T2 Biosystems, Inc.
Form 10-K
March 19, 2018

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, 2017

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number: 001-36571

T2 Biosystems, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

Title of Each Class:	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, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer" "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. Yes No

As of June 30, 2017, 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 $58.6 million based on the closing price for the common stock of $3.21 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 14, 2018 was 36,019,800. 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,” “forecast,” “predict,” “potential” or “c negative of these terms or other similar expressions. The forward-looking statements in this Annual Report on Form 10-K are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described under the sections in this Annual Report on Form 10-K entitled “Item 1A.—Risk Factors”. These forward looking statements are subject to numerous risks, including, without limitation, the following:

- our status as an early stage company;

- our expectation to incur losses in the future;
- the market acceptance of our T2MR technology;
- our ability to timely and successfully develop and commercialize our existing products and future product candidates;
- the length and variability of our anticipated sales cycle;
- our limited sales history;
- our ability to gain the support of leading hospitals and key thought leaders and publish the results of our clinical trials in peer-reviewed journals;
- our ability to successfully manage our growth;
- our future capital needs and our ability to raise additional funds;
- the performance of our diagnostics;
- our ability to compete in the highly competitive diagnostics market;
- our ability to obtain marketing clearance from the FDA or regulatory clearance for new product candidates in the United States or any other jurisdiction;
- federal, state, and foreign regulatory requirements, including diagnostic product reimbursements and FDA regulation of our product candidates;
- our ability to protect and enforce our intellectual property rights, including our trade secret-protected proprietary rights in T2MR;
- our ability to recruit, train and retain key personnel;
- our dependence on third parties;
- our ability to continue as a going concern;
- manufacturing and other product risks;
- the impact of the adoption of new accounting standards; and
- the Tax Cuts and Jobs Act of 2017 (Tax Reform)

These forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report on Form 10-K. Unless required by U.S. federal securities laws, we do not intend to update any of these forward-looking statements to reflect circumstances or events that occur after the statement is made or to conform these statements to actual results. The following discussion should be read in conjunction with the financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors.

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

PART I.

Item 1. BUSINESS

Overview

We are an in vitro diagnostics company that has developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. We are using our T2 Magnetic Resonance 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 1,200 hospitals with the highest concentration of patients at risk for sepsis-related infections. Internationally, we have primarily partnered with distributors that target large hospitals in their respective international markets.

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. On September 8, 2017 the Company filed a 510(k) premarket submission for the T2Bacteria Panel with the FDA. 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%. Based on data published by the U.S. Department of Health and Human Services in 2017, the cost of sepsis was over $27 billion in the United States, building on data from 2013 demonstrating that sepsis was responsible for 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 if a blood culture tests positive. These methods have substantial diagnostic limitations that lead to a high rate of false negative test results, a delay of up to several days in administration of targeted treatment, and the incurrence of unnecessary hospital expense. In addition, the Survey of Physicians’ Perspectives and Knowledge About Diagnostic Tests for Bloodstream Infections in 2015 reported that negative blood culture results are only trusted by 36% of those physicians. Without the ability to rapidly identify pathogens, physicians typically start treatment of at-risk patients with broad-spectrum antibiotics and switch therapies every 12 to 24 hours if a patient is not responding. These drugs, which can be costly, are often ineffective and unnecessary and have contributed to the spread of antimicrobial resistance. The speed to getting the patient on the right targeted therapy is critical. According to a study published by Critical Care Medicine in 2006, in sepsis patients with documented hypotension, administration of effective antimicrobial therapy within the first hour of detection was associated with a survival rate of 79.9% and, over the ensuing six hours, each hour of delay in initiation of treatment was associated with an average decrease in survival of 7.6%.

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.

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.

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

bacteria included in the panel, directly from whole blood. The bacteria species included in the product candidate currently under review by the FDA are Staphylococcus aureus, Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, and Pseudomonas aeruginosa. The five bacteria species in our T2Bacteria Panel are responsible for about half of all septic infections. Additionally, when combined with the use of T2Candida and the practice of empirically administering broad spectrum antibiotics, the rapid detection of these bacteria may enable 90% of patients with sepsis to receive rapid and appropriate therapy. The T2Bacteria Panel that is CE Marked includes A. baumannii, which has an estimated incidence rate of 3.6% in Europe, far higher than the 1% incidence rate in the United States.

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, median 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. 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 T2Candida testing. In addition, antifungal

therapy was discontinued for 100% of the patients who tested negative with T2Candida. Finally, data were presented at the Infectious Disease Society of America annual meeting, IDWeek, demonstrating that T2Candida is more sensitive and more rapid than blood culture for the identification of Candida. This study, the DIRECT2 study, also showed that T2Candida is superior to blood culture when detecting patients with proven infection but are receiving antifungal therapy due to the corresponding suppression of growth in the blood culture system. T2Candida is uninhibited by antifungal therapy; thus, providing a sensitivity of 94.5% compared to blood culture, which was 49.3% sensitive in the study.

We continue to see the clinical evidence of the benefits of the T2Candida test grow. Three recent, peer-reviewed studies further demonstrate the benefit of the T2Candida test. These studies present results of the high clinical sensitivity of T2Candida and that time to appropriate therapy may be greatly reduced with T2Candida. Additionally, the studies show that the use of T2Candida may correspond to significant reductions in certain types of Candida infections.

Study 1:

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

Study 2:

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

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

Study 3:

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

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 internationally, 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 in the United States, T2Bacteria, 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 and expect to initiate a T2Lyme clinical trial in 2018. In early 2017 we initiated a multi-site clinical trial for T2Bacteria, in July 2017 received authorization to affix a CE Mark which clears the product for use in Europe and other countries that accept the CE mark and on September 8, 2017 the Company filed a 510(k) premarket submission for the T2Bacteria Panel with the FDA. We have launched T2Bacteria commercially in Europe and other countries that accept the CE mark and will commercialize T2Bacteria and these product candidates in the US and other countries after obtaining appropriate 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 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, T2Bacteria and the T2Dx internationally through distributors that target large hospitals in their respective markets. We intend to continue to expand in international markets through similar distribution channels. We have received CE marking for T2Candida, T2Bacteria and the T2Dx.

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.

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 early 2017 we initiated a multi-site clinical trial for T2Bacteria, in July 2017 received authorization to affix a CE Mark and on September 8, 2017 the Company filed a 510(k) premarket submission for the T2Bacteria Panel with the FDA.

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 double that of acute myocardial infarction. New data on the number of sepsis cases in the United States published by the U.S. Department of Health and Human Services in 2017 indicate that the economic burden now exceeds $27 billion. 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:

	U.S. hospital costs	Percentage of total

Rank	Condition	(in billions)	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.

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 Sepsis Solution

We believe our T2 Magnetic Resonance technology, or T2MR, delivers a rapid, sensitive and simple diagnostic platform to enable sepsis applications that can identify specific sepsis pathogens directly from an unpurified blood sample in hours instead of days at a level of accuracy equal to or better than blood culture-based diagnostics. The T2Sepsis Solution refers to the approach of combining the standard of care for the management of sepsis patients, including the T2Dx Instrument, or the T2Dx, and T2Candida Panel, and the T2Bacteria Panel, which is commercially available in Europe and other countries that accept the CE mark and currently available for research use only in the United States. Currently, initial empiric therapy typically only covers approximately 60% of patients with sepsis infections. Of the remaining 40% of patients with sepsis infections, approximately 30% of the patients have a bacterial infection and 10% have Candida infections. Test panels included in the T2Sepsis Solution are designed to identify pathogens commonly not covered by initial empiric antimicrobial therapy, which we believe may enable physicians to effectively treat approximately 90% of the patients who are not on the right drugs.

We believe the T2Sepsis Solution provides a pathway for more rapid and targeted treatment of infections, potentially reducing the mortality rate by as much as 50% if a patient is treated within 12 hours of suspicion of infection and significantly reducing the cost burden of sepsis. Each year, approximately 500,000 patients in the United States die from sepsis. According to a study published by Critical Care Medicine in 2006, in sepsis patients with documented hypotension, administration of effective antimicrobial therapy within the first hour of detection was associated with a survival rate of 79.9% and, over the ensuing six hours, each hour of delay in initiation of treatment was associated with an average decrease in survival of 7.6%. According to such study, the survival rate for septic patients who remained untreated for greater than 36 hours was approximately 5%. The toll of sepsis on a patient's health can be severe: more than one-in-five patients die within two years as a consequence of sepsis. Sepsis is also the most prevalent and costly cause of hospital readmissions.

We believe the T2Sepsis Solution addresses a significant unmet need in in vitro diagnostics by providing:

- Limits of Detection as Low as 1 CFU/mL. T2MR is the only technology currently available that can enable identification of sepsis pathogens directly from a patient's blood sample at limits of detection as low as 1 CFU/mL.
- Rapid and Specific Results in as Few as Three Hours. T2MR is the only technology that can enable species-specific results for pathogens associated with sepsis, directly from a patient's blood sample, without the need for blood culture, to deliver an actionable result in three hours.
- Accurate Results Even in the Presence of Antimicrobial Therapy. T2MR is the only technology that can reliably detect pathogens associated with sepsis, including slow-growing pathogens, such as C. glabrata, directly from a patient's blood sample, even in the presence of an antimicrobial therapy.
- Easy-to-Use Platform. T2MR eliminates the need for sample purification or extraction of target pathogens, enabling sample- to-result instruments that can be operated on-site by hospital staff, without the need for highly skilled technicians.

