T2 Biosystems, Inc.
Form 10-K
March 15, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the year ended December 31, 2016

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

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

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

Title of Each Class:	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 NO

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

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

Indicate by check mark whether the registrant has submitted electronically 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 No

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.

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 Accelerated filer Non-accelerated filer
Smaller reporting company

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

As of June 30, 2016, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates was approximately $154.2 million based on the closing price for the common stock of $7.89 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 3, 2017 was 30,576,110. 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.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy, prospective products and product candidates, their expected performance and impact on healthcare costs, marketing clearance from the U.S. Food and Drug Administration, or the FDA, regulatory clearance, reimbursement for our product candidates, research and development costs, timing of regulatory filings, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” o 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;
- 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 ability to successfully manage our growth;

our future capital needs and our need to raise additional funds;

the performance of our diagnostics;

our ability to compete in the highly competitive diagnostics market;

our ability to obtain marketing clearance from the FDA or regulatory clearance for new product candidates in the United States or any other jurisdiction;

federal, state, and foreign regulatory requirements, including FDA regulation of our product candidates; and

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

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-

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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.

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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 technology, 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 target sepsis 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 clearance from the U.S. Food and Drug Administration, or the FDA, for our first two products, the T2Dx Instrument, or the T2Dx 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. In the United States, we have built a direct sales force that is primarily targeting the top 450 hospitals with the highest concentration of patients at risk for Candida infections. In Europe, we have partnered with distributors that target large hospitals in their respective European markets.

Three additional diagnostic applications in development are called T2Bacteria, T2Resistance and T2Lyme, which are focused on bacterial sepsis infections and Lyme disease, respectively. In late 2015 we initiated the collection of patient blood samples to support the clinical trial for T2Bacteria, and in early 2017, we initiated a multi-site clinical trial for T2Bacteria. We expect that existing reimbursement codes will support our sepsis 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, claiming more lives annually than breast cancer, prostate cancer, and AIDS combined, and it is the most expensive hospital-treated condition. Most commonly afflicting immunocompromised, critical care, and elderly patients, sepsis is a severe inflammatory response to a bacterial or fungal infection with a mortality rate of approximately 30%. According to data published by the U.S. Department of Health and Human Services for 2013, the cost of sepsis was over $23 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. These methods have substantial diagnostic limitations that lead to a high rate of false negative test results, a delay of up to several days in administration of targeted treatment, and the incurrence of unnecessary hospital expense. In addition, the Survey of Physicians' Perspectives and Knowledge About Diagnostic Tests for Bloodstream Infections in 2015 reported that negative blood culture results are only trusted by 36% of those physicians. Without the ability to rapidly identify pathogens, physicians typically start treatment of at-risk patients with broad-spectrum antibiotics, 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, which include T2Candida and our product candidate, T2Bacteria, 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. In another study published in Clinical Infectious Diseases in 2012, the delayed administration of appropriate antifungal therapy was associated with higher mortality among patients with septic shock attributed to Candida infection and, on that basis, the study concluded that more rapid and accurate diagnostic techniques are needed.

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Our pivotal clinical trial demonstrated that T2Candida can deliver actionable results in as few as three hours, with an average time to result during the trial of 4.2 hours, compared to the average time to result of one to six or more days typically required for blood-culture-based diagnostics. We believe the speed of the T2Candida test will enable physicians to potentially make treatment decisions and administer targeted treatment to patients in four to six hours versus 24 to 144 hours for blood culture. We believe that our product candidate, T2Bacteria, will also deliver actionable results in similar timeframes because this diagnostic panel operates similarly to T2Candida and is designed to run on the same instrument as T2Candida. In November 2015, the Company presented preliminary data demonstrating the ability of our T2Bacteria Panel product candidate to provide the rapid and sensitive identification of the six sepsis-causing bacteria included in the panel, directly from whole blood. The six clinically relevant bacteria included in our T2Bacteria Panel are Staphylococcus aureus, Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Acinetobacter baumannii. The six bacteria in our T2Bacteria Panel were selected because, when combined with the use of T2Candida and the practice of empirically administering broad spectrum antibiotics, the rapid detection of these bacteria may enable 95% of patients with sepsis to receive rapid and appropriate therapy.

Candida is the fourth leading hospital-acquired bloodstream infection, afflicting more than 135,000 patients per year in the United States, and the most lethal form of common bloodstream infections that cause sepsis, with an average mortality rate of approximately 40%. This high mortality rate is largely due to a delay in providing targeted therapy to the patient due to the elapsed time from Candida infection to positive diagnosis. According to a study published in Antimicrobial Agents and Chemotherapy, the Candida mortality rate can be reduced 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. Furthermore, in April 2015, Future Microbiology published the results of an economic study regarding the use of T2Candida conducted by IMS Health, a healthcare economics agency. In that economic study, IMS demonstrated that an average hospital admitting 5,100 patients at risk for Candida infections could save approximately $5.8 million annually due to decreased hospital stays for patients, reduction in use of antifungal drugs and other associated savings. The economic study further showed T2Candida can potentially reduce the costs of care by $26,887 per Candida patient and that rapid detection of Candida reduces patient deaths by 60.6%. Results from a data analysis of T2Candida for the detection and monitoring of Candida infection and sepsis were published comparing aggregated results from the use of T2Candida to blood culture-based diagnostics for the detection of invasive candidiasis and candidemia. The analysis included samples acquired from more than 1,900 patients. Out of 55 prospective patient cases that were tested with T2Candida and blood culture and determined to be positive or likely to be positive for a Candida infection, T2Candida detected 96.4% of the patients (53 cases) compared to detection of 60% of the patients (33 cases) with blood culture. During 2016, a number of T2Candida users presented data on their experiences with the T2Candida Panel which demonstrated both the clinical and economic benefits of use of the T2Candida Panel in the diagnostic regimen. The Henry Ford Health System in Detroit, Michigan reported data on a pre- and post-T2Candida implementation analysis that covered 6 months of clinical experience. The data showed a statistically significant ($p = 0.009$) seven day reduction in median Intensive Care Unit, or ICU, length of stay per positive patient that was identified as positive for Candida after implementation of the T2Candida test panel and a trend ($p = 0.164$) of total hospital length of stay reduction of four days. The data also showed significant reductions in use of antifungal drugs for negative patients tested with T2Candida. The overall economic savings resulting from these clinical benefits was projected to be approximately $2.3 million on an annualized basis. The Lee Health System in Fort Myers, Florida compared patient and economic experience before and after T2Candida implementation. The data demonstrated that in the post-T2Candida cohort, average length of stay for patients with Candida infections was reduced by 7 days when

