerase chain reaction (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.

T2Lyme will identify the bacteria that cause Lyme disease directly from the patient s blood, without the need fo 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 Instrument, the same instrument currently used to run our T2Candida test panel and in the future, T2Bacteria Panel. We anticipate the T2Lyme test panel to benefit from similar advantages provided by T2MR as the T2Candida test panel, 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.

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

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, initially targeting high-volume hospitals, 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.

The foundation of our commercialization strategy is to build an experienced, direct sales force consisting of approximately 15 commissioned representatives during 2015. Our sales representatives, employing a clinical data-driven sales approach, focus on the clinical performance of our products, the improved outcomes for patients and the economic value for hospitals, including customizable budgetary impact analysis. They demonstrate the ease-of-use of our products and the advantages of our products over blood culture-based diagnostics. We plan to continue to invest in our direct sales force as we expand both the array of diagnostic panels and our customer reach.

Today, our sales force markets T2Dx and T2Candida directly to hospitals in the United States, initially targeting the 450 hospitals treating the largest number of high-risk patients. We estimate that these 450 centers annually treat an average of over 5,000 symptomatic patients at high risk for a *Candida* infection, representing over one-third of the expected market for T2Candida. If these leading institutions adopt our technology, we expect a positive network effect in the hospital community, accelerating adoption of T2Candida. We believe key aspects of healthcare reform, including the focus on cost containment, risk-sharing, and outcomes-based treatment and reimbursement, align with the value proposition of our sepsis products, contributing positively to their adoption. We believe the key decision-makers at hospitals will be infectious disease and critical care physicians, laboratory directors, the hospital pharmacy 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 the key decision-makers, and we believe they will 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 to these decision-makers.

Outside of the United States, we expect to seek regulatory approvals in European and other international markets and to launch our platform through distributor partners who will deploy a similar model to our sales approach in the United States. In July 2014, we received CE marking for our T2Candida Panel and T2Dx Instrument.

Manufacturing

We manufacture our proprietary T2Dx instrument and our T2Candida reagent trays at our approximately 7,600 square foot 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 consumable cartridge to a contract manufacturing organization. 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 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 facility in Wilmington, Massachusetts is 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 are the owner or licensee of over 50 patents and approximately 60 patent applications and 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 product and T2Bacteria and T2Lyme product candidates, as well as protection of certain aspects of the conduct of the assays and detection of analytes. We also own several patent families covering various aspects of our T2HemoStat assay, including the assay architecture and conduct of the analysis. The issued patents in our patent families that cover T2Candida and T2Bacteria are expected to expire between 2023 and 2031, while additional pending applications in these families would be expected to expire, if issued, between 2023 and 2033. Our patent families covering T2HemoStat, if issued, will be expected to expire, between 2026 and 2035. In all cases, the expiration dates are subject to any extension that may be available under applicable law. Our patent family covering T2Lyme, if issued, will be expected to expire in approximately 2035.

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 seek trademark and service mark protection in key markets to safeguard our brand and the brands of our products and product candidates. We intend to file trademark registration applications in the U.S. and foreign jurisdictions to continue to strengthen our brand.

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 will be 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.

Sales Agreement with GE Healthcare

We are currently party to a supply and license agreement with GE Healthcare for the manufacture and supply by GE Healthcare of its proprietary superparamagnetic particles to be used in connection with our products and product candidates. This agreement with GE Healthcare also grants to us a non-exclusive, worldwide, non-royalty bearing, sublicensable license to use the supplied products for the purposes of research, development, manufacture and sale of our products and product candidates for *in vitro* industrial diagnostics, human diagnostics and veterinary diagnostics purposes, but not for use in therapeutics. 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. We are obligated to meet certain minimum purchase requirements in each contract year of the agreement during the five-year term, which ends December 31, 2015. We have met our annual minimum purchase obligations to date and our minimum purchase obligation for the year ended December 31, 2015 is not material to the financial statements.

Either party may terminate the agreement immediately upon the insolvency of the other party, or for uncured breach of the agreement where termination is effective on receipt by the breaching party of a termination notice not less than 30 days after receipt of written notice of a breach. Absent earlier termination, our agreement with GE Healthcare will remain in force until December 31, 2015.

Supply Agreement with SMC Ltd.

We are currently party to a supply agreement with SMC Ltd. for the supply and manufacture of products related to plastic injection molding, including the consumable cartridge used in connection with the T2Candida Panel. 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 the Company 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

We believe we are currently the only diagnostic company developing products with the potential to identify pathogens associated with bloodstream infections in a variety of unpurified patient sample types at limits of detection as low as 1 CFU/mL. Our principal competition is from a number of companies that offer platforms and applications in our target sepsis and hemostasis 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., Bruker Corporation, Cepheid and Siemens AG. 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 competing technologies.

We believe that we have a number of competitive advantages, including:

- T2MR s ability to detect targets directly in complex and high volume samples, 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 initial 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 initial applications may provide substantial economic benefits to hospitals that can accrue the savings related to the rapid treatment of sepsis patients.

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. 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.

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. Based on non-binding communications from the FDA, we expect the T2Bacteria Panel to be eligible for a 510(k) submission.

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 authorization for our T2Dx and T2Candida devices, which were given a Class II designation. We received marketing authorization for these devices from the FDA on September 22, 2014.

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 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 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, allowing us to affix the CE mark to these products.

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 redresss 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 PPACA 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 will be required to collect data starting on March 21, 2015 and will report the data to the Centers for Medicare & Medicaid Services, or CMS, no later than March 30, 2016. 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, general 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 foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system seeking, among other things, to reduce healthcare costs that could affect our future results of operations as we begin to directly commercialize our products.

By way of example, in the United States, the Affordable Care Act was signed into law in March 2010, which is expected to substantially change the way healthcare is delivered and financed by both governmental and private insurers. Among other things, the Affordable Care Act:

- imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States;

- established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;

- implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and

- created an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation s automatic reduction to several government programs. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, including hospitals.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

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 T2MR platform. We incurred research and development expenses of $19.8 million for the year ended December 31, 2014, $14.9 million for the year ended December 31, 2013 and $11.7 million for the year ended December 31, 2012. Research and development expenses represented 64% of our operating expenses for the year ended December 31, 2014, 75% of our operating expenses for the year ended December 31, 2013 and 80% of our operating expenses for the year ended December 31, 2012. Major components of the research and development expenses were salaries and benefits, research-related facility and overhead costs, laboratory supplies, equipment and contract services.

We continuously seek to improve T2MR, including improvements in its technology and accessibility. 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 T2MR to additional potential applications in the *in vitro* diagnostic area. We are continuing our development of T2Bacteria and expect to initiate clinical trials for T2Bacteria in the second half of 2015. We believe that technical advantage is important to sustainable competitive advantage, and therefore our research and development efforts are focused on the continued enhancement of our T2MR platform. We are dedicated to ongoing innovation to T2MR and expanding our pipeline of product candidates. Our goal is for T2MR to become a standard of care by providing technology that offers a rapid, sensitive and simple diagnostic alternative to existing methodologies for identifying both sepsis and impaired hemostasis, with a long-term objective of targeting the broader *in vitro* diagnostics market.

Employees

As of December 31, 2014, we had 110 full-time employees, of which 43 work in operations (which includes manufacturing, clinical and regulatory support, quality control and quality assurance), 38 in research and development, 15 in general and administrative and 14 in sales and marketing.