Our first U.S. Food and Drug Administration, or FDA-cleared products, the T2Dx and T2Candida, focus on the most lethal form of common blood stream infections that cause sepsis, Candida, which has an average mortality rate of approximately 40%. According to a 2005 report published in Antimicrobial Agents and Chemotherapy, this high mortality rate can be reduced to 11% with the initiation of targeted therapy within 12 hours of presentation of symptoms. Currently, a typical patient with a Candida infection averages 40 days in the hospital, including nine days in intensive care, resulting in an average cost per hospital stay of over $130,000 per patient. In a study published in the American Journal of Respiratory and Critical Care Medicine in 2009, providing targeted antifungal therapy within 24

hours of the presentation of symptoms decreased the length of hospital stay by approximately ten days and decreased the average cost of care by approximately $30,000 per patient. In addition, many hospitals initiate antifungal drugs, such as Caspofungin or Micafungin, while waiting for blood culture-based diagnostic results. We estimate this practice costs approximately $500 per patient and is currently in use for over 40% of high-risk patients on average and for all high-risk patients in some hospitals. A negative result from T2Candida can provide timely data allowing physicians to avoid unnecessary antifungal treatment and potentially reduce the treatment cost further.

We believe that by identifying the specific species of Candida, physicians can administer the most effective therapy, significantly improving patient outcomes and reducing hospital costs. We further believe that the adoption of the T2Dx and T2Candida can decrease both the high mortality rate and excessive costs of Candida infections because these products can enable clinicians to make earlier and more informed decisions by providing positive test results to direct therapy and negative test results to reduce the use of antifungal drugs.

T2Bacteria, a multiplex diagnostic panel that detects the major bacterial pathogens associated with sepsis that are frequently not covered by first-line antibiotics, is CE-Marked and available commercially in Europe and other countries that accept the CE mark, as well as available as a research-use-only product in the United States. T2Bacteria runs on the T2Dx, and if cleared by the FDA for sale in the United States is expected to address the same approximately 6.75 million symptomatic high-risk patients as T2Candida while also expanding our reach to an additional two million people presenting with symptoms of infection in the emergency room setting. We believe that these factors make the United States market

opportunity for T2Bacteria over $1.0 billion, and that T2Bacteria has the potential to achieve similar performance capabilities and provide similar benefits as T2Candida.

To the extent that our T2Bacteria panel is performed on an outpatient basis, third-party payors may separately reimburse our customers using existing CPT codes. By way of example, Medicare payment for outpatient clinical laboratory services is the lesser of the amount billed, the local fee for a geographic area, or the national limit established by the Centers for Medicare & Medicaid Services under the Clinical Laboratory Fee Schedule, or CLFS, on an annual basis. For 2017, the national limit for the series of CPT codes used to bill the T2Bacteria panel is approximately $220. Effective January 1, 2018, CLFS rates will be based on weighted median private payor rates as required by the Protecting Access to Medicare Act of 2014. We believe that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our diagnostic products or additional pricing pressures.

Clinical Utility

T2Candida

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

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

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

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

50 known negative samples and 250 contrived samples (50 samples for each of the five Candida species included in the T2Candida Panel) were prepared and run in a blinded manner at the same clinical sites used for processing the prospective samples. The positive contrived samples were prepared by spiking clinical isolates into individual patient specimens at concentrations determined through publications and discussions with the FDA to be equivalent to the clinical state of patients who presented with symptoms of a Candida infection. 20% of the positive contrived samples

were spiked at concentrations levels of less than 1 CFU/mL. The contrived samples were collected from patients referred for a diagnostic blood culture per routine standard of care — the same population of patients from whom prospective samples were collected. Unique isolates of the species were used for each patient sample, which means a total of 50 unique isolates were tested for each of the five species of Candida for a total of 250 unique isolates.

In addition to the pivotal clinical trial data that we submitted to the FDA, we also provided data from an analytical verification study to determine the limit of detection, or LoD, for each species identified by our T2Candida 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 DIRECT trial. Each are listed in abbreviated form in the tables below. These species are Candida albicans, Candida tropicalis, Candida parapsilosis, Candida krusei, and Candida glabrata. The typical naming convention for a species is to abbreviate by using the first letter of the first word and the full second word; for example, Candida krusei is

abbreviated as C. krusei. In the tables below, we also abbreviate each species name by the first letter of the second word; for example, Candida albicans and Candida tropicalis is A/T.

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

Table A

T2Candida Performance Characteristics

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

Table B

Overall Sensitivity and Specificity by Test

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

Table C

Study Arm Sensitivity and Specificity by Test

		95% Confidence Interval		
Specificity (Prospective tests):				
A/T (C. albicans/C. tropicalis)	1479/1497 (98.8%)	98.1 -	99.3	%
P (C. parapsilosis)	1487/1499 (99.2%)	98.6 -	99.6	%
K/G (C. krusei/C. glabrata)	1499/1500 (99.9%)	99.6 -	100.0	%
Total:	4465/4496 (99.3%)	99.0 -	99.5	%

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

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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;
- the LoD of T2Candida was demonstrated to be 1 to 3 CFU/mL depending upon the species of Candida (see Table D). In the Contrived Arm of the study, T2Candida positively detected 97.9% of the samples spiked at and above the LoD while also detecting 72.6% of all samples spiked at concentration levels below the LoD (see Table E);
- in the Contrived Arm of the study, T2Candida detected 97% of cases at or above 1 CFU/mL and 70% of cases below 1 CFU/mL (see Table F);
- in the Contrived Arm of the study, T2Candida detected 98% of cases at or above clinically relevant concentrations of Candida , ranging from 95% to 100% detection depending on the Candida species (see Table G);
- T2Candida demonstrated an average time to positive result of 4.4 hours compared to blood culture average time to result of 129 hours;

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

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

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

Massachusetts General Hospital Study — Science Translational Medicine

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

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

University of Houston Study — Diagnostic Microbiology and Infectious Disease

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

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

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

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

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

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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, 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

Over the past 12 to 18 months, customers have begun to report on their experiences with the T2Candida Panel at conferences and in publications. Below is a summary of some those reports.

- Investigators at the Henry Ford Health System reported data that demonstrated that after the implementation of T2Candida in their hospital system, the hospital system projected that it may save an estimated $2.3M annually, reduced median ICU length of stay by seven days per patient (p=0.009), and reduced total length of stay by four days per patient (p=0.164). Additionally, 75% of negative patients had antifungals discontinued or deescalated.
- Investigators at the Lee Health System reported that after the implementation of T2Candida, they have experienced a reduction in the average length of stay per patient by 7 days, unnecessary antifungal therapy was avoided in 41% of patients, and unnecessary antifungal therapy was discontinued after 1 dose in another 15% of patients, and the average net antifungal savings was $195 for every patient tested with T2Candida.

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

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- 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.
- Investigators at the University Di Roma reported that T2Candida detected invasive candidiasis that were not identified by blood culture. T2Candida identified three cases of C. albicans and one case of C. glabrata that were proven accurate with additional in vitro diagnostic testing and diagnostic imaging.

Candida Auris

In September 2017, we entered into an agreement with the CDC, pursuant to which the CDC agreed to utilize T2Dx in its laboratory for potentially testing and monitoring the emergence and outbreaks of the superbug Candida auris, which we expect to occur in hospitals around the United States.

Candida auris is a multi-drug resistant pathogen recognized by the CDC as a serious global health threat because it can be resistant to all three major classes of antifungal drugs and is difficult to identify. The CDC has also reported that more than one-in-three patients with Candida auris infections have died. Unlike most other species of Candida, Candida auris can spread quickly in a hospital making rapid identification and hospital environment surveillance a critical component of containing these outbreaks. Existing laboratory methods that detect Candida auris, including blood culture, suffer from prolonged detection times and low accuracy, which exacerbates the challenge in the fight to contain the superbug. Recently, reported cases have surged internationally, and the CDC has reported a significant increase in infected patients in the United States. According to the European Centre for Disease Prevention and Control, hospital outbreaks have occurred in the United Kingdom and Spain. Because Candida auris can be resistant to most treatment options and can spread so quickly, these hospital outbreaks have been difficult to contain by even the most enhanced control measures.

The goals of the CDC collaboration are to use the T2Dx Instrument to (i) validate the detection of Candida auris from patient skin samples and hospital environmental samples, (ii) validate a process for surveillance of Candida auris in healthcare facilities from skin and environmental samples, and (iii) assist state and local public health labs in combating the outbreak.

T2Bacteria

T2Bacteria Panel Pivotal Clinical Study Information

On August 4, 2017, T2 Biosystems, Inc. completed a pivotal clinical study of the T2Bacteria® Panel, run on the T2Dx® Instrument (T2Dx), which is a qualitative T2 Magnetic Resonance (T2MR®) assay designed for the direct detection of bacterial species in EDTA human whole blood specimens from patients with suspected bacteremia. The T2Bacteria Panel is designed to identify species of bacteria directly from human whole blood specimens: Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Staphylococcus aureus. Outside of the United States, the CE marked T2Bacteria panel identifies all 5 of these species along with a 6th species, Acinetobacter Baumannii

The performance characteristics of the T2Bacteria Panel were evaluated through a series of analytical studies as well as a multi-center clinical study. The clinical study evaluated the performance of the T2Bacteria Panel in comparison to the current standard of care, blood culture. All of the data generated in the analytical studies and the clinical study were submitted to the United States Food and Drug Administration, or FDA, in a 510(k) premarket notification on September 8, 2017.