detected by T2Candida while unnecessary antifungal therapy was avoided in 41% of patients tested and was discontinued after one dose in another 15% of patients tested. The economic savings derived solely from reduction in antifungal drug use was $195 per patient tested, net of the cost of the T2Candida test panel. Huntsville Hospital in Huntsville, Alabama, reported that the use of the T2Candida test panel resulted in a reduction in the duration of therapy and time to de-escalation in patients that tested negative for Candida on the T2Candida test panel, yielding net pharmacy savings of approximately $280 per patient tested. T2Candida also detected 56% more positive patients than blood culture. Finally, Riverside Community Hospital in Riverside, California, demonstrated improvements in time to appropriate therapy, increased sensitivity, and rapid discontinuation of antifungal therapy when using T2Candida. Specifically, 83% of patients who tested positive with T2Candida received appropriate therapy within six hours of the blood draw and 100% of patients received appropriate therapy in under nine hours. None of the patients who tested positive had been identified to have been treated with antifungals prior to

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T2Candida testing. In addition, antifungal therapy was discontinued for 100% of the patients who tested negative with T2Candida.

Due to the high mortality rate associated with Candida infections, physicians often will place patients on antifungal drugs while they await blood culture diagnostic results which generally take at least five days to generate a negative test result. Antifungal drugs are toxic and may result in side effects and can cost over $50 per day. Our T2Candida Panel's speed to result coupled with its superior sensitivity as compared to blood culture may help reduce the overuse of ineffective, or even unnecessary, antimicrobial therapy which may reduce side effects for patients, lower hospital costs and potentially counteract the growing resistance to antifungal therapy. The administration of inappropriate therapy is a driving force behind the spread of antimicrobial-resistant pathogens, which the United States Centers for Disease Control and Prevention, or the CDC, recently called "one of our most serious health threats."

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 and have partnered with distributors in Europe, all of whom are 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 the T2Dx, T2Candida, our product candidate, T2Bacteria, 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 the T2Dx 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. Our product development pipeline includes additional diagnostic panels that provide near-term and complementary market expansion opportunities. Our next sepsis product candidate will focus on bacterial infections, will run on the 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 will also expand our panels through partnerships similar to our agreement with Allergan, in which Allergan agreed to cover a portion of the costs of our development of certain additional products, including antibiotic resistance tests. We also are utilizing T2MR to address the challenges of providing rapid and sensitive diagnosis of Lyme disease. In late 2015 we initiated the collection of samples to support clinical trials for T2Bacteria, and in early 2017 we initiated a multi-site clinical trial for T2Bacteria. We are targeting to commercialize these product candidates after obtaining marketing clearance or regulatory clearance.

Broaden Our Addressable Markets Beyond Infectious Disease. We intend to expand our product offerings by applying T2MR to new applications beyond sepsis and Lyme disease. We are utilizing T2MR to address the challenges of providing rapid hemostasis monitoring and 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.

Drive International Expansion. We are commercializing T2Candida and the T2Dx in Europe through distributors that target large hospitals in their respective markets. We intend to continue to expand in

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Europe and other international markets through similar distribution channels. We have received CE marking for T2Candida and the T2Dx and expect to receive CE marking for our T2Bacteria Panel in 2017.

Our Technology Platform

T2 Magnetic Resonance Technology Overview

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

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

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

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 our T2MR technology will have potential applications within and outside of the in vitro diagnostics market, including environmental, food safety, industrial and veterinary applications.

Our Instruments

Utilizing T2MR, we have developed and received FDA marketing clearance for the T2Dx, a bench-top instrument for detecting pathogens associated with sepsis and Lyme disease, as well as other applications, and we have developed the T2Plex Instrument, or the T2Plex, a compact, fully integrated instrument for hemostasis applications.

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T2Dx

The 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 the T2Dx, which automatically processes the sample and then delivers a diagnostic test result.

The initial panels designed to run on the T2Dx are T2Candida and T2Bacteria, which are focused on identifying life-threatening pathogens associated with sepsis. In 2014 we received FDA marketing clearance for the T2Dx and T2Candida. In late 2015 we initiated the collection of samples to support clinical trials for T2Bacteria and in early 2017 we initiated a multi-site clinical trial for T2Bacteria. T2Lyme, which is in development, will also run on the T2Dx.

T2Plex

We have also applied T2MR to develop the T2Plex, which is a compact, fully integrated instrument capable of rapidly providing comprehensive hemostasis measurements, including platelet function, clotting time and clot degradation, also known as fibrinolysis.

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 2016, 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 $23 billion annually, almost

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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 one to six or more days to generate species-specific results.

The following table reflects key statistics from the 2016 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	$ 23.6	6.2 %
2	Osteoarthritis	16.5	4.3
3	Liveborn	13.3	3.5
4	Complication of device, implant or graft	12.4	3.3
5	Acute myocardial infarction (heart attack)	12.0	3.2

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 therefore more targeted drugs are required.

We estimate that approximately 15 million patients are tested for bloodstream infections in the United States annually. Of these, approximately 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.

Each year, over 18 million cases of sepsis are diagnosed outside of the United States, with estimated mortalities exceeding five million patients, making sepsis a leading cause of death worldwide.

Limitations of Traditional In Vitro Diagnostics for Sepsis

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

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

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Blood culture-based diagnostics have substantial limitations, including:

Time to Result Delays Targeted Treatment. Blood culture-based diagnostics typically require a minimum of one and as many as six or more days to identify a pathogen species, and blood culture always requires at least five days to generate a negative test result.

Antimicrobial Therapy Can Cause False Negative Results. Antimicrobial therapies may be administered to a patient prior to taking a blood sample. As a result, the therapeutic agent is contained in the blood sample and its ability to stop or slow the growth of pathogens can delay or completely inhibit the growth of the pathogen during the blood culture process leading to time delays in detection or false negative results.

Slow-Growing Pathogens Can Cause False Negative Results. Some sepsis pathogens grow slowly or not at all and can require up to five or more days to reach sufficient concentrations to be detected by blood culture-based diagnostics. Blood culture procedures are typically stopped after five days and declared negative. Often, pathogens that grow too slowly are not detected by blood culture during this time frame, leading to a false negative diagnosis. For example, C. glabrata, one of the most lethal species of Candida due to its growing resistance to antifungal therapy, often requires more than five days of growth to reach a detectable concentration, and therefore is frequently undetected by blood culture.