Facilities

Our corporate headquarters is located in Lexington, Massachusetts, where we currently lease approximately 32,000 square feet of office space and 22,800 square feet of laboratory space in various facilities. Our base rent, for leases at our corporate headquarters, is $1.7 million annually. We also lease approximately 7,600 square feet in Wilmington, Massachusetts for our manufacturing facility, under a lease that expires in 2016 for $61,000 of base rent annually. We also lease laboratory space in Worcester, Massachusetts.

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. We also make these documents and certain public financial information available 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. Some of the information found on our website is not part of this 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 risks 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 also may impair our business operations.

Risks Related to our Business and Strategy

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, 2014 and expect to incur losses in the future. Our accumulated deficit as of December 31, 2014 was $103.6 million and we incurred net losses of $31.4 million and $20.6 million for the years ended December 31, 2014 and 2013, respectively. We expect that our losses will continue for at least the next several years as we will be required to invest significant additional funds toward the continued development and commercialization of our technology. We also expect that our selling, general and administrative expenses will continue to increase due to the additional costs associated with growing our sales and marketing infrastructure, expanding our manufacturing capabilities, obtaining regulatory clearance or approval for our products currently under development and the increased administrative costs associated with being a public company. 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 authorization from the FDA or regulatory clearance for future product candidates, and our market penetration and margins. We may never be able to generate sufficient revenue to achieve or sustain profitability.

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 authorization from the FDA for the T2Dx Instrument and the T2Candida Panel on September 22, 2014 and began commercializing these products in the fourth quarter of 2014. Accordingly, we have a 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.

Due to our limited operating history, 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.

Until we achieve scale in our business model our revenue will be primarily generated from the T2Dx Instrument and the T2Candida Panel, 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 initial sepsis products for sale in the fourth quarter of 2014 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 and T2Candida 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 and T2Candida products and the future commercialization of our other product candidates in the United States and other jurisdictions in which we intend to pursue marketing authorization 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, the T2Candida Panel is labeled for the presumptive diagnosis of *Candida* infection. 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 and impaired hemostasis, 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 and hemostasis 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, our future revenue could be negatively impacted.

We believe that the T2Lyme test panel will be able to rapidly identify the bacteria that cause Lyme disease directly from patients blood with similar limits of detection as our current sepsis test, T2Candida. If T2Lyme does not successfully identify Lyme disease in clinical patients, the revenue opportunity for this product candidate could be limited or not realized at all.

We have 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 authorization to sell our initial sepsis products in the fourth quarter of 2014, we have limited experience marketing and selling our products. As of December 31, 2014, our direct sales organization, including marketing, consisted of 14 employees, having increased from 4 employees as of December 31, 2013. Our financial condition and operating results are highly dependent upon the sales and marketing efforts of our sales and marketing employees. 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 in the United States. Accordingly, our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled sales and marketing personnel. Because the competition for their services 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 expect to 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 product candidates 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.

Our sales cycle is lengthy and variable and we have no 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, will vary significantly and could be up to 12 months or longer. Given the length and uncertainty of our anticipated sales cycle, we likely will experience fluctuations in our product sales on 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 only recently started selling the T2Dx and T2Candida products and have no sales history to rely on when forecasting revenue and other operating results.

We may not be able to gain 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 successful completion of our pivotal T2Dx and T2Candida clinical trial, 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 commercialize our initial sepsis products, build a targeted sales force and as seek marketing authorization from the FDA or regulatory clearance of 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 supplier, 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 believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements for at least the next 12 months. However, 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 authorization from the FDA or clearance from the FDA 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;

- the cost and timing of marketing authorization 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.

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.

We only recently began marketing our initial sepsis products to the approximately 450 leading hospitals in the United States in which the top one-third of patients highest at risk of suffering from sepsis are concentrated. We may not be successful in promoting adoption of our technologies in those targeted hospitals, which may make it difficult for us to achieve broader market acceptance of these products.

We utilize third-party, single-source suppliers for some components and materials used in our products, 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. 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. 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, train, retain and motivate key personnel, including our senior management, research and development, science and engineering, manufacturing and sales and marketing personnel. In particular, we are highly dependent on the management and business expertise of John McDonough, 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 trained sales personnel with the necessary scientific background and ability to understand our systems at a technical level. In addition, we may need 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, train, 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 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 failed to detect the presence of *Candida* or another bacterial pathogen and a patient subsequently

suffered from sepsis, or if our technology failed to detect impaired hemostasis and a patient faced adverse consequences from the misdiagnosis, 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.

We compete with commercial diagnostics companies. We believe our principal competition will come from 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., Bruker Corporation, Cepheid and Siemens AG.

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 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 or product candidates 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.

We are developing additional product candidates that we intend to be used with T2Dx, including T2Bacteria for detection of certain strains of sepsis-causing bacteria and T2Lyme for detection of certain strains of Lyme disease-causing bacteria. We are also developing T2Stat, to be used with our developmental T2HemoStat panel, which is designed to detect impaired hemostasis. 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 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.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes. 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 and T2Candida panel, 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.

We currently develop, manufacture and test our products and product candidates and some of their components in three 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 and product candidates exclusively in a facility in Lexington, Massachusetts and manufacture and test some components of our products and product candidates in separate facilities in Worcester and Wilmington, Massachusetts, respectively. 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, T2Dx 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 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 authorization 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 authorization 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 authorization to market T2Dx 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 authorization from the FDA for a revised test that would distinguish between the two species.

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

As of December 31, 2014, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of $84.8 million, which are available to offset future taxable income, if any, through 2034. Under Section 382 of the Internal Revenue Code, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We may have already experienced one or more ownership changes. Depending on the timing of any future utilization of our carryforwards, we may be limited as to the amount that can be utilized each year as a result of such previous ownership changes. 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 Internal Revenue Code. Our NOLs may also be impaired under similar provisions of state law. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets 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 expect to generate a portion of our future revenue internationally and are subject to various risks relating to our international activities which could adversely affect our operating results.

We believe that a portion of our future revenue will come from international sources as we implement and expand overseas operations. 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; and

- difficulties protecting or procuring intellectual property rights.

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 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 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 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.

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 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 test panel under the de novo application procedure in September 2014. From time to time, we may make modifications to these products that may require a new 510(k). Based on non-binding communications from the FDA, we expect the T2Bacteria panel to be eligible for a 510(k) submission.

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.

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.

Furthermore, the FDA s ongoing review of the 510(k) program may make it more difficult for us to make modifications to any products for which we obtain clearance, either by imposing more strict requirements on when a manufacturer must submit a new 510(k) for a modification to a previously cleared product, or by applying more onerous

review criteria to such submissions. For example, in accordance with FDASIA, the FDA was obligated to prepare a report for Congress on the FDA s approach for determining when a new 510(k) will be required for modifications or changes to a previously cleared device. The FDA recently issued this report and indicated that manufacturers should continue to adhere to the FDA s 1997 Guidance on this topic when making a determination as to whether or not a new 510(k) is required for a change or modification to a device. However, the practical impact of the FDA s continuing scrutiny of the 510(k) program remains unclear.

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 authorization from the FDA or regulatory clearance for our product candidates.

Our future customers are highly dependent on payment from third-party payors, and inadequate coverage and reimbursement for diagnostic tests using our technology or 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, to the extent 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.

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.