The clinical study consisted of two arms, a prospective arm and a seeded arm. In the prospective arm, a total of 1,427 subjects were tested at eleven geographically dispersed and demographically diverse sites in the United States. In the seeded arm, 300 specimens of known bacterial composition were evaluated at three sites. Seeded specimens were prepared by spiking whole blood with multiple strains of the bacterial species detected by the T2Bacteria Panel at

defined concentrations (CFU/mL). Fifty negative blood samples also were evaluated as part of the seeded arm of the study. In total, 1,777 (1,427 prospective specimens and 350 seeded and negative) clinical samples were tested to evaluate the clinical performance of the T2Bacteria Panel.

The study findings submitted to the FDA include:

- The overall sensitivity for the prospective and seeded arms combined was 95.8% (see Table I below);
  - In the seeded arm of the study, the average sensitivity was 96.8% (see Table K), with the sensitivity by bacterial target ranging from 90.9% to 100.0% (see Table L);
- In the prospective arm of the study, the average sensitivity was 89.7% (see Table M), with the sensitivity by bacterial target ranging from 81.3%% to 100.0% (see Table N);

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

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

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

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

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

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

Table K: T2Bacteria Panel Seeded Sample Performance

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

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

Table L: T2Bacteria Panel Seeded Sample Performance

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

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

Table M: T2Bacteria Panel Overall Performance for Prospective Arm

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

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

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

Table N: Percentage of Positive results with negative paired Blood Cultures that were Found to be Culture Positive +/- 14 Days of Paired T2/Blood Culture Draw

	Percentage of T2(+)/BC(-) results
Bacteria	with other Positive Cultures*
E.coli	23/70 (33%)
E. faecium	4/9 (44%)
K. pneumoniae	8/21 (38%)
P. aeruginosa	7/32 (22%)
S. aureus	21/28 (75%)
Total	63/173 (36%)

Customer Presentations

In 2017, two customers reported on their experiences with the T2Bacteria Panel. Below is a summary of those reports.

- Investigators at the Catholic University School of Medicine in Rome, Italy, presented interim data from a study in which T2Bacteria achieved 100% sensitivity and 97% specificity in analytical studies, and in clinical studies, it identified patients with infection in as fast as four hours, while blood culture took up to five days, inclusive of multiple cases where T2Bacteria identified patients missed by blood culture with proven infections.
- Investigators at Northwestern University in Chicago, Illinois, presented data demonstrating that the T2Bacteria Panel had 89% sensitivity for bacterial infections while blood culture only detected 68% of infections, and positive T2Bacteria Panel results for patients on antibiotic therapy correlated to more serious and poorly controlled infections.

Lyme Disease

We believe that T2MR can also address the significant unmet need associated with Lyme disease, a tick-borne illness that can cause prolonged neurological disease and musculoskeletal disease. For patients with Lyme disease, early diagnosis and appropriate treatment significantly reduces both the likelihood of developing neurological and musculoskeletal disorders, as well as the significant costs associated with treating these complications. Multiple diagnostic methods are used to test for Lyme disease today, which are labor-intensive, can take weeks to process, and 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 to initiate a T2Lyme clinical trial in 2018.

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 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.

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 primarily to support our network of European distributors.

At the end of 2017, our direct sales force consisted of 17 people, excluding managers. Our sales team, 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 providing hospitals with customized budget impact analysis. They demonstrate the ease-of-use of our products and the advantages of our products over existing diagnostics and empiric therapy practices. 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, targeting 1,200 hospitals treating the largest number of high-risk patients. The same sales force will market T2Bacteria to those same hospitals after FDA clearance. We estimate that these 1,200 hospitals annually see an average of over 3,400 symptomatic patients at high risk for a Candida infection. If these institutions adopt our technology, we expect a positive network effect in the hospital community, accelerating adoption of T2Candida and T2Bacteria. We believe key aspects of healthcare reform, including 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 are 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 key decision-makers, and we believe they can provide a central forum to present the benefits of our products. In addition, we plan to continue to publish scientific data in peer-reviewed journals, present at major industry conferences and conduct and support clinical trials to provide additional data relative to the performance of T2Candida and T2Bacteria to these decision-makers. For the year ended December 31, 2017, the Company derived approximately 19% of its total revenue from one customer and 10% of its total revenue from a second customer.

Outside of the United States, we have received regulatory approvals in Europe and expect to seek regulatory approvals in other international markets. We market our platform primarily through distributor partners who deploy a similar model to our sales approach in the United States. In July 2014, we received CE marking for T2Candida and the T2Dx and in September 2017 we received CE marking for T2Bacteria. As of the end of 2017, we had distributors with territories in Italy, Spain, Portugal, Germany, France, Denmark, Sweden, Norway, Poland, the Czech Republic, Austria, Slovenia, Slovakia, Hungary, Romania, Croatia, Bulgaria, Serbia and Kuwait. These distributors have knowledge of infectious diseases and/or microbiology. They typically have strong, existing relationships with international thought leaders in these areas and have good relationships with important hospitals in their respective countries. We continue to develop partner relationships in other key international markets and will further investigate potential distribution channels in other key markets around the world. We have employed a small team of direct sales/marketing and field service personnel primarily 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 and T2Bacteria 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 and T2Bacteria consumable cartridge to a contract manufacturing organization. Our particles are supplied by a sole source supplier, GE Healthcare. We believe we can secure arrangements with other suppliers on commercially reasonable terms for the products and parts we outsource.

We have implemented a quality management system designed to comply with FDA regulations and International Standards Organization, or ISO, standards governing medical device products. These regulations govern the design, manufacture, testing, release and service of diagnostic products as well as raw material receipt and control. We have received ISO 13485:2012 registration from the National Standards Authority of Ireland. Our key outsourcing partners are ISO-certified.

We plan to continue to manufacture components that we determine are proprietary or require special processes to produce, while outsourcing the manufacture of more commodity-like components. We expect to establish additional outsourcing partnerships as we manufacture more products. We believe our facility in Wilmington, Massachusetts is adequate to meet our current manufacturing needs and that additional manufacturing space is readily available for future expansion.

Intellectual Property

We strive to protect and enhance the proprietary technologies that we believe are important to our business, and seek to obtain and maintain patents for any patentable aspects of our product and product candidates, including their methods of use and any other inventions that are important to the development of our business. Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important proprietary technology, inventions and know-how related to our business, including our methods, processes and product candidate designs, and our ability to defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on trademarks, copyrights, know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the fields targeted by our products and product candidates. Protecting these rights is a primary focus in our relationships with other parties, and we seek to protect such rights, in part, by entering into confidentiality and non-disclosure agreements with such third parties and including protections for such proprietary information and intellectual property rights in our other contracts with such third parties, including material transfer agreements, licenses and research agreements.

We are the owner or licensee of over 60 patents and over 40 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 2034, while additional pending applications covering T2Candida and T2Bacteria would be expected, if issued, to expire as late as 2037. The issued patents in our patent families that cover 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 2034, while additional pending applications covering T2Lyme would be expected, if issued, to expire as late as 2037. In all cases, the expiration dates are subject to any extension that may be available under applicable law.

Proprietary Rights and Processes

We rely, in some circumstances, on proprietary technology and processes (including trade secrets) to protect our technology. However, these can be difficult to protect. We require all full-time and temporary employees, scientific advisors, contractors and consultants working for us who have access to our confidential information to execute confidentiality agreements in order to safeguard our proprietary technologies, methods, processes, know-how, and trade secrets. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. All of our full-time and temporary employees and independent contractors and consultants are also bound by invention assignment obligations, pursuant to which rights to all inventions and other types of intellectual property conceived by them during the course of their employment are assigned to us.

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

Trademarks

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

License Agreements

License Agreement with Massachusetts General Hospital

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

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

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

We 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 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 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;
- 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 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.

Clinical Trials

A clinical trial is typically required to support a PMA application and is sometimes required for a 510(k) pre-market notification. Clinical trials generally require submission of an application for an Investigational Device Exemption, or IDE, to the FDA. The IDE application must be

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

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

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

- the Quality System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process;
- establishment registration, which requires establishments involved in the production and distribution of medical devices, intended for commercial distribution in the United States, to register with the FDA;
- medical device listing, which requires manufacturers to list the devices they have in commercial distribution with the FDA;
- labeling regulations, which prohibit "misbranded" devices from entering the market, as well as prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; and
- post-market surveillance including Medical Device Reporting, which requires manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury, or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

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

- untitled letters or warning letters;
- fines, injunctions and civil penalties;
- mandatory recall or seizure of our products;
- administrative detention or banning of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our request for 510(k) clearance or pre-market approval of new product versions;
- revocation of 510(k) clearance or pre-market approvals previously granted; and
- criminal prosecution and penalties.