Labor-Intensive Workflow Increases Costs and May Delay Targeted Treatment. Blood culture is only the first step in identifying a pathogen that causes sepsis. After a blood culture is determined to be positive, highly trained technicians are required to perform multiple post-culture procedures on the blood culture specimen to identify the specific pathogen. These additional procedures can be expensive and time-consuming and may delay targeted treatment.

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

This inefficient therapeutic approach has resulted in unnecessary treatment of a significant number of high-risk patients with expensive and often toxic therapies that can worsen a patient’s condition. Such treatments may extend for many days while clinicians await blood culture-based diagnostic results. The overuse of ineffective, or even unnecessary, antimicrobial therapy is also the driving force behind the spread of antimicrobial-resistant pathogens, which the CDC recently called “one of our most serious health threats.” The CDC has specifically noted increasing

incidence of Candida infections due to azole- and echinocandin-resistant strains and considers it a “serious” threat level. According to the CDC, at least two million people in the United States acquire serious infections each year that are resistant to one or more of the antimicrobial therapies used to treat these patients. At least 23,000 of these people are estimated to die as a direct result of the resistant infections and many more may die from other conditions that are complicated by a resistant infection. Further, antimicrobial-resistant infections add considerable and avoidable costs to the already overburdened U.S. healthcare system, with the total economic cost estimated to be as high as $20 billion in excess of direct healthcare costs, with additional costs to society as high as $35 billion, due to lost productivity.

Our 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 our product candidate, 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

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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 in as Few as Three Hours. T2MR is the only technology that can enable species-specific results for pathogens associated with sepsis, directly from a patient's blood sample, without the need for blood culture, to deliver an actionable result in three hours.

Accurate Results Even in the Presence of Antimicrobial Therapy. T2MR is the only technology that can reliably detect pathogens associated with sepsis, including slow-growing pathogens, such as C. glabrata, directly from a patient's blood sample, even in the presence of an antimicrobial therapy.

Easy-to-Use Platform. T2MR eliminates the need for sample purification or extraction of target pathogens, enabling sample- to-result instruments that can be operated on-site by hospital staff, without the need for highly skilled technicians.

Our first FDA-cleared products, the T2Dx and T2Candida, focus on the most lethal form of common blood stream infections that cause sepsis, Candida, which has an average mortality rate of approximately 40%, 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 the T2Dx and T2Candida can decrease both the high mortality rate and excessive costs of Candida infections because these products can enable clinicians to make earlier and more informed decisions by providing positive test results to direct therapy and negative test results to reduce the use of antifungal drugs.

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 the 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

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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.

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.

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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 the T2Dx are included in the remaining tables.

Table A

T2Candida Performance Characteristics

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

Table B

Overall Sensitivity and Specificity by Test

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

Table C

Study Arm Sensitivity and Specificity by Test

	95% Confidence Interval
Specificity (Prospective tests):	

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

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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	%

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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;

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the LoD of T2Candida was demonstrated to be 1 to 3 CFU/mL depending upon the species of Candida (see Table D). In the Contrived Arm of the study, T2Candida positively detected 97.9% of the samples spiked at and above the LoD while also detecting 72.6% of all samples spiked at concentration levels below the LoD (see Table E);

in the Contrived Arm of the study, T2Candida detected 97% of cases at or above 1 CFU/mL and 70% of cases below 1 CFU/mL (see Table F);

in the Contrived Arm of the study, T2Candida detected 98% of cases at or above clinically relevant concentrations of Candida, ranging from 95% to 100% detection depending on the Candida species (see Table G);

T2Candida demonstrated an average time to positive result of 4.4 hours compared to blood culture average time to result of 129 hours;

T2Candida demonstrated an average time to negative result of 4.2 hours compared to blood culture average time to result of >120 hours; and

T2Candida has a negative predictive value of 99.8% in a standard population. Negative predictive value is the probability that subjects with a negative result truly do not have the disease.

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

Because mortality due to invasive candidiasis has remained high and unchanged for the past two decades and early initiation of appropriate antifungal therapy has been reported to reduce mortality by at least two-thirds, the rapid and accurate diagnostic capability offered by this novel technology has the potential to change the management and prognosis of the disease.

The ability to rapidly and accurately exclude the possibility of candidemia can have significant implications in clinical practice, by decreasing the number of patients who need to be on empiric antifungal therapy, and thus decreasing the incidence of resistant strains, the potential of side effects of antifungal treatment, and substantial healthcare costs.

A key advantage of T2MR over other biosensors is that it does not require culture and sample purification or preparation.

Massachusetts General Hospital Study — Science Translational Medicine

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

T2MR was tested across 320 contrived whole blood samples, each containing one of the five clinically relevant species of Candida, and was able to detect each of the species at 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.

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University of Houston Study — Diagnostic Microbiology and Infectious Disease

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

T2Candida detected all of the samples of C. glabrata at concentrations of 2.8 CFU/mL, while blood culture was not able to detect C. glabrata in any of the samples, even at a higher concentration of 11 CFU/mL and with the standard five-day run time.

T2Candida detected all of the samples for all of the species of Candida at concentration levels of 3.1 to 11 CFU/mL.

The average time to species identification was approximately three hours for T2Candida, as opposed to over 60 hours for blood culture.

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

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

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

Specificity	98	%

Clinical Data Review of T2MR and T2Candida—Future Microbiology

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

There is an urgent need to rapidly and accurately detect and identify fungal pathogens. Current culture-based methodologies are too slow and, with some organisms like C. glabrata, may fail altogether due to the insensitivity of some blood culture systems to detect this slow-growing species.

The development and FDA approval of the T2Candida Panel represents the advent of a new class of infectious disease diagnostics that enable rapid, direct detection and identification of pathogens in a culture-independent manner. The new panel will reduce the time to detection and species identification for common Candida species.

As of the date of publication of the article, the T2Candida Panel had identified over 31 cases of candidemia and 12 cases of candidiasis. In the latter 12 cases, blood culture was unable to detect any of those proven infections. There were an additional ten patients with probable or suspected invasive candidiasis, but patient record review was not available to include these cases. More specifically, across all studies to date,

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T2Candida had successfully detected 43 of 45 patients with confirmed candidemia (31/33) or candidiasis (12/12). When including patients with probable candidiasis, T2Candida detected 10 of 10 patients, totaling 53 of 55 cases detected for candidemia or candidiasis. In this aggregate population, blood culture only detected 33 of 55 patients. Table 7 from the article summarizes the data showing increases in sensitivity for T2Candida vs. blood culture.