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 are subject to federal and state healthcare fraud and abuse laws and other federal and state 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 privacy and security regulation by both the federal government and the states in which we conduct our business. The laws 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, 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 new 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 protects the security and privacy of protected health information;

- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, ACA, which requires manufacturers of drugs, devices, biologicals, and medical supplies to report annually to the CMS information related to payments

and other transfers of value to physicians 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 or marketing expenditures; 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 ACA, 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. The ACA codified case law by amending the False Claims Act, such that violations of the 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 administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and individual 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 ACA, enacted in March 2010, makes changes that are expected to significantly impact the pharmaceutical and medical device industries and clinical laboratories. Since 2013, certain medical device manufacturers have had to pay an excise tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. We expect that the excise tax will apply to some or all of our diagnostic products and product candidates.

The ACA also mandates 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 contained in the ACA include 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 ACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. In addition, the ACA establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce healthcare expenditures, which may have a negative impact on payment rates for services, including our tests. The IPAB proposals may impact payments for clinical laboratory services that our diagnostics customers use our technology to deliver beginning in 2016, and for hospital services beginning in 2020, and may indirectly reduce demand for our diagnostic products and product candidates. To the extent that the reimbursement amounts for sepsis decrease, it could adversely affect the market acceptance and hospital adoption of our technologies.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation s automatic reduction to several government programs. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The full impact on our business of the ACA and the other new laws is uncertain. Nor is it clear whether other legislative changes will be adopted or how such changes would affect our industry generally or our ability to successfully commercialize our products and product candidates. Changes in healthcare policy, such as the creation of broad test utilization limits for diagnostic products in general or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially impact the sales of our tests, increase costs and divert management s attention from our business. Such co-payments by Medicare beneficiaries for laboratory services were discussed as possible cost savings for the Medicare program as part of the debt ceiling budget discussions in mid-2011 and may be enacted in the future. In addition, sales of our tests outside of the United States will subject us to foreign regulatory requirements, which may also change over time.

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, all 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 20 issued U.S. patents and 30 pending U.S. patent applications, including provisional and non-provisional filings. We also own or license 63 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 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 reexamination, 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, to be sufficiently broad to cover our technologies or to provide meaningful protection from our competitors. Nor can we assure you that the 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 clam 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 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. While we have not received notices of claims of infringement or misappropriation or misuse of other parties proprietary rights in the past, we may from time to time receive such 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 diversion of 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. 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. We cannot assure you that third parties 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, including T2HemoStat, T2Bacteria and T2Lyme, 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

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control all matters submitted to stockholders for approval.

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock and their respective affiliates, in the aggregate, hold shares representing the majority of our outstanding voting stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

- delay, defer or prevent a change in control;

- entrench our management and the board of directors; or

- impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

An active trading market for our common stock may not continue to develop or be sustained.

Since our initial listing on The NASDAQ Global Market in August 2014, the trading market in our common stock has been extremely 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 develop or be sustained in the future.

Our executive officers, directors and 5% stockholders and their respective affiliates in the aggregate own a significant percentage of our outstanding shares of common stock, which may adversely affect the liquidity of the trading market for our common stock. If these stockholders continue to hold their shares of common stock, there will be limited trading volume in our common stock, which may make it more difficult for investors to sell their shares and may increase the volatility of our stock price. 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;

- 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;

- general economic, industry and market conditions; and

- the other factors described in this Risk Factors section.

We are an emerging growth company, and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company for up to five years following the IPO. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor s report providing additional information about the audit and the financial statements;

- reduced disclosure obligations regarding executive compensation; and

- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this annual report. In particular, we may not include all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The NASDAQ 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 devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. 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.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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 will be 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 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.

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.

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 and 22,800 square feet of laboratory space. Our base rent, for leases at our corporate headquarters, is $1.7 million annually. In addition, we lease approximately 7,600 square feet in Wilmington, Massachusetts for our manufacturing facility, under a lease that expires in 2015 for $61,000 of base rent annually. We also lease laboratory space in Worcester, Massachusetts, under a month-to-month lease that is cancelable with 60 days notice, for monthly rent of approximately $4,300.

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

Our common stock has been quoted on The NASDAQ Global Market under the symbol TTOO and has been trading since August 7, 2014. The following table sets forth, for the periods indicated, the quarterly high and low sales prices per share of our common stock as reported on The NASDAQ Global Market.

Year Ended Year Ended December 31, 2014	High	Low
Third Quarter	$ 24.50	$ 13.40
Fourth Quarter	$ 19.82	$ 13.50

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.

Stock Performance Graph

The graph below compares the cumulative total stockholder returns on our common stock for the period indicated with the cumulative total stockholder returns on the NASDAQ Composite Index for the same period. The graph assumes that $100 was invested on August 7, 2014 in our common stock in each index and that all dividends were reinvested. No cash dividends have been declared on our common stock. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns.

Stockholders

The last reported sale price of common stock on March 2, 2015 as reported on the NASDAQ Global Market was $15.76. As of March 2, 2015, there were 36 holders of record of our common stock.

Equity Compensation Plan Information

For information regarding securities authorized for issuance under equity compensation plans, see Part III Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Sales of Unregistered Securities

Upon the closing of our initial public offering, or IPO, all of the outstanding shares of our convertible preferred stock were converted into 12,516,298 shares of common stock. The shares of common stock issued pursuant to such conversion were issued in reliance on the exemption from registration provided by Section 3(a)(9) of the Securities Act, which exemption is available for transactions involving securities exchanged by the issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange. In addition, upon the closing of our IPO, we issued an aggregate of 68,700 shares of common stock to various holders upon the cashless exercise of a warrants to purchase our common stock. The shares of common stock issued pursuant to such exercise were issued in reliance on the exemption from registration provided by Section 3(a)(9) of the Securities Act, which exemption is available for transactions involving securities exchanged by the issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange. From January 1, 2014 through December 31, 2014, we granted stock options to purchase an aggregate of 793,842 shares of our common stock, with a weighted-average exercise price of $12.64 per share, to employees and directors pursuant to our stock option plans. From January 1, 2014 through December 31, 2014, we issued and sold an aggregate of 64,661 shares of our common stock upon exercise of stock options granted pursuant to our stock option plans, at an average exercise price of $2.37 per share, for an aggregate consideration of $153,000. The issuance of common stock upon exercise of the options were exempt either pursuant to Rule 701 of the Securities Act, as a transaction pursuant to a compensatory benefit plan, or pursuant to Section 4(2) of the Securities Act, as a transaction by an issuer not involving a public offering. The common stock issued upon exercise of options is deemed restricted securities for the purposes of the Securities Act. No underwriters were used in the foregoing transactions.

Use of Proceeds

Use of Proceeds from the Sale of Unregistered Securities

Proceeds of approximately $153,000 received from the issuance of common stock upon the exercise of options were principally used to fund operations.