International Regulation

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

In the European Economic Area, or EEA, which comprises the 28 Member States of the EU plus Liechtenstein, Norway and Iceland, in vitro medical devices are required to conform with the essential requirements of the EU Directive on in vitro diagnostic medical devices (Directive 98/79/EC, as amended). To demonstrate compliance with the essential requirements, the manufacturer must undergo a conformity assessment procedure. The conformity

assessment varies according to the type of medical device and its classification. For low-risk devices, the conformity assessment can be carried out internally, but for higher risk devices (self-test devices and those included in List A and B of Annex II of Directive 98/79/EC) it requires the intervention of an accredited EEA Notified Body. If successful, the conformity assessment concludes with the drawing up by the manufacturer of an EC Declaration of Conformity entitling the manufacturer to affix the CE mark to its products and to sell them throughout the EEA. We concluded an assessment of the conformity of the T2Dx and T2Candida with the EU in vitro diagnostic medical devices directive in late 2014, based upon an EC Declaration of Conformity dated July 7, 2014 and updated on September 9, 2015 and May 26, 2016, allowing us to affix the CE mark to these products.

Other Healthcare Laws

Our current and future business activities are subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual, for an item or service or the purchasing, leasing, ordering, or arranging for or recommending the purchase, lease or order of any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated.

Further, the recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback Statute and certain criminal statute governing healthcare fraud statutes to a stricter standard. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them. In addition, the Affordable Care Act codifies case law that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. The majority of states also have anti-kickback laws which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Additionally, the civil False Claims Act prohibits, among other things, knowingly presenting or causing the presentation of a false or fraudulent claim for payment to, or approval by, the U.S. government. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government intervenes and is ultimately successful in obtaining redress in the matter, or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of life sciences companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in

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

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Also, as stated above, many states have similar fraud and abuse laws that may be broader in scope and may apply regardless of payor.

Moreover, Section 6002 of the Affordable Care Act included new requirements for device manufacturers, among others, to report certain payments or “transfers of value” provided to physicians and teaching hospitals, and to report ownership and investment interests held by physicians and their immediate family members during the preceding calendar year. Section 6002 of the Affordable Care Act includes in its reporting requirements a broad range of transfers of value including, but not limited to, consulting fees, speaker honoraria, charitable contributions, research payments and grants. We collect data annually and report it to the 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 attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our future operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Coverage and Reimbursement

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

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

insurance plans is central to the acceptance of our products. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels.

Healthcare Reform

In the United States and 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.

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 $23.7 million for the year ended December 31 2017, $24.0 million for the year ended December 31, 2016 and $25.4 million for the year ended December 31, 2015. Research and development expenses represented 41% of our total costs and expenses for the year ended December 31, 2017, 44% of our total costs and expenses for the year ended December 31, 2016 and 55% of our total costs and expenses for the year ended December 31, 2015. 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 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 sepsis, with a long-term objective of targeting the broader in vitro diagnostics market.

Employees

As of December 31, 2017, we had 161 full-time employees, of which 73 work in operations (which includes manufacturing, service and support, clinical and regulatory support, quality control and quality assurance), 40 in research and development, 21 in general and administrative and 27 in sales and marketing.

Facilities

Our corporate headquarters is located in Lexington, Massachusetts, where we currently lease approximately 31,300 square feet of office space, 20,500 square feet of laboratory space and 3,400 square feet of manufacturing space in

various facilities. Our base rent, for leases at our corporate headquarters, is $2.1 million annually. We also lease approximately 7,600 square feet in Wilmington, Massachusetts for our manufacturing facility, for $0.1 million 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 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 identified conditions and events that raise substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.

As of December 31, 2017, we had cash and cash equivalents of $41.8 million, which we believe that, together with the additional remaining liquidity remaining on our Term Loan with CRG, should be sufficient to fund our operating expenses through March 2019. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Pursuant to the requirements of Accounting Standards Codification (ASC) 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, and as a result of our financial condition and other factors described herein, there is substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern will depend on our ability to obtain additional funding, as to which no assurances can be given. Our future success depends on our ability to raise capital and/or execute our current operating plan. However, we cannot be certain that these initiatives or raising additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current shareholders may experience dilution. If we are unable to obtain funds when needed or on acceptable terms, we may be required to curtail our current development programs, cut operating costs, forego future development and other opportunities or even terminate our operations, which may involve seeking bankruptcy protection.

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, 2017 and expect to incur losses in the future. Our accumulated deficit as of December 31, 2017 was $266.1 million and we incurred net losses of $62.4 million for the year ended December 31, 2017, and $54.8 million and $45.3 million for the years ended December 31, 2016 and 2015, 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. As noted above, we and our auditors have identified conditions and events that raise doubt about our ability to continue as a going concern.

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

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

- implement and execute our business strategy;
- expand and improve the productivity of our sales and marketing infrastructure to grow sales of our products and product candidates;
- increase awareness of our brand;
- manage expanding operations;
- expand our manufacturing capabilities, including increasing production of current products efficiently while maintaining quality standards and adapting our manufacturing facilities to the production of new product candidates;
- respond effectively to competitive pressures and developments;
- enhance our existing products and develop new products;

- obtain and maintain regulatory clearance or approval to commercialize product candidates and enhance our existing products;
- effectively perform clinical trials with respect to our proposed products;
- attract, retain and motivate qualified personnel in various areas of our business; and
- implement and maintain systems and processes that are compliant with applicable regulatory standards.

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, including T2Bacteria, 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, including T2Bacteria, 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.

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.

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, 2017, our direct sales organization, including marketing, consisted of 27 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 a limited sales history, which makes it difficult for us to forecast revenue and other operating results.

Our sales process involves numerous interactions with multiple individuals within an organization and often includes in-depth analysis by potential customers of our products, performance of proof-of-principle studies, preparation of extensive documentation and a lengthy review process. As a result of these factors and the budget cycles of our potential customers, the time from initial contact with a potential customer to our receipt of a purchase order from such potential customer, varies significantly and can 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 started selling the T2Dx and T2Candida products in the fourth quarter of 2014 and have a limited sales history to rely on when forecasting revenue and other operating results.

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

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

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

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

During the past few years, we have significantly expanded our operations. We expect this expansion to continue to an even greater degree as we continue to commercialize our initial sepsis products, build a targeted sales force, and seek marketing clearance from the FDA and international regulatory bodies for our future product candidates. Our growth

has placed, and will continue to place, a significant strain on our management, operating and financial systems and our sales, marketing and administrative resources. As a result of our growth, operating costs may escalate even faster than planned, and some of our internal systems and processes, including those relating to manufacturing our products, may need to be enhanced, updated or replaced. Additionally, our anticipated growth will increase demands placed on our suppliers, resulting in an increased need for us to manage our suppliers and monitor for quality assurance. If we cannot effectively manage our expanding operations, manufacturing capacity and costs, including scaling to meet increased demand and properly managing suppliers, we may not be able to continue to grow or we may grow at a slower pace than expected and our business could be adversely affected.

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

We 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 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 1,200 leading hospitals in the United States. 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 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;

- speed, accuracy and reproducibility of results; and
- ability to implement a consumables-based model for panels.

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

- breadth of clinical decisions that can be influenced by information generated by diagnostic tests;
- volume, quality and strength of clinical and analytical validation data;

- availability of adequate reimbursement for testing services and procedures for healthcare providers using our products; and
- economic benefit accrued to hospitals based on the total cost to treat a patient for a health condition.

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

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

Our products or product candidates may contain undetected errors or defects. Disruptions or other performance problems with our products or product candidates may damage our customers' businesses and could harm our reputation. If that occurs, we may incur significant costs, the attention of our key personnel could be diverted or other significant customer relations problems may arise. We may also be subject to warranty and liability claims for damages related to errors or defects in our products or product candidates. A material liability claim or other occurrence that harms our reputation or decreases market acceptance of our products or product candidates could harm our business and operating results.

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

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

Our industry is characterized by rapid technological changes, frequent new product introductions and enhancements and evolving industry standards. Our success depends on our ability to develop new product candidates and applications for our technology in new markets that develop as a result of technological and scientific advances, while improving the performance and cost-effectiveness of our existing product candidates. New technologies, techniques or products could emerge that might offer better combinations of price and performance than the products and systems that we plan to sell. Existing markets for our intended diagnostic product candidates are characterized by rapid technological change and innovation. It is critical to our success that we anticipate changes in technology and customer requirements and physician, hospital and healthcare provider practices and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost-effective basis. At the same time, however, we must carefully manage our introduction of new products. If potential customers believe that such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory of older products as we transition to new products, and we have no experience in managing product transitions. If we do not successfully innovate and introduce new technology into our anticipated product lines or manage the transitions of our technology to new product offerings, our revenue, results of operations and business will be adversely impacted.

Competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. We anticipate that we will face strong competition in the future as

expected competitors develop new or improved products and as new companies enter the market with new technologies and products.

We are developing additional product candidates that we intend to be used with the T2Dx, 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 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, 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.

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

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

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

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

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

- disruption in our relationships with future customers or with current or future distributors or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- diversion of management time and focus from operating our business to acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- possible write-offs or impairment charges relating to acquired businesses; and
- inability to develop a sales force for any additional product candidates.