- Across all studies to date, T2Candida had an overall specificity of greater than 99.4% from more than 1,560 patients.

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

Customer Presentations

In 2016, four customers reported on their experiences with the T2Candida Panel. Below is a summary of those reports.

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

- Investigators at the Lee Health System reported that after the implementation of T2Candida, they have experienced a reduction in the average length of stay per patient by 7 days, unnecessary antifungal therapy was avoided in 41% of patients, and unnecessary antifungal therapy was discontinued after 1 dose in another 15% of patients, and the average net antifungal savings was $195 for every patient tested with T2Candida.

- Investigators at Riverside Community Hospital reported that implementation of T2Candida led to therapy being discontinued for 100% of patients who tested negative, and for patients who tested positive and had not been on antifungals prior to testing, 83% of patients who tested positive received appropriate therapy within six hours of blood drawing and 100% within nine hours of blood draw.

· Investigators at Huntsville Hospital, showed that use of the T2Candida panel resulted in reduction in duration of therapy and time to de-escalation in negative patients. This yielded net pharmacy savings of approximately $280 per patient tested. T2Candida also detected 56% more positive patients than blood culture.

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

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musculoskeletal disorders, as well as the significant costs associated with treating these complications. Multiple diagnostic methods are used to test for Lyme disease today, which are labor-intensive, can take weeks to process, and are subject to high false negative rates due to their inability to detect the disease, making each method unreliable in the diagnosis of the condition. Because of these limitations, patients are frequently misdiagnosed or are delayed in the diagnosis of this disease.

According to the CDC, Lyme disease affects approximately 30,000 people in the U.S. each year, but the CDC also estimates that the actual number is closer to 360,000 due to under-reporting because of poor diagnostic methods. Approximately 3.4 million tests are run for Lyme disease each year, including serology testing, PCR techniques and blood culture, which has low sensitivity and takes approximately two to three weeks to provide results. Inadequate identification of Lyme disease may lead to antibiotic resistance, significant costs, and transmission of the disease through healthcare procedures such as blood transfusion. The misdiagnosis of Lyme disease has been reported to have an annual cost of more than $10,000 per patient in the United States, representing over $3 billion per year.

Our product candidate, T2Lyme is designed to identify the bacteria that cause Lyme disease directly from the patient's blood, without the need for blood culture which, for the bacteria associated with Lyme disease, can take several weeks. The test panel is expected to be run on the T2Dx Instrument, the same instrument currently used to run our T2Candida test panel and in the future, our T2Bacteria Panel product candidate. We anticipate the T2Lyme test panel to benefit from similar advantages provided by T2MR as the T2Candida 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.

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

In 2016 Dr. Tom Lowery, our Chief Scientific Officer, presented on the T2Lyme Panel at a forum titled "Diagnostic Tests for Lyme Disease: A Reassessment" held at the Banbury Center of the Cold Spring Harbor Laboratory. In this presentation he reported preliminary T2Lyme limit of detection data that consisted of N=60 replicates for each target species consisting of three spike preparations of N=20 across three successive days prepared with a quantitative spiking method. Positivity rates were ≥95% for B. afzelii and B. burgdorferi at 5 cells/mL and B. garinii at 8 cells/mL. Additionally, Dr. Lowery shared data from initial clinical samples. Samples were frozen, ethylenediaminetetraacetic acid whole blood samples from patients diagnosed with Early Stage Lyme disease at the Gunderson Clinic in

Wisconsin. All 21 samples had confirmed Erythema multiforme lesions and were tested with a Gunderson Clinic PCR test and the T2Lyme T2MR test. Only one sample tested positive by PCR, which was confirmed by T2MR. Seven additional samples were tested negative by PCR but were tested positive by T2MR. Of the 21 samples, 8 were positive for B. burgdorferi by T2MR, demonstrating that T2MR can detect Borrelia cells in blood samples from infected patients.

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 rates were 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%.

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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 the T2Plex 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.

The T2Plex and T2HemoStat are designed to utilize T2MR and are designed to provide hemostasis measurements in less than 45 minutes. Our product candidate, T2HemoStat, is a comprehensive panel of diagnostic tests that can provide data across the hemostasis spectrum, including measurements of fibrinogen, platelet activity, and clot lysis. We believe that T2HemoStat may 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 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.

The company is exploring partnership opportunities to complete the development and commercialization of these products.

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. We have added a small team of employees in Europe to support our network of European distributors.

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During 2016 we expanded our direct sales force to 18 commissioned representatives, excluding managers. 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 the 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 have received regulatory approvals in Europe and expect to seek regulatory approvals in 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 T2Candida and the T2Dx. As of the end of 2016, we had distributors in Italy, Spain, Portugal, Germany, France, Denmark, Sweden, and Norway. These distributors have extensive knowledge of infectious diseases and microbiology. They have strong, existing relationships with European thought leaders in these areas and have good relationships with important hospitals in their respective countries. We continue to develop partner relationships in other key European markets and will further investigate potential distribution channels in other key markets around the world. We have employed a small team of direct sales/marketing and field service providers to support the efforts of our distributors in the European Union, or the EU.

Manufacturing

We manufacture our proprietary T2Dx at our manufacturing facility in Lexington, Massachusetts and our T2Candida reagent trays at our manufacturing facility in Wilmington, Massachusetts. We perform all instrument and tray manufacturing and packaging of final components in accordance with applicable guidelines for medical device

manufacturing. We outsource manufacturing of our T2Candida 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.

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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 over 50 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 our 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 covering T2Candida and T2Bacteria would be expected, if issued, to expire as late as 2037. The issued patents in our patent families that cover T2HemoStat are expected to expire between 2029 and 2032, while additional pending applications covering T2HemoStat, if issued, will be expected to expire as late as 2037. The issued patents in our patent families that cover T2Lyme are expected to expire between 2023 and 2031, while additional pending applications covering T2Lyme would be expected, if issued, to expire as late as 2037. In all cases, the expiration dates are subject to any extension that may be available under applicable law.