Use of Proceeds from the Sale of Registered Securities

On August 6, 2014, the SEC declared effective our Registration Statement on Form S-1 (File No. 333-197920), as amended, or Registration Statement, filed in connection with our IPO of our common stock. Pursuant to the Registration Statement, we registered the offer and sale of 5,200,000 shares of common stock with an aggregate offering price of approximately $57.2 million. Goldman Sachs & Co and Morgan Stanley acted as joint book-running managers for the offering; Leerink Partners and Janney Montgomery Scott acted as co-managers. On August 8, 2014, the underwriters exercised in full their option to purchase additional shares of our common stock pursuant to the underwriting agreement. On August 12, 2014, we closed our IPO, including 780,000 of additional shares related to the option to purchase additional shares pursuant to the underwriting agreement, and sold a total of 5,980,000 shares at a price to the public of $11.00 per share for net proceeds of approximately $58.1 million, which is comprised of gross proceeds of approximately $65.8 million, offset by underwriting discounts and commissions of approximately $4.6 million and offering expenses of approximately $3.1 million. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

The net proceeds of approximately $58.1 million from our IPO have been invested in accordance with the Company s investment policy. From the date of the closing of our IPO through December 31, 2014, we have not fully used cash on hand that was available prior to the closing of our IPO. There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus,

dated August 6, 2014, filed with the SEC pursuant to Rule 424(b) relating to our Registration Statement.

Issuer Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. SELECTED FINANCIAL DATA

The following tables set forth, for the periods and as of the dates indicated, our selected financial data. The consolidated statement of operations data for the years ended December 31, 2014, 2013 and 2012 and consolidated balance sheet data as of December 31, 2014 and 2013 are derived from our audited financial statements in this Annual Report on Form 10-K. You should read this data together with our financial statements and related notes included elsewhere in the Annual Report on Form 10-K and the information under the caption Management s Discussion and Analysis of Financial Condition and Results of Operations . Our historical results are not necessarily indicative of our future results.

	Year Ended December 31,		
Consolidated Statement of Operations Data:	**2014**	**2013**	**2012**
Research and grant revenue	$ 119	$ 266	$ 19
Operating expenses:			
Research and development	19,782	14,936	11,727
Selling, general and administrative	11,018	5,022	2,945
Total operating expenses	30,800	19,958	14,672
Interest expense, net	(721)	(403)	(154)
Other income (expense), net	12	(515)	352
Net loss	(31,390)	(20,610)	(14,455)
Accretion of redeemable convertible preferred stock to redemption value	(4,570)	(6,908)	(4,412)
Net loss applicable to common stockholders	$ (35,960)	$ (27,518)	$ (18,867)
Net loss per share applicable to common stockholders basic and diluted	$ (4.15)	$ (19.72)	$ (13.86)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders basic and diluted (1)(3)	8,674,931	1,395,562	1,361,616

Consolidated Balance Sheet Data:	2014	As of December 31, 2013	2012
		(in thousands)	
Cash and cash equivalents (1) (2)	$ 73,849	$ 30,198	$ 9,709
Total assets	79,134	31,885	11,431
Notes payable, net of current portion (2)	20,660	3,299	5,058
Current liabilities	5,172	4,046	2,129
Warrants to purchase redeemable securities (3)		1,225	695
Redeemable convertible preferred stock (3)		112,813	66,137
Total stockholders equity (deficit) (3)	53,001	(89,543)	(62,658)

(1) On August 12, 2014, we issued 5,980,000 shares of common stock in connection with our IPO at $11.00 per share. We raised approximately $58.1 million in net proceeds.

(2) On July 11, 2014 and December 30, 2014, we received net proceeds of $9.7 million and $10.0 million, respectively, from our loan and security agreement with Solar Capital, Ltd.

(3) In connection with the closing of our IPO on August 12, 2014, all warrants were net settled into shares of common stock and all shares of redeemable convertible preferred stock were converted into common stock.

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

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 and Section 21E of 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 authorization from the U.S. Food and Drug Administration, or 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, 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 prospectus entitled Item 1A. Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this Annual Report on Form 10-K. These forward looking statements are subject to numerous risks, including, without limitation, the following:

- *our expectation to incur losses in the future;*
- *our ability to obtain marketing authorization from the FDA or regulatory clearance for new product candidates in the United States or any other jurisdiction;*
- *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 of our anticipated sales cycle;*
- *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 future capital needs and our need to raise additional funds;*

- *the performance of our diagnostics;*

- *our ability to successfully manage our growth;*

- *our ability to compete in the highly competitive diagnostics market;*

- *our ability to protect and enforce our intellectual property rights, including our trade secret-protected proprietary rights in T2MR; and*

- *federal, state, and foreign regulatory requirements, including FDA regulation of our product candidates.*

These forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report on Form 10-K. 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. The following discussion should be read in conjunction with the financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under Item 1A. Risk Factors in this Annual Report on Form 10-K, and elsewhere in this Annual Report on Form 10-K.

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 that has developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. We are using our T2 Magnetic Resonance platform, or 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. Our initial development efforts utilizing T2MR target sepsis and hemostasis, which are areas of significant unmet medical need where existing therapies could be more effective with improved diagnostics. On September 22, 2014, we received market authorization from the U.S. Food and Drug Administration for our first two products, the T2Dx diagnostic instrument, or T2DX and the T2Candida Panel or T2Candida, for the direct detection of *Candida* species in human whole blood specimens and independent of blood culture from patients with symptoms of, or medical conditions predisposing the patient to, invasive fungal infections. We have begun a launch of the T2Dx and T2Candida with select hospitals in the United States and we are building a direct sales force that is targeting the top 450 hospitals in the United States that have the highest concentration of patients at risk for *Candida* infections. Our next three diagnostic applications are called T2Bacteria, T2HemoStat, and T2Lyme, which are focused on bacterial sepsis infections, hemostasis, and Lyme disease, respectively. We plan to initiate clinical trials in the second half of 2015 for T2Bacteria and in 2016 for T2HemoStat. We expect that existing reimbursement codes will support our sepsis, hemostasis and Lyme disease product candidates, and that the anticipated economic savings associated with our sepsis products will be realized directly by hospitals. We believe our combined initial annual addressable market opportunity for sepsis, hemostasis and Lyme disease is over $3.7 billion in the United States alone, when the market opportunity for T2Candida, T2Bacteria , T2Lyme and our initial hemostasis diagnostic panel is combined.

We have never been profitable and have incurred net losses in each year since inception. Our accumulated deficit at December 31, 2014 was $103.6 million. Substantially all our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. Having recently obtained authorization from the FDA to market the T2Dx and T2Candida, we now expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. In addition, we expect that our expenses will increase substantially as we continue the research and development of our other product candidates and maintain, expand and protect our intellectual property portfolio. Accordingly, we may seek to fund our operations through public or private equity or debt financings or 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 as and when needed would have a negative impact on our financial condition and our ability to develop and commercialize the T2Dx, T2Candida and our other product candidates.

Historically, the Company has funded its operations primarily through private placements of its redeemable convertible preferred stock and through debt financing arrangements. On August 12, 2014, the Company completed its IPO whereby the Company sold 5,980,000 shares of its common stock for net proceeds of approximately $58.1 million. As a result of the completion of the IPO and additional liquidity of up to $30.0

million obtained under the loan and security agreement that the Company entered into on July 11, 2014, management believes that its cash resources will be sufficient to allow the Company to fund its current operating plan through at least the next 12 months.

Our Commercial Products and the Unmet Clinical Need

Our initial FDA-authorized products, the T2Dx and T2Candida utilize T2MR to detect species-specific *Candida* directly from whole blood in three to five hours versus the two to five days required by blood culture-based diagnostics. The T2Candida runs on the T2Dx and provides high sensitivity with a limit of detection as low as 1 CFU/mL, even in the presence of antimicrobial therapy.