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

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

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

If treatment guidelines for sepsis change, or the standard of care evolves, we may need to redesign and seek new marketing clearance from the FDA for our products. For example, current treatment recommendations for Candida infections, including those published by the Infectious Diseases Society of America , call for identical treatment for two species of Candida, C. albicans and C. tropicalis , and identical treatment for two other species, C. glabrata and C. krusei . Although our T2Candida test is technically capable of distinguishing among these species, we have designed it based on current treatment guidelines and therefore it does not distinguish between two species if they are subject to the same recommended treatment. Our FDA clearance to market the T2Dx 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, 2017, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of $229.1 million, which are available to offset future taxable income, if any, through 2037. 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;
- 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, distributors and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, principal investigators, consultants, commercial partners, distributors and vendors. Misconduct by these parties could include intentional, reckless or negligent failures to: comply with the regulations of the FDA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar regulatory bodies; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws and regulations in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately, or disclose unauthorized activities to us. These laws may impact, among other things, our activities with principal investigators and research subjects, as well

as our sales, marketing and education programs. In particular, the promotion, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We currently have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and our code of conduct and the other precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Any of these actions or investigations could result in substantial costs to us, including legal fees, and divert the attention of management from operating our business.

We depend on our information technology systems, and any failure of these systems could harm our business.

We depend on information technology systems for significant elements of our operations, including the storage of data and retrieval of critical business information. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including systems handling human resources, financial controls and reporting, contract management, regulatory compliance, sales management and other infrastructure operations. These information technology systems may support a variety of functions, including laboratory operations, test validation, quality control, customer service support, billing and reimbursement, research and development activities and general administrative activities. Our clinical trial data is currently stored on a third party’s servers.

Information technology systems are vulnerable to damage from a variety of sources, including network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology systems, failures or significant downtime of our information technology systems or those used by our third-party service providers could prevent us from conducting our general business operations. Any disruption or loss of information technology systems on which critical aspects of our operations depend could have an adverse effect on our business. Further, we store highly confidential information on our information technology systems, including information related to clinical data, product designs and plans to create new products. If our servers or the servers of the third party on which our clinical data is stored are attacked by a physical or electronic break-in, computer virus or other malicious human action, our confidential information could be stolen or destroyed.

Our internal computer systems, or those used by our third-party research institution collaborators, vendors or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our vendors and other contractors and consultants may be vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our business operations. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or

systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed, which could adversely affect our business, results of operations and financial condition.

Risks Related to Government Regulation and Diagnostic Product Reimbursement

Approval and clearance by the FDA and foreign regulatory authorities for our diagnostic tests takes significant time and requires significant research, development and clinical study expenditures and ultimately may not succeed.

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state regulatory agencies. The regulations are very complex and are subject to rapid change and varying interpretations. Regulatory restrictions or changes could limit our ability to carry on or expand our operations or result in higher than anticipated costs or lower than anticipated sales. The FDA and other U.S. governmental agencies regulate numerous elements of our business, including:

- product design and development;
- pre-clinical and clinical testing and trials;
- product safety;
- establishment registration and product listing;
- labeling and storage;

- marketing, manufacturing, sales and distribution;
- pre-market clearance or approval;
- servicing and post-market surveillance;
- advertising and promotion; and
- recalls and field safety corrective actions.

Before we begin to label and market our product candidates for use as clinical diagnostics in the United States, we are required to obtain clearance from the FDA under Section 510(k) of the Federal Food, Drug and Cosmetic Act, approval of a de novo reclassification petition for our product, or approval of pre-market approval, or PMA, application from the FDA, unless an exemption from pre-market review applies. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. However, some devices are automatically subject to the PMA pathway regardless of the level of risk they pose because they have not previously been classified into a lower risk class by the FDA. Manufacturers of these devices may request that FDA review such devices in accordance with the de novo classification procedure, which allows a manufacturer whose novel device would otherwise require the submission and approval of a PMA prior to marketing to request down-classification of the device on the basis that the device presents low or moderate risk. If the FDA agrees with the down-classification, the applicant will then receive approval to market the device. This device type can then be used as a predicate device for future 510(k) submissions. The process of obtaining regulatory clearances or approvals, or completing the de novo classification process, to market a medical device can be costly and time consuming, and we may not be able to successfully obtain pre-market reviews on a timely basis, if at all.

We received pre-market clearance for our T2Dx Instrument and T2Candida panel under the de novo application procedure in September 2014. From time to time, we may make modifications to these products that may require a new 510(k). On September 8, 2017 the Company filed a 510(k) premarket submission for the T2Bacteria Panel with the FDA.

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

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

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

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. For example, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) regulatory pathway, the FDA initiated an evaluation of the program, and in January 2011, announced several proposed actions intended to reform the review process governing the clearance of medical devices. The FDA intends these reform actions to improve the efficiency and transparency of the clearance process, as well as bolster

patient safety. In addition, as part of the Food and Drug Administration Safety and Innovation Act, or FDASIA, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms which are further intended to clarify and improve medical device regulation both pre- and post-approval.

Any delay in, or failure to receive or maintain, clearance or approval for our product candidates could prevent us from generating revenue from these product candidates and adversely affect our business operations and financial results. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could affect the perceived safety and efficacy of our products and product candidates and dissuade our customers from using our products and product candidates.

Obtaining FDA clearance, de novo down classification, or approval for diagnostics can be expensive and uncertain, and generally takes from several months to several years, and generally requires detailed and comprehensive scientific and clinical data. Notwithstanding the expense, these efforts may never result in FDA clearance. Even if we were to obtain regulatory clearance, it may not be for the uses we believe are important or commercially attractive, in which case we would not be permitted to market our product for those uses.

Even if granted, a 510(k) clearance, de novo down classification, or PMA approval for any future product would likely place substantial restrictions on how our device is marketed or sold, and the FDA will continue to place considerable restrictions on our products and operations.

For example, the manufacture of medical devices must comply with the FDA's Quality System Regulation, or QSR. In addition, manufacturers must register their manufacturing facilities, list the products with the FDA, and comply with requirements relating to labeling, marketing, complaint handling, adverse event and medical device reporting, reporting of corrections and removals, and import and export. The FDA monitors compliance with the QSR and these other requirements through periodic inspections. If our facilities or those of our manufacturers or suppliers are found to be in violation of applicable laws and regulations, or if we or our manufacturers or suppliers fail to take satisfactory corrective action in response to an adverse inspection, the regulatory authority could take enforcement action, including any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) marketing clearances or PMA approvals that have already been granted;
- refusing to provide Certificates for Foreign Government;
- refusing to grant export approval for our products; or
- pursuing criminal prosecution.

Any of these sanctions could impair our ability to produce our products and product candidates in a cost-effective and timely manner in order to meet our customers' demands, and could have a material adverse effect on our reputation, business, results of operations and financial condition. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

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

Modifications to our products, if cleared or approved, may require new 510(k) clearances or pre-market approvals, or may require us to cease marketing or recall the modified products until clearances are obtained.

Any modification to a device authorized for marketing that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMAs for modifications to previously cleared products for which we conclude that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Furthermore, the FDA's ongoing review of the 510(k) program may make it more difficult for us to make modifications to any products for which we obtain clearance, either by imposing more strict requirements on when a manufacturer must submit a new 510(k) for a modification to a previously cleared product, or by applying more onerous review criteria to such submissions. For example, in accordance with FDASIA, the FDA was obligated to prepare a report for Congress on the FDA's approach for determining when a new 510(k) will be required for

modifications or changes to a previously cleared device. The FDA recently issued this report and indicated that manufacturers should continue to adhere to the FDA's 1997 Guidance on this topic when making a determination as to whether or not a new 510(k) is required for a change or modification to a device. However, the practical impact of the FDA's continuing scrutiny of the 510(k) program remains unclear.

A recall of our products, either voluntarily or at the direction of the FDA, or the discovery of serious safety issues with our products that leads to corrective actions, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Under the FDA's medical device reporting regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if

the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future.

Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

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

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

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

Successful commercialization of our diagnostic products and product candidates depends, in large part, on the extent to which the costs of our products and product candidates purchased by our customers are reimbursed, either separately or through bundled payment, by third-party private and governmental payors, including Medicare, Medicaid, managed care organizations and private insurance plans. There is significant uncertainty surrounding third-party coverage and reimbursement for the use of tests that incorporate new technology, such as T2MR. There may be significant delays in obtaining coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities.

Hospitals, clinical laboratories and other healthcare provider customers that may purchase our products and product candidates, if approved, generally bill various third-party payors to cover all or a portion of the costs and fees associated with diagnostic tests, including the cost of the purchase of our products and product candidates. We currently expect that the majority of our diagnostic tests will be performed in a hospital inpatient setting, where governmental payors, such as Medicare, generally reimburse hospitals a single bundled payment that is based on the

patients' diagnosis under a classification system known as the Medicare severity diagnosis-related groups, classification for all items and services provided to the patient during a single hospitalization, regardless of whether our diagnostic tests are performed during such hospitalization. To the extent that our diagnostic tests will be performed in an outpatient setting, our products and product candidates may be eligible for separate payment, for example, under the Clinical Laboratory Fee Schedule using existing Current Procedural Terminology codes. Third-party payors may deny coverage, however, if they determine that the diagnostic tests using our products are not cost-effective compared to the use of alternative testing methods as determined by the payor, or is deemed by the third-party payor to be experimental or medically unnecessary. Even if third-party payors make coverage and reimbursement available, such reimbursement may not be adequate or these payors' reimbursement policies may have an adverse effect on our business, results of operations, financial condition and cash flows. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for various products. Our customers' access to adequate coverage and reimbursement for inpatient procedures using our products and product candidates by government and private insurance plans is central to the acceptance of our products. We cannot predict at this time the adequacy of payments, whether made separately in an outpatient setting or with a bundled payment amount in an inpatient setting. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels.