Proprietary Rights and Processes

We rely, in some circumstances, on proprietary technology and processes (including trade secrets) to protect our technology. However, these can be difficult to protect. We require all full-time and temporary employees, scientific advisors, contractors and consultants working for us who have access to our confidential information to execute confidentiality agreements in order to safeguard our proprietary technologies, methods, processes, know-how, and trade secrets. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. All of our full-time and temporary employees and independent contractors and consultants are also bound by

invention assignment obligations, pursuant to which rights to all inventions and other types of intellectual property conceived by them during the course of their employment are assigned to us.

While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. To the extent that our employees, consultants, scientific advisors, contractors, or any future collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Further, any of our intellectual property and proprietary rights could be challenged, invalidated, circumvented, infringed or misappropriated, or such intellectual property and proprietary rights may not be sufficient to provide competitive advantages. For more information, please see “Risks Related to Intellectual Property.”

Trademarks

We 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.

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License Agreements

License Agreement with Massachusetts General Hospital

In 2006, we entered into an exclusive license agreement with MGH, pursuant to which MGH granted to us an exclusive, worldwide, sublicensable license under certain patent rights to make, use, import and commercialize products and processes for diagnostic, industrial and research and development purposes. In 2008 and 2011, we amended our agreement with MGH to add patent rights and to modify, among other things, our diligence and payment obligations.

We are required to use reasonable commercial efforts to develop and make available to the public products and processes covered by the agreement, and to achieve specified organizational, development and commercialization milestones by specified dates. To date, we have met all of our diligence obligations pursuant to this agreement.

We paid MGH an upfront fee and issued to MGH shares of our common stock equal to a low single-digit percentage of our then-outstanding common stock, subject to limited adjustments to prevent dilution in certain circumstances. In addition, we are responsible for reimbursing MGH's costs associated with prosecution and maintenance of the patent rights licensed to us under the agreement. We will also be required to make payments for achievement of specified regulatory milestones with respect to products and processes covered by the agreement. In addition, we are required to pay an annual license maintenance fee, which is creditable against any royalty payments we are obligated to make to MGH under the agreement.

We are required to pay royalties to MGH on net sales of products and processes that are covered by patent rights licensed to us under the agreement at percentages in the low single digits, subject to reductions and offsets in specified circumstances. The products and processes covered by the agreement include T2Candida, T2Bacteria and other particle-based T2MR panels that we may develop in the future. Our royalty obligations, if any, and their duration, will depend on the specific patent rights covering the product or process being sold, and the particular category of product or process, as noted above. With respect to T2Candida and T2Bacteria and other potential particle-based T2MR panels we may develop in the future, our obligation to pay royalties to MGH will expire upon the later of ten years after the first commercial sale of the first product or process in the particular category and the expiration of the patent rights licensed to us under the agreement. We will also be required to pay to MGH a low double-digit percentage of specified gross revenue that we receive from our sublicensees. In addition, we will be required to pay royalties to MGH of less than one percent on net sales of specified products and processes that are not covered by the patent rights licensed to us under the agreement. Our obligation to pay royalties to MGH with respect to such products and processes will expire upon the earlier of 12 years after the first commercial sale of the first such product or process and the termination by MGH of all of the licenses granted to us under the agreement.

We have the right to terminate our agreement with MGH for any reason upon 90 days' written notice to MGH. MGH may terminate our agreement in its entirety if we fail to make a payment required under the agreement and do not cure such failure within a specified time period, if we fail to maintain adequate insurance coverage or if we become insolvent. MGH may also terminate our agreement, with respect to a given category of products or processes, on 60 days' notice for our uncured breach with respect to such category of products or processes. Absent earlier termination, our agreement with MGH will remain in force until the later of the expiration or abandonment of the licensed patents and patent applications, and the expiration of our obligations under the agreement.

Supply Agreement with SMC Ltd.

We are currently party to a supply agreement with SMC Ltd. for the supply and manufacture of 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

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purchasing finished products, inventory, raw materials and work-in-progress held by SMC to the extent SMC, after the use of commercially reasonable efforts to use such inventory, cannot use such inventory in a financially viable way.

Competition

While we believe that we are currently the only diagnostic company 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, we compete with commercial diagnostics companies for the limited resources of our customers. Our principal competition is from a number of companies that offer platforms and applications in our target sepsis 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. (and its affiliate, BioFire Diagnostics, Inc.), Bruker Corporation, Accelerate Diagnostics, Luminex, Genmark, Cepheid and Beckman Coulter, a Danaher company. These post-culture competitors rely on a positive result from blood culture in order to perform their tests, significantly prolonging their results when compared to T2MR. Some of the products offered by our competitors require hours of extensive hands-on labor by an operator, while some rely on high concentrations of pathogens present in a positive blood culture, which can require a final concentration of at least 1,000,000 CFU/mL. In addition, there may be a number of new market entrants in the process of developing other post-blood culture diagnostic technologies that may be perceived as competitive with our technology.

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;

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- 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 our 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

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

Pre-market Approval Process

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

After a PMA application is submitted and filed, the FDA begins an in-depth review of the submitted information, which typically takes between one and three years, but may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA will usually be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with Quality System Regulation, or QSR, which imposes elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process. The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long-term follow-up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. New PMA applications or supplements are required for significant modifications to the manufacturing process, labeling of the product and design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an original PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

De novo Classification Process

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification procedure. This procedure allows a manufacturer whose novel device is automatically classified

into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, in July 2012, a medical device could only be eligible for de novo classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the de novo classification pathway by permitting manufacturers to request de novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, FDA is required to classify the device within 120 days following receipt of the de novo application. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. We utilized the de novo classification process to obtain marketing clearance for our T2Dx and T2Candida devices, which were given a Class II designation. We received marketing clearance for these devices from the FDA on September 22, 2014.

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Clinical Trials

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

Pervasive and Continuing U.S. Food and Drug Administration Regulation

After a medical device is placed on the market, numerous FDA regulatory requirements apply, including, but not limited to the following:

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

- establishment registration, which requires establishments involved in the production and distribution of medical devices, intended for commercial distribution in the United States, to register with the FDA;

- medical device listing, which requires manufacturers to list the devices they have in commercial distribution with the FDA;

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

post-market surveillance including Medical Device Reporting, which requires manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury, or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

The FDA enforces these requirements by inspection and market surveillance. Failure to comply with applicable regulatory requirements may result in enforcement action by the FDA, which may include one or more of the following sanctions:

untitled letters or warning letters;

fines, injunctions and civil penalties;

mandatory recall or seizure of our products;

administrative detention or banning of our products;

operating restrictions, partial suspension or total shutdown of production;

refusing our request for 510(k) clearance or pre-market approval of new product versions;

revocation of 510(k) clearance or pre-market approvals previously granted; and

criminal prosecution and penalties.