Our T2Candida Panel

Our direcT2 pivotal clinical trial was designed to evaluate the sensitivity and specificity of T2Candida on the T2Dx. The direcT2 trial consisted of two patient arms: a prospective arm with 1,501 samples from patients with a possible infection and a seeded arm with 300 samples, also obtained from patients with a possible infection. T2Candida and T2Dx demonstrated a sensitivity of 91.1 percent and a specificity of 99.4 percent. In addition, the speed to a species-specific positive result with T2Candida was 4.4 hours versus 129 hours with blood culture. A negative result from T2Candida was obtained in just 4.2 hours versus 120 hours with blood culture.

Candida is the fourth leading hospital-acquired bloodstream infection 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 the elapsed time from *Candida* infection to positive diagnosis and treatment. According to a study published in Antimicrobial Agents and Chemotherapy, the *Candida* 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.

Additionally, the speed to result of the T2Candida, run on the T2Dx, can help reduce the empiric overuse of ineffective, or even unnecessary, antimicrobial therapy. This inappropriate therapy is driving force behind the spread of antimicrobial-resistant pathogens, which the CDC recently called one of our most serious health threats.

Our T2Dx Instrument

Our FDA-authorized T2Dx is an easy-to-use, fully-automated, benchtop instrument utilizing T2MR for use in hospitals and labs for a broad range of diagnostic tests. To operate the system, a patient sample tube is snapped onto a disposable test cartridge, which is pre-loaded with all necessary reagents. The cartridge is then inserted into the T2Dx, which automatically processes the sample and then delivers a diagnostic test result. Test results are displayed on screen or directly through the lab information system.

By utilizing our proprietary T2MR for direct detection, the T2Dx 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 incorporates a simple user interface and is designed to efficiently process up to seven specimens simultaneously.

Our T2MR Platform

T2MR is a miniaturized, magnetic resonance-based approach that measures how water molecules react in the presence of magnetic fields. For molecular and immunodiagnostics targets, T2MR introduces nanoparticles to the sample that are coated with target-specific binding agents. If the target is present, the nanoparticles bind to and cluster around it, disrupting the surrounding water molecules and altering the magnetic resonance signal.

For hemostasis measurements, T2MR is highly sensitive to changes in viscosity in a blood sample (such as clot formation, stabilization or dissipation), which alter the magnetic resonance signal and enable identification of clinically relevant hemostasis changes.

We believe T2MR is the first technology with the ability to detect directly from a clinical sample of whole blood, plasma, serum, saliva, sputum or urine, saving time and potentially improving sensitivity by eliminating the need for purification or the extraction of target pathogens. T2MR has been demonstrated to detect cellular targets at limits of detection as low as one colony-forming unit per milliliter (CFU/mL). More than 100 studies published in peer reviewed journals have featured T2MR in a breadth of applications.

Financial Overview

Revenue

To date, we have generated revenue primarily from research and development agreements and government grants and have not generated any revenue from the sale of products. Revenue earned from activities performed pursuant to research and development agreements and grants is reported as revenue using the proportional performance method as the work is completed, and the related costs are expensed as incurred as research and development expense.

Product revenue will be derived from the sale of our instruments and related consumable diagnostic tests. In the majority of cases, we expect to place instruments in hospitals at minimal or no direct cost to customers in exchange for longer-term agreements and minimum commitments for the purchase of our consumable diagnostic tests. Under this business model, we believe we will recover the cost of placing our instruments in hospitals through the margins realized from our consumable diagnostic tests. Our consumable diagnostic tests can only be used with our instruments, and accordingly, as the installed base of our instruments grows, we expect the following to occur:

- recurring revenue from our consumable diagnostic tests will increase and become subject to less period-to-period fluctuation;
- consumable revenue will become an increasingly predictable and important contributor to our total revenue; and
- we will gain economies of scale through the growth in our sales, resulting in improving gross margins and operating margins.

Revenue from consumables is expected to be based on the volume of tests sold and the price of each consumable unit.

We plan to continue to expand our capacity to support our growth, which will result in higher cost of revenue in absolute dollars. However, we expect cost of revenue, as a percentage of revenue, to decline as revenue grows.

Research and development expenses

Our research and development expenses consist primarily of costs incurred for 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. We expense all research and development costs as incurred.

We have incurred a total of $74.1 million in research and development expenses from our inception, with a majority of the expenses incurred on the development of T2MR, and applications of T2MR, and the remainder being spent on clinical trials and research and development of additional applications using T2MR. We expect that our overall research and development expenses will continue to increase in absolute dollars. We have committed, and expect to commit, significant resources developing additional product candidates, improving product performance and reliability, conducting ongoing and new clinical trials and expanding our laboratory capabilities.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of costs for our sales and marketing, finance, 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 increase in future periods as we commercialize products and future product candidates that receive marketing authorization or regulatory clearance and as our needs for sales, marketing and administrative personnel grow. 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 also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with being a public company. 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 and the amortization of deferred financing costs, partially offset by interest earned on our cash and cash equivalents.

Other income (expense), net

Other income (expense), net, consists of government grant income and the gain or loss associated with the change in the fair value of our liability for warrants to purchase redeemable securities.

Results of Operations for the Years Ended December 31, 2014 and 2013

	Years Ended December 31,		
	2014	2013	Change
	(in thousands)		
Research and grant revenue	$ 119	$ 266	$ (147)
Operating expenses:			
Research and development	19,782	14,936	4,846
Selling, general and administrative	11,018	5,022	5,996
Total operating expenses	30,800	19,958	10,842
Loss from operations	(30,681)	(19,692)	(10,989)
Interest expense, net	(721)	(403)	(318)
Other income (expense), net	12	(515)	527
Net loss	$ (31,390)	$ (20,610)	$ (10,780)

Revenue

We recorded $119,000 of research and grant revenue for the year ended December 31, 2014 compared to $266,000 of research and grant revenue for the year ended December 31, 2013. In the year ended December 31, 2014, the Company entered into one research and development arrangement in the fourth quarter, compared with three such arrangements in the year ended December 31, 2013.

Research and development expenses

Research and development expenses were $19.8 million for the year ended December 31, 2014, compared to $14.9 million for the year ended December 31, 2013, an increase of $4.9 million. The increase was primarily due to increased payroll and payroll related expenses of $2.7 million, including $332,000 of incremental stock compensation expense, as we hired new employees and expanded our use of contractors and

temporary help, $803,000 of increased lab expenses due to increased headcount, $617,000 of increased facilities-related expenses due to increased headcount and expansion of facilities, increased licensing fees of $323,000 resulting primarily from milestone payments that became due pursuant to our license arrangement with MGH as a result of our achievement of FDA marketing authorization and European CE Mark for T2Dx and T2Candida during the third quarter, increased travel and site expenses of $248,000 related to the completion of the pivotal clinical trial for T2Dx and T2Candida, and $212,000 of increased consulting expense incurred to support product development.

Selling, general and administrative expenses

Selling, general and administrative expenses were $11.0 million for year ended December 31, 2014, compared to $5.0 million for year ended December 31, 2013. The increase of $6.0 million was due primarily to increased payroll and related expenses of $3.7 million, including $743,000 of incremental stock compensation expense, as we hired new executive, administrative, direct sales and marketing employees, increased marketing program expenses of $536,000 (related to exhibits at tradeshows, clinical studies and collateral), $520,000 of increased other public company expenditures (related to insurance and board of directors fees), $483,000 of increased consulting related expenses, $270,000 of increased facilities expenses, increased legal expenses of $265,000 related to corporate and intellectual property matters, and increased travel expenses of $248,000 resulting from the expansion of the sales force and increased tradeshow activity.