In many countries outside of the United States, various coverage, pricing and reimbursement approvals are required. We expect that it will take several years to establish broad coverage and reimbursement for testing services based on our products with payors in countries outside of the United States, and our efforts may not be successful.

We may be subject to federal and state healthcare fraud and abuse laws and other federal and state healthcare laws applicable to our business activities. If we are unable to comply, or have not complied, with such laws, we could face substantial penalties.

Our operations are, and will continue to be, directly or indirectly subject to various federal and state fraud and abuse laws, including, without limitation, the federal and state anti-kickback statutes, physician payment transparency laws and false claims laws. These laws impact, among other things, our sales and marketing and education programs and require us to implement additional internal systems for tracking certain marketing expenditures and reporting them to government authorities. In addition, we may be subject to patient data privacy and security regulation by both the federal government and the states in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly or willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or services for which payment may be made, in whole or in part, under a federal healthcare program such as the Medicare and Medicaid programs;
- federal false claims laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from or approval by a governmental payor program that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which established additional federal crimes for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;
    - HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and imposes obligations, including mandatory contractual terms, on certain types of people and entities regarding the security and privacy of protected health information;
- the Physician Payments Sunshine Act under the Affordable Care Act, which requires manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the CMS information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and
- state or foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require manufacturers to report information related to payments and other transfers of value to physicians, hospitals and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reforms have strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback statute. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. The Affordable Care Act also codified case law by amending the False Claims Act, such that violations of the federal Anti-Kickback Statute are now

deemed violations of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect our ability to operate our business and our results of operations.

Healthcare policy changes, including legislation reforming the United States healthcare system, may have a material adverse effect on our financial condition and results of operations.

The Affordable Care Act, enacted in March 2010, made changes that significantly impacted the pharmaceutical and medical device industries and clinical laboratories. Beginning in 2013, certain medical device manufacturers were to be required to pay a medical device excise tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. The excise tax applies to our T2Dx Instrument and T2Candida Panel, and we expect that it will apply to some or all of our product candidates. The Consolidated Appropriations Act of 2016, signed into law on December 18, 2015, temporarily suspended the 2.3% medical device excise tax for a two-year period from January 1, 2016 through December 31, 2017. In early 2018, the implementation of this excise tax was once again temporarily suspended until January 1, 2020.

The Affordable Care Act also mandated a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule, or CLFS, of 1.75% for the years 2011 through 2015 and a productivity adjustment to the CLFS, further reducing payment rates. Some commercial payors are guided by the CLFS in establishing their reimbursement rates. Clinicians may decide not to order clinical diagnostic tests if third-party payments are inadequate, and we cannot predict whether third-party payors will offer adequate reimbursement for procedures utilizing our products and product candidates to make them commercially attractive. To the extent that the diagnostic tests using our products and product candidates are performed on an outpatient basis, these or any future proposed or mandated reductions in payments under the CLFS may apply to some or all of the clinical laboratory tests that our diagnostics customers may use our technology to deliver to Medicare beneficiaries and may indirectly reduce demand for our diagnostic products and product candidates.

Other significant measures for our industry contained in the Affordable Care Act included coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures; initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians; and initiatives to promote quality indicators in payment methodologies. The Affordable Care Act also includes significant fraud and abuse measures, including required disclosures of certain financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. In addition, the Affordable Care Act established an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce healthcare expenditures, which may have a negative impact on payment rates for services, including our tests. The IPAB proposals may impact payments for clinical laboratory services that our diagnostics customers use our technology to deliver, and for hospital services beginning in 2020, and may indirectly reduce demand for our diagnostic products and product candidates. To the extent that the reimbursement amounts for sepsis decrease, it could adversely affect the market acceptance and hospital adoption of our technologies.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs, including reductions of Medicare payments to providers of up to 2% per fiscal year effective April 1, 2013. Due to subsequent legislative amendments, these reductions will stay in effect through 2024 unless additional congressional action is taken. Further, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The current presidential administration and U.S. Congress has sought to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. Since taking office, President Trump has continued to support the repeal of all or portions of the Affordable Care Act. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation and the expansion in government's effect on the United States healthcare industry may result in decreased profits to us, lower reimbursements by payors for our products and product candidates or reduced medical procedure volumes, any of which may adversely affect our business, financial condition and results of operations.

Risks Related to Intellectual Property

If we are unable to protect our intellectual property effectively, our business would be harmed.

We rely on patent protection as well as trademark, copyright, trade secret protection and confidentiality agreements to protect the intellectual property rights related to our proprietary technologies. The strength of patents in our field involves complex legal and scientific questions. Uncertainty created by these questions means that our patents may provide only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We own or exclusively license over 35 issued U.S. patents and over 15 pending U.S. patent applications, including provisional and non-provisional filings. We also own or license over 50 pending or granted counterpart applications worldwide. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

We cannot assure you that any of our currently pending or future patent applications will result in issued patents with claims that cover our products and technologies in the United States or in other foreign countries, and we cannot predict how long it will take for such patents to be issued. Further, issuance of a patent is not conclusive as to its inventorship or scope, and there is no guarantee that our issued patents will include claims that are sufficiently broad to cover our technologies or to provide meaningful protection of our products from our competitors. Further, we cannot be certain that all relevant prior art relating to our patents and patent applications has been found. Accordingly, there may be prior art that can invalidate our issued patents or prevent a patent from issuing from a pending patent application, at all or with claims that have a scope broad enough to provide meaningful protection from our competitors.

Even if patents do successfully issue and even if such patents cover our products and technologies, we cannot assure you that other parties will not challenge the validity, enforceability or scope of such issued patents in the United States and in foreign countries, including by proceedings such as re-examination, inter-partes review, interference, opposition, or other patent office or court proceedings. Moreover, we cannot assure you that if such patents were challenged in court or before a regulatory agency that the patent claims will be held valid, enforceable, or be sufficiently broad to cover our technologies or to provide meaningful protection from our competitors. Nor can we assure you that the applicable court or agency will uphold our ownership rights in such patents. Accordingly, we cannot guarantee that we will be successful in defending challenges made against our patents and patent applications. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents, or narrowing of claim scope, such that we could be deprived of patent protection necessary for the successful commercialization of our products and technologies, which could adversely affect our business.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our products and technologies or prevent others from designing around our claims. Others may independently develop similar or alternative products and technologies or duplicate any of our products and technologies. These products and technologies may not be covered by claims of issued patents owned by our company. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of the protections provided by our intellectual property rights. If our intellectual property, including licensed intellectual property, does not adequately protect our market position against competitors' products and methods, our competitive position could be adversely affected, as could our business.

Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product or product candidate under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to make the inventions covered by our pending patent applications, or that we were the first to file any patent application related to a product or product candidate. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by a third party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

We depend on certain technologies that are licensed to us. We do not control the intellectual property rights covering these technologies and any loss of our rights to these technologies or the rights licensed to us could prevent us from selling our products.

We are a party to a number of license agreements under which we are granted rights to intellectual property that is important to our business and we expect that we may need to enter into additional license agreements in the future. We rely on these licenses in order to be able to use various proprietary technologies that are material to our business, including an exclusive license to patents and patent applications from Massachusetts General Hospital, or MGH, and non-exclusive licenses from other third parties related to materials used currently in our research and development

activities, and which we use in our commercial activities. Our rights to use these technologies and employ the inventions claimed in the licensed patents are subject to the continuation of and our compliance with the terms of those licenses. Our existing license agreements impose, and we expect that future license agreements will impose on us, various diligence obligations, payment of milestones or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

As we have done previously, we may need to obtain licenses from third parties to advance our research or allow commercialization of our products and technologies, and we cannot provide any assurances that third-party patents do not exist which might be enforced against our current products and technologies or future products in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products and technologies, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation.

In some cases, we do not control the prosecution, maintenance, or filing of the patents that are licensed to us, or the enforcement of these patents against infringement by third parties. Some of our patents and patent applications were not filed by us, but were either acquired by us or are licensed from third parties. Thus, these patents and patent applications were not drafted by us or our attorneys, and we did not control or have any input into the prosecution of these patents and patent applications either prior to our acquisition of, or entry into a license with respect to, such patents and patent applications. With respect to the patents we license from MGH, although we have rights under our agreement to provide input into prosecution and maintenance activities, and are actively involved in such ongoing prosecution, MGH retains ultimate control over such

prosecution and maintenance. We therefore cannot be certain that the same attention was given, or will continue to be given, to the drafting and prosecution of these patents and patent applications as we may have exercised if we had control over the drafting and prosecution of such patents and patent applications, or that we will agree with decisions taken by MGH in relation to ongoing prosecution activities. We also cannot be certain that drafting or prosecution of the patents and patent applications licensed to us have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. Further, as MGH retains the right to enforce these patents against third-party infringement, we cannot be certain that MGH will elect to enforce these patents to the extent that we would choose to do so, or in a way that will ensure that we retain the rights we currently have under our license with MGH. If MGH fails to properly enforce the patents subject to our license in the event of third-party infringement, our ability to retain our competitive advantage with respect to our products and product candidates may be materially affected.