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International Regulation

Sales of medical devices outside the United States are subject to foreign government regulations, which vary substantially from country to country. In order to market our products in other countries, we must obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ significantly.

In the European Economic Area, or EEA, which comprises the 28 Member States of the EU plus Liechtenstein, Norway and Iceland, in vitro medical devices are required to conform with the essential requirements of the EU Directive on in vitro diagnostic medical devices (Directive 98/79/EC, as amended). To demonstrate compliance with the essential requirements, the manufacturer must undergo a conformity assessment procedure. The conformity assessment varies according to the type of medical device and its classification. For low-risk devices, the conformity assessment can be carried out internally, but for higher risk devices (self-test devices and those included in List A and B of Annex II of Directive 98/79/EC) it requires the intervention of an accredited EEA Notified Body. If successful, the conformity assessment concludes with the drawing up by the manufacturer of an EC Declaration of Conformity entitling the manufacturer to affix the CE mark to its products and to sell them throughout the EEA. We concluded an assessment of the conformity of the T2Dx and T2Candida with the EU in vitro diagnostic medical devices directive in late 2014, based upon an EC Declaration of Conformity dated July 7, 2014 and updated on September 9, 2015 and May 26, 2016, allowing us to affix the CE mark to these products.

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

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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 the Affordable Care Act includes in its reporting requirements a broad range of transfers of value including, but not limited to, consulting fees, speaker honoraria, charitable contributions, research payments and grants. We collect data annually and report it to the Centers for Medicare & Medicaid Services, or CMS, no later than the last day of March each year. Failure to report could subject companies to significant financial penalties. Tracking and reporting the required payments and transfers of value may result in considerable expense and additional resources. Several states currently have similar laws and more states may enact similar legislation, some of which may be broader in scope. For example, certain states require the implementation of compliance programs, compliance with industry ethics codes, implementation of gift bans and spending limits, and/or reporting of gifts, compensation and other remuneration to healthcare professionals.

We also may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH, through its implementing regulations, makes certain of HIPAA's privacy and security standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains or transmits protected health information for or on behalf of a covered entity for a function or activity regulated by HIPAA. In addition to HIPAA criminal penalties, HITECH created four new tiers of civil and monetary penalties and gave state attorney generals 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

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penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Coverage and Reimbursement

Maintaining and growing sales of our products and product candidates depends in large part on the availability of adequate coverage and reimbursement from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. These third-party payors are increasingly limiting coverage and reducing reimbursement for medical products and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls and restrictions on coverage and reimbursement. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our products and/or product candidates or a decision by a third-party payor to not cover our products and/or product candidates could reduce physician utilization of our products, if approved, and have a material adverse effect on our sales, results of operations and financial condition.

Hospitals, clinical laboratories and other healthcare provider customers that may purchase our products and/or product candidates generally bill various third-party payors to cover all or a portion of the costs and fees associated with diagnostic tests, including the cost of the purchase of our products and/or product candidates. We currently expect that the majority of our diagnostic tests will be performed in a hospital inpatient setting, where governmental payors, such as Medicare, generally reimburse hospitals with a single bundled payment that is based on the patients' diagnosis under a classification system known as the Medicare severity diagnosis-related groups, or MS-DRGs, classification for all items and services provided to the patient during a single hospitalization, regardless of whether our diagnostic tests are performed during such hospitalization. To the extent that our diagnostic tests will be performed in an outpatient setting, our products and/or product candidates may be eligible for separate payment using existing Current Procedural Terminology, or CPT, codes. Third-party payors may deny coverage, however, if they determine that our products are not cost-effective as determined by the payor, or are deemed by the third-party payor to be experimental or medically unnecessary. We are unable to predict at this time whether our products and/or product candidates, if approved, will be covered by third-party payors. Nor can we predict at this time the adequacy of payments, whether made separately in an outpatient setting or with a bundled payment amount in an inpatient setting. Our customers' access to adequate coverage and reimbursement for our products and/or product candidates by government and private insurance plans is central to the acceptance of our products. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels.

Healthcare Reform

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

- 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.

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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 $24.0 million for the year ended December 31, 2016, $25.4 million for the year ended December 31, 2015 and $19.8 million for the year ended December 31, 2014. Research and development expenses represented 44% of our total costs and expenses for the year ended December 31, 2016, 55% of our total costs and expenses for the year ended December 31, 2015 and 64% of our total costs and expenses for the year ended December 31, 2014. 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 diagnostics area. We are continuing our development of T2Bacteria and have initiated the collection of samples to support clinical trials for T2Bacteria through 2017. We believe that technical advantage is important to sustain a competitive advantage, and therefore our research and development efforts are focused on the continued enhancement of our 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, 2016, we had 178 full-time employees, of which 70 work in operations (which includes manufacturing, service and support, clinical and regulatory support, quality control and quality assurance), 52 in research and development, 26 in general and administrative and 30 in sales and marketing.

Facilities

Our corporate headquarters is located in Lexington, Massachusetts, where we currently lease approximately 32,400 square feet of office space, 22,800 square feet of laboratory space and 4,600 square feet of manufacturing space in various facilities. Our base rent, for leases at our corporate headquarters, is $1.9 million annually. We also lease approximately 7,600 square feet in Wilmington, Massachusetts for our manufacturing facility, under a lease that expires in 2017 for $68,000 of base rent annually.

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

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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, 2016 and expect to incur losses in the future. Our accumulated deficit as of December 31, 2016 was $203.7 million and we incurred net losses of $54.8 million for the year ended December 31, 2016, and $45.3 million and $31.4 million for the years ended December 31, 2015 and 2014, respectively. We expect that our losses will continue for at least the next few years as we will be required to invest significant additional funds toward the continued development and commercialization of our technology. 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, and obtaining regulatory clearance or approval for our products currently under development. Our ability to achieve or sustain profitability depends on numerous factors, many of which are beyond our control, including the market acceptance of our products and future product candidates, future product development, our ability to achieve marketing clearance from the FDA and international regulatory clearance for future product candidates, our ability to compete effectively against an increasing number of competitors and new products, and our market penetration and margins. 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 clearance 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;

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

These hurdles may make it difficult to demonstrate to physicians, hospitals and other healthcare providers that our current diagnostic products and future product candidates are appropriate options for diagnosing sepsis 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 with adequate clinical sensitivity and specificity, the revenue opportunity for this product candidate could be limited or not realized at all.