Interest expense, net

Interest expense, net, was $721,000 for the year ended December 31, 2014, compared to $403,000 for the year ended December 31, 2013, an increase of $318,000. The increase was primarily due to higher borrowing levels on our notes payable, primary from borrowing from Solar Capital, Ltd., and the write-off of deferred financing costs in connection with the repayment of outstanding borrowings from Silicon Valley Bank.

Other income (expense), net

Other income (expense), net, for the year ended December 31, 2014 increased to $12,000 of income, net, compared with $515,000 of expense, net, for the year ended December 31, 2013, due to the expense recorded related to the change in the fair value of the liability for warrants to purchase redeemable securities for the year ended December 31, 2013. The underlying warrants were converted into common stock upon completion of our IPO on August 12, 2014.

Results of Operations for the Years Ended December 31, 2013 and 2012

	Year Ended December 31,		
	2013	2012	Change
	(in thousands)		
Research and grant revenue	$ 266	$ 19	$ 247
Operating expenses:			
Research and development	14,936	11,727	3,209
Selling, general and administrative	5,022	2,945	2,077
Total operating expenses	19,958	14,672	5,286
Loss from operations	(19,692)	(14,653)	(5,039)
Interest expense, net	(403)	(154)	(249)
Other income (expense), net	(515)	352	(867)
Net loss	$ (20,610)	$ (14,455)	$ (6,155)

Revenue

We recorded $266,000 of research and grant revenue for the year ended December 31, 2013, which primarily consisted of revenue related to feasibility studies and co-development efforts with three companies. For the year ended December 31, 2012, we recorded $19,000 in research and grant revenue, which primarily consisted of work completed under a third-party development agreement, offset by the fair value of warrants issued in conjunction with the agreement, which were recorded as a reduction to revenue.

Research and development expenses

Research and development expenses were $14.9 million for the year ended December 31, 2013, compared to $11.7 million for the year ended December 31, 2012, an increase of $3.2 million. The increase was primarily due to increased payroll and payroll related expenses of $1.1 million, including stock compensation expenses, as we hired new employees, increased lab expenses to support product development, increased travel and site expenses of $2.1 million related to the pivotal clinical trial for T2Dx and T2Candida.

Selling, general and administrative expenses

Selling, general and administrative expenses were $5.0 million for the year ended December 31, 2013, compared to $2.9 million for the year ended December 31, 2012. The increase of $2.1 million was due primarily to increased payroll and related expenses of $925,000, including stock compensation expense, as we hired new administrative employees, increased marketing program expenses of $544,000, including tradeshows and collateral, increased legal expenses of $210,000 related to corporate and intellectual property matters, and increased consulting related expenses of $208,000.

Interest expense, net

Interest expense, net, was $403,000 for the year ended December 31, 2013, compared to $154,000 for the year ended December 31, 2012, an increase of $249,000. The increase is due to higher borrowing levels in 2013 under our credit facility with Silicon Valley Bank.

Other income (expense), net

Other income (expense), net, for the year ended December 31, 2013 decreased to $515,000 of expense, compared to $352,000 of income for the year ended December 31, 2012, due to an increase in the fair value of the liability for warrants to purchase redeemable securities.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception, and as of December 31, 2014, we had an accumulated deficit of $103.6 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and selling, general and administrative expenses will continue to increase and, as a result, we may need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

Since our inception through December 31, 2014, we have raised an aggregate of $179.9 million to fund our operations, of which $93.4 million was from the sale of preferred stock, $58.1 million was from the issuance of 5,980,000 of common stock upon completion of our IPO on August 12, 2014, and $28.1 million and $0.3 million were from the issuance of debt and common stock from stock incentive awards, respectively. As of December 31, 2014, we had cash and cash equivalents of $73.8 million. Currently, our funds are primarily held in money market funds invested in U.S. government agency securities.

Indebtedness

On May 9, 2011, we entered into a promissory note with Massachusetts Development Finance Company to borrow up to $1.7 million for the purchase of laboratory equipment and office equipment. The amounts borrowed are collateralized by the associated equipment and bear interest at a fixed annual rate of 6.5%. Pursuant to the note, we are required to meet a liquidity covenant whereby we must maintain a cash balance of $0.3 million in cash and marketable securities. We paid interest only on the borrowings through December 2013 and will continue to make equal monthly payments of principal and interest through the maturity date of May 2018. In connection with the note, we issued a warrant that is exercisable for shares of our Series C preferred stock. In connection with the closing of our IPO on August 12, 2014, the warrant was net settled into shares of common stock.

In addition, the promissory note with Massachusetts Development Finance Company contains a subjective acceleration clause whereby an event of default and immediate acceleration of the amount borrowed under the security and loan agreement occurs if we experience a material adverse change in the business, operations or condition (financial or otherwise) or a material impairment of the prospect of repayment of any portion of the obligations. The lender has not exercised its right under this clause, as there have been no such events. The Company believes the likelihood of the lender exercising this right is remote.

On July 11, 2014, we entered into a loan and security agreement with Solar Capital, Ltd., as collateral agent and lender, and Comerica Bank, as lender, for a $30.0 million senior secured term loan facility. The borrowed funds are available in two tranches; $20.0 million for tranche A and $10.0 million for tranche B. We drew $20.0 million under tranche A for the year ended December 31, 2014. We are able to draw the $10.0 million for tranche B prior to June 30, 2015, as we have received Section 510(k) clearance from the FDA for T2Dx and T2Candida.

Interest on outstanding balances accrues at an annual rate equal to the one-month London Interbank Offered Rate, or LIBOR, plus 7.05%, which was 7.22% as of December 31, 2014. We are required to make interest-only payments through July 31, 2016. After the interest-only repayment period, we will repay the amounts borrowed in equal monthly installments until the maturity date of July 1, 2019. In connection with the term loan facility, we paid a closing fee of $125,000 and other transactional and legal costs. Upon the maturity, acceleration or prepayment of any or all of the loans made under the term loan facility, we will be required to pay a final fee equal to 4.75% of the aggregate amount of such loans. We are permitted to prepay borrowed amounts, subject to the payment of a repayment premium of 1.5% of amounts prepaid prior to July 2015, which premium decreases to 1.0% for amounts prepaid after July 2015 but before July 2016, and further decreases to 0.5% for amounts prepaid after July 2016 but before the maturity date.

Amounts borrowed under the loan facility are secured by substantially all of our existing assets, and assets we may acquire in the future, in each case other than capital stock, leased real property, licenses that are not assignable without the licensor s consent, leased equipment and intellectual property, except for proceeds from intellectual property.

In addition, the loan and security agreement with Solar Capital, Ltd. contains a subjective acceleration clause whereby upon an event of default, which includes a material adverse change in the business, operations, or conditions (financial or otherwise) of the Company or a material impairment of the prospect of repayment of any portion of the obligations, there can be an immediate acceleration of the borrowings under the loan and security agreement. The lender has not exercised its right under this clause, as there have been no such events. The Company believes the likelihood of the lender exercising this right is remote.

As of December 31, 2014, we had $21.1 million of principal outstanding under these debt instruments and were in compliance with all covenants.

Plan of operations and future funding requirements

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.

We believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

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 potential research and development and other collaboration agreements. If we raise additional funds in the future, we may need relinquish valuable rights to our technologies, future revenue streams or grant licenses on terms that may not be favorable to us.