In addition, certain of the patents we have licensed relate to technology that was developed with U.S. government grants. Federal regulations impose certain domestic manufacturing requirements and other obligations with respect to some of our products embodying these patents.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products and technologies, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected products and technologies.

We may be involved in lawsuits to protect or enforce our patents and proprietary rights, to determine the scope, enforceability and validity of others' proprietary rights, or to defend against third-party claims of intellectual property infringement, any of which could be time-intensive and costly and may adversely impact our business or stock price.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the medical device and diagnostics industries, including patent infringement lawsuits, interferences, oppositions and inter partes review proceedings before the U.S. Patent and Trademark Office, or U.S. PTO, and corresponding foreign patent offices. While we have not received notices of claims of infringement or misappropriation or misuse of other parties' proprietary rights in the past, we may from time to time receive such notices in the future. Some of these claims may lead to litigation. Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, methods of manufacture or methods of use of our products and technologies. Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result in issued patents that our products and technologies may infringe, or which such third parties claim are infringed by the use of our technologies. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets or infringement by us of third-party patents, trademarks or other rights, or challenging the validity of our patents, trademarks or other rights, will not be asserted against us.

Litigation may be necessary for us to enforce our patent and proprietary rights or to determine the scope, enforceability or validity of the proprietary rights of others. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the medical diagnostics industry. Third parties may assert that we are employing their proprietary technology without authorization. Many of our competitors have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product revenue and against whom our own patents may provide little or no deterrence or protection. Parties making claims against us for infringement of their intellectual property rights may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our products and technologies. Further, defense of such claims in litigation, regardless of merit, could result in substantial legal fees and could adversely affect the scope of our patent protection, and would be a substantial diversion of employee, management and technical personnel resources from our business. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us. In the event of a successful claim of infringement against us, we could be required to redesign our infringing products or obtain a license from such third party to continue developing and commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could therefore incur substantial costs for licenses obtained from third parties, if such licenses were available at all, which could negatively affect our gross margins, or prevent us from commercializing our products and technologies. Further, we could encounter delays

in product introductions, or interruptions in product sales, as we develop alternative methods or products to avoid infringing third-party rights. In addition, if we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, enforceability or scope of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. Any litigation that may be necessary in the future could result in substantial costs and the diversion of our resources and could have a material adverse effect on our business, operating results or financial condition. Further, if the scope of protection provided by our patents or patent applications is threatened or reduced as a result of litigation, it could discourage third parties from entering into collaborations with us that are important to the commercialization of our products.

We cannot guarantee that we have identified all relevant third-party intellectual property rights that may be infringed by our technology, nor is there any assurance that patents will not issue in the future from currently pending applications that may be infringed by our technology or products or product candidates. We are aware of third parties that have issued patents and pending patent applications in the United States, Europe, Canada, and other jurisdictions in the field of magnetic resonance devices and methods for analyte detection, including the preparation and use of reagents. While we continue to evaluate third-party patents in this area on an ongoing basis, we cannot guarantee that patents we currently are aware of will be found invalid or not infringed if we are accused of infringing them, or if our products are found to infringe, that we will be able to modify our products to cause them to be non-infringing on a timely or cost-effective basis, or at all. We currently monitor the intellectual property positions of some companies in this field that are potential competitors or are conducting research and development in areas that relate to our business, and will continue to do so as we progress the development and commercialization of our products or product candidates. While we continue to evaluate third-party patents in this area on an ongoing basis, we cannot assure you that third parties do not currently have or will not in the future have issued patents or other intellectual property rights that may be infringed by the practice of our technology or the commercialization of our products or product candidates.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or you perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In addition, certain of our agreements with suppliers, distributors, customers and other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims relating to our technologies or products, or rights licensed to them by us. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify any of these third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to pursuing patents on our technology, we also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our products and technologies and discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents, in order to maintain our competitive position. We take steps to protect our intellectual property, proprietary technologies and trade secrets, in part, by entering into confidentiality agreements with our employees, consultants, corporate partners, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to assign to us any inventions developed in the course of their work for us. We also seek to preserve the integrity and confidentiality of our data and

trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Our agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. If any of the technology or information that we protect as trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA’s disclosure policies may change in the future, if at all.

We may be subject to damages resulting from claims that we or our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees were previously employed at universities or other medical device companies, including our competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of our employees' former employers, or we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our products and technologies. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could hamper our ability to commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our products and technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The U.S. PTO is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, were enacted March 16, 2013. However, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be paid to the U.S. PTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural,

documentary, fee payment and other provisions during the patent process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, however there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be adversely affected.

We have not yet registered certain of our trademarks, including T2HemoStat, T2Bacteria and T2Lyme, in all of our potential markets, including in international markets. If we apply to register these trademarks, our applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

We may not be able to protect our intellectual property rights throughout the world.

The laws of some non-U.S. countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to technologies relating to biotechnology, which could make it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Also, because we have not pursued patents in all countries, there exist jurisdictions where we are not protected against third parties using our proprietary technologies. Further, compulsory licensing laws or limited enforceability of patents against government agencies or contractors in certain countries may limit our remedies or reduce the value of our patents in those countries.

We use third-party software that may be difficult to replace or cause errors or failures of our products that could lead to lost customers or harm to our reputation.

We use software licensed from third parties in our products. In the future, this software may not be available to us on commercially reasonable terms, or at all. Any loss of the right to use any of this software could result in delays in the production of our products until equivalent technology is either developed by us, or, if available, is identified, obtained and integrated with our technologies and products, which could harm our business. In addition, any errors or defects in, or failures of, such third-party software could result in errors or defects in the operation of our products or cause our products to fail, which could harm our business and reputation and be costly to correct. Many of the licensors of the software we use in our products attempt to impose limitations on their liability for such errors, defects or failures. If enforceable, such limitations would require us to bear the liability for such errors, defects or failures, which could harm our reputation and increase our operating costs.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make diagnostic products and technologies that are similar to our products or product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Our Common Stock

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

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

- delay, defer or prevent a change in control;
- entrench our management and the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

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

Since our initial listing on The NASDAQ Global Market in August 2014, the trading market in our common stock has been extremely limited. The listing of our common stock on The NASDAQ Global Market does not assure that a meaningful, consistent and liquid trading market currently exists. We cannot predict whether a more active market for our common stock will develop or be sustained in the future.

Our executive officers, directors and 5% stockholders and their respective affiliates in the aggregate own a significant percentage of our outstanding shares of common stock, which may adversely affect the liquidity of the trading market for our common stock. If these stockholders continue to hold their shares of common stock, there will be limited trading volume in our common stock, which may make it more difficult for investors to sell their shares and may increase the volatility of our stock price. The absence of an active trading market could adversely affect our stockholders' ability to sell our common stock at current market prices in short time periods, or possibly at all. Additionally, market visibility for our common stock may be limited and such lack of visibility may have a depressive effect on the market price for our common stock.

The price of our common stock has been volatile and is likely to continue to be volatile, which could result in substantial losses for purchasers of our common stock.

Our stock price has been and is likely to continue be volatile. The stock market in general has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the current market price. The market price for our common stock may be influenced by many factors, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- announcements by us relating to the timing of regulatory clearance for our product candidates;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- development of new technologies that may address our markets and may make our technology less attractive;
- changes in physician, hospital or healthcare provider practices that may make our products or product candidates less useful;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes to reimbursement levels by commercial third-party payors and government payors, including Medicare, and any announcements relating to reimbursement levels;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company for up to five years following the IPO. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements

that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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

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

As a public company, and particularly after we are no longer an emerging growth company, we will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The NASDAQ Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We continue to be subject to applicable securities rules and regulations. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. In the event any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our regulatory clearance timelines, clinical trial results or operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could

lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Provisions in our restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;

- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Our ability to pay cash dividends is prohibited by the terms of our existing credit facility. Any future debt agreements may also preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.

We are required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, subject to certain exceptions. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and to obtain attestations of the effectiveness of internal controls by independent auditors. However, as discussed in detail below, as an emerging growth company, we are not required to obtain an auditor attestation.

Under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, issuers that qualify as “emerging growth companies” under the JOBS Act will not be required to provide an auditor’s attestation report on internal controls for so long as the issuer qualifies as an emerging growth company. We currently qualify as an emerging growth company under the JOBS Act, and we may choose not to provide an auditor’s attestation report on internal controls. However, if we cannot favorably assess the effectiveness of our internal control over financial reporting, or if we require an attestation report from our independent registered public accounting firm in the future and that firm is unable to provide an unqualified attestation report on the effectiveness of our internal controls over financial reporting, investor confidence and, in turn, our stock price could be materially adversely affected.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. Our failure to remediate our material weakness in internal controls and thereafter to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on the tradability of our common stock, which in turn would negatively impact our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the

price of our common stock. In addition, if our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Based on our assessment under the [COSO Internal Control-Integrated Framework], management believes that, as of December 31, 2017, our internal control over financial reporting was not effective, as described below in "Management's Annual Report on Internal Control over Financial Reporting".