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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 clearance to sell our initial sepsis products in the third quarter of 2014, we have limited experience marketing and selling our products. As of December 31, 2016, our direct sales organization, including marketing, consisted of 30 employees. 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 sell our products through distribution partners and there is no guarantee that we will be successful in attracting or retaining desirable distribution partners for these markets or that we will be able to enter into such arrangements on favorable terms. Distributors may not commit the necessary resources to market and sell our products effectively or may choose to favor marketing the products of our competitors. If distributors do not perform adequately, or if we are unable to enter into effective arrangements with distributors in particular geographic areas, we may not realize international sales and growth.

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 a period-to-period basis. Expected revenue streams are highly dependent on hospitals' adoption of our consumables-based business model, and we cannot assure you that our potential hospital clients will follow a consistent purchasing pattern. Moreover, it is difficult for us to forecast our revenue as it is dependent upon our ability to convince the medical community of the clinical utility and economic benefits of our products and their potential advantages over existing diagnostic tests, the willingness of hospitals to utilize our products and the cost of our products to hospitals. In addition, we only recently started selling the T2Dx and T2Candida products and have a

limited 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 T2Bacteria 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.

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

During the past few years, we have significantly expanded our operations. We expect this expansion to continue to an even greater degree as we continue to commercialize our initial sepsis products, continue to build a targeted sales force and as we seek marketing clearance from the FDA and international 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 suppliers, we may not be able to continue to grow or we may grow at a slower pace than expected and our business could be adversely affected.

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

We believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements for at least the next 12 months from the date of issuance of these consolidated financial statements. 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 clearance from the FDA and international regulatory clearance to market our future product candidates;

market acceptance of our products and product candidates;

the cost and timing of establishing sales, marketing and distribution capabilities;

the cost of our research and development activities;

the ability of healthcare providers to obtain coverage and adequate reimbursement by third-party payors for procedures using our products and product candidates;

the cost and timing of marketing clearance or regulatory clearances;

the cost of goods associated with our products and product candidates;

the effect of competing technological and market developments; and

the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for products or technology.

We cannot assure you that we will be able to obtain additional funds on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or

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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 market our initial sepsis products to the approximately 450 leading hospitals in the United States in which the top one-third of patients at highest risk of suffering from sepsis are concentrated. We are also targeting the top-tier hospitals in each of the European markets where we currently sell our products. 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 product candidates, and the loss of any of these suppliers could have an adverse impact on our business.

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

While we believe replacement suppliers exist for all components and materials we obtain from single sources, establishing additional or replacement suppliers for any of these components or materials, if required, may not be accomplished quickly. Even if we are able to find a replacement supplier, the replacement supplier would need to be

qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single-source components and materials used in our products in the event of disruption, those inventories may not be sufficient.

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

If we are unable to recruit, train and retain key personnel, we may not achieve our goals.

Our future success depends on our ability to recruit, 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

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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 future success will depend on the market's confidence that our technologies can provide reliable, high-quality diagnostic results. We believe that our customers are likely to be particularly sensitive to any defects or errors in our products. If our technology fails to detect the presence of Candida or another bacterial pathogen and a patient subsequently suffers from sepsis, or if our technology fails to detect impaired hemostasis and a patient faces 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.

While the technology of our products and product candidates is different than other products currently available, we compete with commercial diagnostics companies for the limited resources of our customers. In this regard, our principal competition is from a number of companies that offer platforms and applications in our target sepsis and hemostasis markets, most of which are more established commercial organizations with considerable name recognition and significant financial resources.

We compete with companies that currently provide traditional blood culture-based diagnostics, including Becton Dickinson & Co. and bioMerieux, Inc. In addition, companies offering post-culture species identification using both molecular and non-molecular methods include bioMerieux, Inc. (and its affiliate, BioFire Diagnostics, Inc.), Bruker Corporation, Accelerate Diagnostics, Luminex, Genmark, Cepheid and Beckman Coulter, a Danaher company.

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;

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- speed, accuracy and reproducibility of results; and

- ability to implement a consumables-based model for panels.

We believe that additional competitive factors specific to the diagnostics market include:

- breadth of clinical decisions that can be influenced by information generated by diagnostic tests;

- volume, quality and strength of clinical and analytical validation data;

- availability of adequate reimbursement for testing services and procedures for healthcare providers using our products; and

- economic benefit accrued to hospitals based on the total cost to treat a patient for a health condition.

We cannot assure you that we will effectively compete or that we will be successful in the face of increasing competition from new products and technologies introduced by our existing competitors or new companies entering our markets. In addition, we cannot assure you that our future competitors do not have or will not develop products or technologies that enable them to produce competitive products with greater capabilities or at lower costs than our products and product candidates. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

Undetected errors or defects in our products or product candidates could harm our reputation, decrease market acceptance of our products or expose us to product liability claims.

Our products or product candidates may contain undetected errors or defects. Disruptions or other performance problems with our products or product candidates may damage our customers' businesses and could harm our reputation. If that occurs, we may incur significant costs, the attention of our key personnel could be diverted or other significant customer relations problems may arise. We may also be subject to warranty and liability claims for

damages related to errors or defects in our products or product candidates. A material liability claim or other occurrence that harms our reputation or decreases market acceptance of our products or product candidates could harm our business and operating results.

The sale and use of products or product candidates or services based on our technologies, or activities related to our research and clinical studies, could lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We cannot assure you that our product liability insurance would adequately protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

We may not be able to develop new product candidates or enhance the capabilities of our systems to keep pace with our industry's rapidly changing technology and customer requirements, which could have a material adverse impact on our revenue, results of operations and business.

Our industry is characterized by rapid technological changes, frequent new product introductions and enhancements and evolving industry standards. Our success depends on our ability to develop new product candidates and applications for our technology in new markets that develop as a result of technological and scientific advances, while improving the performance and cost-effectiveness of our existing product candidates. New technologies, techniques or products could emerge that might offer better combinations of price and performance than the products and systems that we plan to sell. Existing markets for our intended diagnostic product candidates are characterized by rapid technological change and innovation. It is critical to our success that we anticipate changes in technology and customer requirements and physician, hospital and healthcare provider practices and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost-effective basis. At the same time, however, we must carefully manage our introduction of new products. If potential customers believe that such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such

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products are available. We may also have excess or obsolete inventory of older products as we transition to new products, and we have no experience in managing product transitions. If we do not successfully innovate and introduce new technology into our anticipated product lines or manage the transitions of our technology to new product offerings, our revenue, results of operations and business will be adversely impacted.

Competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. We anticipate that we will face strong competition in the future as expected competitors develop new or improved products and as new companies enter the market with new technologies and products.

We are developing additional product candidates that we intend to be used with the T2Dx, including T2Bacteria for the detection of certain strains of sepsis-causing bacteria and T2Lyme for the detection of certain strains of Lyme disease-causing bacteria. We are also developing the T2Plex, which we previously referred to as the 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 and assemble our current and proposed products in sufficient quantities and on a timely basis so as to meet consumer demand, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. We are subject to numerous risks relating to our manufacturing capabilities, including:

- quality or reliability defects in product components that we source from third party suppliers;
- our inability to secure product components in a timely manner, in sufficient quantities or on commercially reasonable terms;
- our failure to increase production of products to meet demand;
- the challenge of implementing and maintaining acceptable quality systems while experiencing rapid growth;
- our inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements; and
- difficulty identifying and qualifying alternative suppliers for components in a timely manner.

As demand for our products increases, we will need to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes and quality systems. If we fail to increase our production capacity efficiently while also maintaining quality requirements, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline. In addition, although we expect some of our product candidates to share product features and components with the T2Dx and the 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. Any future interruptions we experience in the manufacturing or shipping of our products could delay our ability to recognize revenues in a particular quarter and could also adversely affect our relationships with our customers.

We currently develop, manufacture and test our products and product candidates and some of their components in two facilities. If these or any future facility or our equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed.

We currently develop our diagnostic products exclusively in a facility in Lexington, Massachusetts and manufacture and test some components of our products and product candidates in, both, Wilmington and Lexington, Massachusetts. If these or any future facility were to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages,

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or otherwise, or if our business is disrupted for any other reason, we may not be able to develop or test our products and product candidates as promptly as our potential customers expect, or possibly not at all.

The manufacture of components of our products and product candidates at our Wilmington facility involves complex processes, sophisticated equipment and strict adherence to specifications and quality systems procedures. Any unforeseen manufacturing problems, such as contamination of our facility, equipment malfunction, or failure to strictly follow procedures or meet specifications, could result in delays or shortfalls in production of our products. Identifying and resolving the cause of any manufacturing issues could require substantial time and resources. If we are unable to keep up with future demand for our products by successfully manufacturing and shipping our products in a timely manner, our revenue growth could be impaired and market acceptance of our product candidates could be adversely affected.

We maintain insurance coverage against damage to our property and equipment, subject to deductibles and other limitations that we believe is adequate. If we have underestimated our insurance needs with respect to an interruption, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses.

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

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

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

Our credit facilities require us, and any debt instruments we may enter into in the future may require us, to comply with various covenants that limit our ability to, among other things:

convey, lease, sell, transfer, assign or otherwise dispose of assets;

change the nature or location of our business;

complete mergers or acquisitions;

incur indebtedness;

encumber assets;

pay dividends or make other distributions to holders of our capital stock (other than dividends paid solely in common stock);

make specified investments;

change certain key management personnel; and

engage in material transactions with our affiliates.

These restrictions could inhibit our ability to pursue our business strategies. If we default, which includes a material adverse change, under our credit facilities, and such event of default was not cured or waived, the lenders could terminate commitments to lend and cause all amounts outstanding with respect to the debt to be due and payable immediately, which in turn could result in cross defaults under other debt instruments. Our assets and cash flow may not be sufficient to fully repay borrowings under all of our outstanding debt instruments if some or all of these instruments are accelerated upon a default.

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We may incur additional indebtedness in the future. The debt instruments governing such indebtedness could contain provisions that are as, or more, restrictive than our existing debt instruments. If we are unable to repay, refinance or restructure our indebtedness when payment is due, the lenders could proceed against the collateral granted to them to secure such indebtedness or force us into bankruptcy or liquidation.

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

We intend to enter into strategic relationships with third parties for future diagnostic products. However, there is no assurance that we will be successful in doing so. Establishing strategic relationships can be difficult and time-consuming. Discussions may not lead to agreements on favorable terms, if at all. To the extent we agree to work exclusively with a party in a given area, our opportunities to collaborate with others or develop opportunities independently could be limited. Potential collaborators or licensors may elect not to work with us based upon their assessment of our financial, regulatory or intellectual property position. Even if we establish new strategic relationships, they may never result in the successful development or commercialization of future products.

Acquisitions or joint ventures could disrupt our business, cause dilution to our stockholders and otherwise harm our business.

We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses. We have not made any acquisitions to date, and our ability to do so successfully is unproven. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with future customers or with current or future distributors or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;

diversion of management time and focus from operating our business to acquisition integration challenges;

increases in our expenses and reductions in our cash available for operations and other uses;

possible write-offs or impairment charges relating to acquired businesses; and

inability to develop a sales force for any additional product candidates.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the anticipated benefit of any acquisition may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

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

If treatment guidelines for sepsis change, or the standard of care evolves, we may need to redesign and seek new marketing clearance from the FDA for our products. For example, current treatment recommendations for Candida infections, including those published by the Infectious Diseases Society of America, call for identical treatment for two species of Candida, C. albicans and C. tropicalis, and identical treatment for two other species, C. glabrata and

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C. krusei. Although our T2Candida test is technically capable of distinguishing among these species, we have designed it based on current treatment guidelines and therefore it does not distinguish between two species if they are subject to the same recommended treatment. Our FDA clearance to market the T2Dx and T2Candida in the United States is also based on current treatment guidelines. If treatment guidelines change so that different treatments become desirable for the two species currently subject to the same recommended treatment, the clinical utility of our T2Candida test could be diminished and we could be required to seek marketing clearance from the FDA for a revised test that would distinguish between the two species.

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

As of December 31, 2016, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of $174.9 million, which are available to offset future taxable income, if any, through 2036. 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 generate a portion of our revenue internationally and are subject to various risks relating to our international activities which could adversely affect our operating results.

A portion of our revenue comes from international sources, and we anticipate that we will continue to 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;

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- 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

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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