Cash flows

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

	Year Ended December 31,		
	2014	2013	2012
		(in thousands)	
Net cash (used in) provided by:			

Operating activities	$ (28,184)	$ (18,053)	$ (13,303)
Investing activities	(2,084)	(433)	(283)
Financing activities	73,919	38,975	4,551
Net increase (decrease) in cash and cash equivalents	$ 43,651	$ 20,489	$ (9,035)

Net cash used in operating activities

Net cash used in operating activities was $28.2 million for the year ended December 31, 2014, and consisted primarily of a net loss of $31.4 million adjusted for non-cash items including depreciation and amortization expense of $0.7 million and stock-based compensation expense of $1.7 million, partially offset by a net change in operating assets and liabilities of $0.8 million.

Net cash used in operating activities was $18.1 million for the year ended December 31, 2013, and consisted primarily of a net loss of $20.6 million adjusted for non-cash items including depreciation and amortization expense of $0.6 million, stock-based compensation expense of $0.6 million, an increase in the fair value of warrants of $0.5 million and a net change in operating assets and liabilities of $0.8 million.

Net cash used in operating activities was $13.3 million for the year ended December 31, 2012, and consisted primarily of a net loss of $14.5 million adjusted for non-cash items including depreciation and amortization expense of $0.6 million, stock-based compensation expense of $0.4 million, decrease in the fair value of warrants of $0.1 million and a net change in operating assets and liabilities of $0.2 million.

Net cash used in investing activities

Net cash used in investing activities was $2.1 million for the year ended December 31, 2014, and consisted of $2.1 million of purchases of leasehold improvements and furniture for new facilities, instrument components, laboratory equipment and computer software.

Net cash used in investing activities was $0.4 million for the year ended December 31, 2013, and consisted primarily of capital expenditures of $0.5 million, for purchases of laboratory equipment and leasehold improvements, partially offset by $0.1 million of proceeds from restricted cash accounts related to an operating lease agreement.

Net cash used in investing activities was $0.3 million for the year ended December 31, 2012, and consisted primarily of purchases of laboratory equipment.

Net cash provided by financing activities

Net cash provided by financing activities was $73.9 million for the year ended December 31, 2014, and consisted of $58.1 million of net proceeds from the Company s IPO that closed on August 12, 2014, $19.7 million of proceeds from borrowings from our loan agreement with Solar Capital, Ltd., net of deferred financing costs paid and $0.2 million of proceeds from the exercise of stock options, partially offset by repayments of notes payable of $4.0 million.

Net cash provided by financing activities during the year ended December 31, 2013 was primarily related to the sale of 6.9 million shares of our redeemable convertible preferred stock for net proceeds of $39.8 million, partially offset by repayments of notes payable of $0.8 million.

Net cash provided by financing activities during the year ended December 31, 2012 was primarily related to the issuance of notes payable for net proceeds of $4.9 million, partially offset by repayments of notes payable of $0.4 million.

Contractual Obligations and Contingent Liabilities

The following summarizes our significant contractual obligations as of December 31, 2014:

	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
			(in thousands)		
Operating leases(1)	$ 4,142	$ 1,713	$ 1,079	$ 818	$ 532
Notes payable(2)	26,702	1,812	12,622	12,268	

Total obligations	$ 30,844	$ 3,525	$ 13,701	$ 13,086	$ 532

(1) Represents the leases of approximately 62,400 square feet for office, laboratory and manufacturing space in Lexington, and Wilmington, Massachusetts under noncancelable operating leases.

(2) Represents our promissory note with Massachusetts Development Finance Company and our loan and security agreement with Solar Capital, Ltd. that currently bear interest at annual rates of 6.5% and 7.22%, respectively, and have principal repayment dates through July 2019. The balance for these debt instruments includes estimated interest payment obligations. Our loan and security agreement with Solar Capital, Ltd. includes a final fee payment of 4.75% of the principal borrowed, which totaled $950,000 at December 31, 2014, and becomes due in the period the principal paid in full or partially pre-paid. The final fee payment is assumed to be paid at the end of the loan and security agreement term in the above table.

Net operating loss carryforwards

We have deferred tax assets of $42.9 million as of December 31, 2014, 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, or NOL, tax carryforwards and research and development tax credit carryforwards. As of December 31, 2014, we had federal NOL carryforwards of $84.8 million available to reduce future taxable income, if any. These federal NOL carryforwards are available to offset future taxable income, if any, through 2034. In general, if we experience, or have experienced, a greater than 50% aggregate change in ownership of certain significant stockholders over a three-year period, or a Section 382 ownership change, utilization of our pre-change NOL carryforwards are subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended. Such limitations may result in expiration of a portion of the

NOL carryforwards before utilization and may be substantial. 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 carryforwards may be limited or lost. The Company has not conducted an assessment to determine whether there may have been a Section 382 or 383 ownership change.

Critical Accounting Policies and Use of Estimates

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, or 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 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.

Revenue recognition

We have generated revenue primarily from research and development agreements and government grants. The timing of cash received from our research and development agreements generally differs from when revenue is recognized. Revenue is recognized when persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collection is reasonably assured. Revenue earned from activities performed pursuant to research and development agreements and grants are reported as revenue on a proportional performance basis as the work is completed, and the related costs are expensed as incurred as research and development expense.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue.

For multiple-element arrangements, the Company identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting. The Company accounts for those components as separate elements when the following criteria are met: (1) the delivered items have value to the customer on a stand-alone basis; and, (2) if there is a general right of return relative to the delivered items, delivery or performance of the undelivered items is considered probable and within its control. The consideration received is allocated among the separate units of accounting based on management s best estimate of selling price, and the applicable revenue recognition criteria are applied to each of the separate units. The determination that multiple elements in an arrangement meet the criteria for separate units of accounting requires the Company s management to exercise its judgment.

Stock-based compensation

Prior to becoming a public company, we utilized significant estimates and assumptions in determining the fair value of our common stock. The board of directors determined the estimated fair value of our common stock based on a number of objective and subjective factors, including our capital structure; lack of marketability of our common stock; historical operating results; current business conditions and projections; our stage of development; likelihood of achieving a liquidity event, such as an initial public offering or a merger or acquisition of our company, given prevailing market conditions; and the market performance of comparable publicly traded companies.

We utilized various valuation methodologies in accordance with the framework of the 2004 American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of our common stock. Our board of directors determined the equity value of our business using the income approach valuation method or, when applicable due to a recent offering of our redeemable convertible preferred stock, the back solve method of the option pricing model, or OPM, to determine the enterprise value. The income approach determines our enterprise value on the basis of the estimated present value of our projected future cash

flows. These future cash flows are discounted to their present values using a discount rate derived from an analysis of the cost of capital of comparable publicly traded companies in our industry or similar lines of business as of each valuation date and this discount rate is adjusted to reflect the risks inherent in our cash flows. Once calculated, the results of the income approach were relied upon to determine an estimated enterprise value. Additionally, each valuation reflects a marketability discount, resulting from the illiquidity of our common stock.

We issue stock-based awards to employees and non-employees, generally in the form of stock options and restricted stock. We account for our 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 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. We account for stock-based awards to non-employees in accordance with FASB ASC Topic 505-50, *Equity-Based Payments to Non-Employees*, which requires the fair value of the award to be remeasured at fair value as the award vests. We recognize the compensation cost of stock-based awards to employees and non-employees on a straight-line basis over the vesting period. See below for a detailed description of how we estimate fair value for purposes of option grants and the methodology used in measuring stock-based compensation expense.

We estimate the fair value of our stock-based awards to employees and non-employees using the Black-Scholes-Merton option pricing model, which requires the input of highly subjective assumptions, including (a) the expected volatility of our stock, (b) the expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of a public market for the trading of our common stock, prior to our IPO, and a lack of company specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, we have selected companies with comparable characteristics to ours, including enterprise value, risk profiles and position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. We compute the historical volatility data using the daily closing prices for the selected companies shares during the equivalent period of the calculated expected term of our stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. We have estimated the expected life of our 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.

We are also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from our estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our 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 our actual forfeiture rate is materially different from the estimate, our stock-based compensation expense could be different from what we have recorded in the current period.

These assumptions used to determine stock compensation expense represent our best estimates, but the estimates involve inherent uncertainties and the application of our judgment. As a result, if factors change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

Inventories

Inventories are stated at the lower of cost or market. 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 recoverability of capitalized inventory during each reporting period, and writes down any excess and obsolete inventories to realizable value in the period in which the impairment is first identified. Shipping and handling costs incurred for inventory purchases are capitalized and recorded upon sale in

cost of product revenues in the statements of operations.

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 and the T2Candida Panel was when we achieved regulatory clearance, 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 and the T2Candida Panel was when we achieved 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, including commercial sale.

Costs associated with development products prior to satisfying the inventory capitalization criteria are charged to research and development expense as incurred.

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

Emerging Growth Company Status

In April 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was enacted in the United States. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

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.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of December 31, 2014, we had cash and cash equivalents of $73.8 million held primarily in money market funds consisting of U.S. government agency securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate one percent change in interest rates would not have a material effect on the fair market value of our portfolio. We are also subject to interest rate risk from the loans under our credit facility with Solar Capital, Ltd., which has an outstanding principal balance of $20.0 million as of December 31, 2014 and bears interest at an annual rate equal to the one-month LIBOR plus 7.05%. A 10% increase in the one-month LIBOR annual rate would result in an immaterial increase in our annual interest expense under our credit facility with Solar Capital, Ltd., as a result of the current low interest rate environment.

71

Item 8. **FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of

T2 Biosystems, Inc.

We have audited the accompanying consolidated balance sheets of T2 Biosystems, Inc. (the Company) as of December 31, 2014 and 2013, and the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders equity (deficit) and cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of T2 Biosystems, Inc. at December 31, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 4, 2015

T2 Biosystems, Inc.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	December 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 73,849	$ 30,198
Accounts receivable	201	
Prepaid expenses and other current assets	1,076	195
Inventories	115	
Restricted cash, current portion	80	
Total current assets	75,321	30,393
Property and equipment, net	2,760	1,118
Restricted cash, net of current portion	260	340
Deferred tax assets	313	
Other assets	480	34
Total assets	$ 79,134	$ 31,885
Liabilities, redeemable convertible preferred stock and stockholders equity (deficit)		
Current liabilities:		
Accounts payable	$ 735	$ 943
Accrued expenses and other current liabilities	3,662	1,319
Current portion of notes payable	295	1,759
Deferred revenue	80	
Deferred tax liabilities	313	
Current portion of deferred rent	87	25
Total current liabilities	5,172	4,046
Notes payable, net of current portion	20,660	3,299
Deferred rent, net of current portion	106	45
Warrants to purchase redeemable securities		1,225
Other liabilities	195	
Commitments and contingencies *(Note 13)*		
Redeemable convertible preferred stock (*Note 7*)		112,813
Stockholders equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2014 and 2013		
Common stock, $0.001 par value; 200,000,000 and 28,254,907 shares authorized at December 31, 2014 and 2013, respectively; 20,041,645 and 1,411,986 shares issued and outstanding at December 31, 2014 and 2013, respectively	20	1
Additional paid-in capital	156,576	
Accumulated deficit	(103,595)	(89,544)
Total stockholders equity (deficit)	53,001	(89,543)
Total liabilities, redeemable convertible preferred stock and stockholders equity (deficit)	$ 79,134	$ 31,885

See accompanying notes to financial statements.

T2 Biosystems, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

	Year Ended December 31,		
	2014	2013	2012
Research and grant revenue	$ 119	$ 266	$ 19
Operating expenses:			
Research and development	19,782	14,936	11,727
Selling, general and administrative	11,018	5,022	2,945
Total operating expenses	30,800	19,958	14,672
Loss from operations	(30,681)	(19,692)	(14,653)
Interest expense, net	(721)	(403)	(154)
Other income (expense), net	12	(515)	352
Net loss	$ (31,390)	$ (20,610)	$ (14,455)
Comprehensive loss	$ (31,390)	$ (20,610)	$ (14,455)
Reconciliation of net loss to net loss applicable to common stockholders:			
Net loss	$ (31,390)	$ (20,610)	$ (14,455)
Accretion of redeemable convertible preferred stock to redemption value	$ (4,570)	$ (6,908)	$ (4,412)
Net loss applicable to common stockholders	$ (35,960)	$ (27,518)	$ (18,867)
Net loss per share applicable to common stockholders basic and diluted	$ (4.15)	$ (19.72)	$ (13.86)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders basic and diluted	8,674,931	1,395,562	1,361,616

See accompanying notes to financial statements.

T2 Biosystems, Inc.

Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders Equity (Deficit)

(In thousands, except share and per share data)

	Series A-1 Redeemable Convertible Preferred Stock		Series A-2 Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Series D Redeemable Convertible Preferred Stock		Series E Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Sto
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2011	282,849	$ 784	1,703,959	$ 6,918	3,249,877	$ 13,720	4,055,125	$ 16,681	5,054,945	$ 23,622		$	1,359,718	$ 1	$	$ (44,196)	$
Accretion of Series A-1, A-2, B, C, and D redeemable convertible preferred stock to redemption value		46		404		874		1,214		1,874					(404)	(4,008)	
Exercise of stock options													2,325		1		
Stock-based compensation expense															403		
Net loss																(14,455)	
Balance at December 31, 2012	282,849	830	1,703,959	7,322	3,249,877	14,594	4,055,125	17,895	5,054,945	25,496			1,362,043	1		(62,659)	
Issuance of Series E redeemable convertible preferred stock, net of issuance costs of $232											6,930,967	27,768					
Accretion of Series A-1, A-2, B, C, D, and E redeemable convertible preferred stock to redemption value		44		402		870		1,205		1,861		2,526			(633)	(6,275)	
Exercise of stock options													49,943		55		
Stock-based compensation expense															578		
Net loss																(20,610)	
Balance at December 31, 2013	282,849	874	1,703,959	7,724	3,249,877	15,464	4,055,125	19,100	5,054,945	27,357	6,930,967	30,294	1,411,986	1		(89,544)	

Accretion of Series A-1, A-2, B, C, D, and E redeemable convertible preferred stock to redemption value	26	240	520	722	1,115	1,947						(880)		(3,690)
Stock-based compensation expense												1,653		
Conversion of redeemable convertible preferred stock into common stock	(282,849)	(900)	(1,703,959)	(7,964)	(3,249,877)	(15,984)	(4,055,125)	(19,822)	(5,054,945)	(28,472)	(6,930,947)	(47,241)	12,516,298	963	341	21,029
Issuance of common stock upon net settlement of warrants to purchase redeemable convertible preferred stock													68,700&nbs			