Item 1B. UNRESOLVED STAFF COMMENTS
None.

Item 2. PROPERTY
Our corporate headquarters is located in Lexington, Massachusetts, where we currently lease approximately 31,300 square feet of office space, 20,500 square feet of laboratory space and 3,400 square feet of manufacturing space. Our base rent, for leases at our corporate headquarters, is approximately $2.1 million annually. In addition, we lease approximately 7,600 square feet in Wilmington, Massachusetts for our manufacturing facility, under a lease that expires in 2018 for $0.1 million of base rent annually.

Item 3. LEGAL PROCEEDINGS
We are not party to any material legal proceedings.

Item 4. MINE SAFETY DISCLOSURES
Not applicable.

PART II.

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

Market Information

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

Year ended December 31, 2017	High	Low
First Quarter	$6.42	$4.95
Second Quarter	$5.40	$3.02
Third Quarter	$6.99	$2.50
Fourth Quarter	$4.86	$3.60

Year ended December 31, 2016	High	Low
First Quarter	$11.20	$7.45
Second Quarter	$11.30	$7.65
Third Quarter	$8.12	$4.92
Fourth Quarter	$7.46	$4.89

Dividend Policy

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

Stock Performance Graph

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

Stockholders

The last reported sale price of common stock on March 15, 2018 as reported on the NASDAQ Global Market was $6.38. As of March 15, 2018, there were 12 holders of record of our common stock.

Equity Compensation Plan Information

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

Issuer Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth, for the periods and as of the dates indicated, our selected financial data. The consolidated statement of operations data for the years ended December 31, 2017, 2016, and 2015 and consolidated balance sheet data as of December 31, 2017 and 2016 are derived from our audited financial statements in this Annual Report on Form 10-K. We have derived the consolidated statement of operations data for the year ended December 31, 2014 and 2013 and the consolidated balance sheet data as of December 31, 2015, 2014 and 2013 from our audited financial statements not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of our future results.

Consolidated Statement of Operations Data:	Year ended December 31, 2017	2016	2015	2014	2013
	(in thousands)				
Revenue:					
Product revenue	$3,440	$1,747	$599	$—	$—
Research revenue	1,226	2,333	2,214	119	266
Total revenue	4,666	4,080	2,813	119	266
Costs and expenses:					
Cost of product revenue	12,028	6,872	1,740	—	—
Research and development	23,733	24,009	25,362	19,782	14,936
Selling, general and administrative	22,757	24,077	19,094	11,018	5,022
Total costs and expenses	58,518	54,958	46,196	30,800	19,958
Loss from operations	(53,852)	(50,878)	(43,383)	(30,681)	(19,692)
Interest expense, net	(8,907)	(4,098)	(1,967)	(721)	(403)
Other income (expense), net	331	172	60	12	(515)
Net loss	(62,428)	(54,804)	(45,290)	(31,390)	(20,610)
Accretion of redeemable convertible preferred stock to redemption value	—	—	—	(4,570)	(6,908)
Net loss applicable to common stockholders	$(62,428)	$(54,804)	$(45,290)	$(35,960)	$(27,518)
Net loss per share applicable to common stockholders — basic and diluted	$(1.94)	$(2.11)	$(2.21)	$(4.15)	$(19.72)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders — basic and diluted[1][2][4][6][7]	32,131,512	26,015,751	20,501,748	8,674,931	1,395,562

Consolidated Balance Sheet Data:	As of December 31, 2017	2016	2015	2014	2013
	(in thousands)				
Cash and cash equivalents[1][2][3][4][5][7]	$41,799	$73,488	$73,662	$73,849	$30,198

Total assets	54,861	89,568	86,825	78,978	31,837
Current liabilities[8]	51,197	9,885	12,253	5,179	4,060
Notes payable, net of current portion [3][5]	1,008	39,504	26,121	20,809	3,333
Warrants to purchase redeemable securities [6]	—	—	—	—	1,225
Total liabilities	53,521	50,230	39,886	26,289	8,663
Redeemable convertible preferred stock [6]	—	—	—	—	112,813
Total stockholders' equity (deficit)[6]	1,340	39,338	46,939	53,001	(89,543)

[1] On December 9, 2015 and December 21, 2015, we issued 3,500,000 shares and 191,049 shares of common stock, respectively, in connection with our secondary public offering at $9.75 per share. We raised approximately $33.3 million in net proceeds.

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

[3] On July 11, 2014, December 30, 2014 and December 28, 2015, we received net proceeds of $9.7 million, $10.0 million and $10.0 million, respectively, from our loan and security agreement with Solar Capital, Ltd.

[4] On September 21, 2016, we sold 6,055,341 shares of common stock at $6.56 per share to Canon U.S.A, Inc., for an aggregate cash purchase price of $39.7 million.

[5] On December 30, 2016, we received net proceeds of $39.2 million from our term loan agreement with CRG Servicing LLC and used $28.0 million from the net proceeds to primarily repay the outstanding balance on our loan and security agreement with Solar Capital, Ltd.

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

[7] On September 15, 2017, the Company sold 5,031,250 shares of its common stock in a CMPO at $4.00 per share, for an aggregate gross cash purchase price of $20.1 million, or proceeds of $18.8 million after underwriters discount and expenses

[8] Current liabilities, as of December 31, 2017, includes a derivative liability of $2.2 million and $39.2 million of CRG debt that was classified as current based on the probability of violating a minimum liquidity covenant included in the debt agreement.

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

This Annual Report on Form 10-K contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy, prospective products and product candidates, their expected performance and impact on healthcare costs, marketing 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" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual Report on Form 10-K. These forward looking statements are subject to numerous risks, including, without limitation, the following:

- our status as an early stage company;
- our expectation to incur losses in the future;
- the market acceptance of our T2MR technology;
- our ability to timely and successfully develop and commercialize our existing products and future product candidates;
- the length and variability of our anticipated sales cycle;
- limited sales history;
- our ability to gain the support of leading hospitals and key thought leaders and publish the results of our clinical trials in peer-reviewed journals;
- our ability to successfully manage our growth;
- our future capital needs and our ability to raise additional funds;
- the performance of our diagnostics;
- our ability to compete in the highly competitive diagnostics market;
- our ability to obtain marketing clearance from the FDA or regulatory clearance for new product candidates in the United States or any other jurisdiction;
- federal, state, and foreign regulatory requirements, including FDA regulation of our product candidates;
- our ability to protect and enforce our intellectual property rights, including our trade secret-protected proprietary rights in T2MR;
- our ability to recruit, train and retain key personnel;
- our dependence on third parties;
- our ability to continue as a going concern;
- manufacturing and other product risks;
- the impact of adoption of new accounting standards; and
- the Tax Cuts and Jobs Act of 2017 (Tax Reform).

These forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report on Form 10-K. Unless required by U.S. federal securities laws, we do not intend to update any of these forward-looking statements to reflect circumstances or events that occur after the statement is made or to conform these statements to actual results. The following discussion should be read in conjunction with the financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under “Item 1A. Risk Factors” in this Annual Report on Form 10-K, and elsewhere in this Annual Report on Form 10-K.

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

Business Overview

We are an in vitro diagnostics company that has developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. We are using our T2 Magnetic Resonance technology ("T2MR") to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. T2MR enables rapid detection of pathogens, biomarkers and other abnormalities in a variety of unpurified patient sample types, including whole blood, plasma, serum, saliva, sputum and urine, and can detect cellular targets at limits of detection as low as one colony forming unit per milliliter ("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 FDA for our first two products, the T2Dx Instrument (the "T2Dx") and the T2Candida Panel ("T2Candida"), 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 1,200 hospitals with the highest concentration of patients at risk for sepsis-related infections. Outside of the United States, we have primarily partnered with distributors that target large hospitals in their respective markets. Four additional diagnostic applications in various stages of development are called T2Bacteria, T2Candida-auris, T2GNR and T2Lyme, which are focused on bacterial and fungal infections and Lyme disease, respectively. In late 2015, we initiated the collection of patient blood samples to support the clinical trial in the United States for T2Bacteria, and in early 2017, we initiated a multi-site clinical trial for T2Bacteria. The T2Bacteria Panel received authorization to affix a CE mark in July 2017 and is being commercially marketed in Europe and other countries that accept the CE mark. The multi-site clinical study was completed in the United States in August 2017. On September 8, 2017, we filed a 510(k) premarket submission with the FDA requesting market clearance to enable commercial launch of T2Bacteria for clinical use in the United States. T2 Bacteria is currently available in the United States for Research Use Only (RUO). We believe that we may receive a determination from the FDA on our application for the T2Bacteria possibly as early as the second quarter of 2018, although it may take longer for the FDA to reach a decision and there can be no assurance of such a determination within this timeframe or at all. We believe that T2Bacteria, if approved, may expand the number of high risk patients who could be candidates for testing with T2Bacteria. We expect that existing reimbursement codes will support our sepsis and Lyme disease products and product candidates, and that the anticipated economic savings associated with testing of hospital inpatients in the United States with our sepsis products will be realized directly by hospitals.

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. 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. T2Candida'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 CDC recently called "one of our most serious health threats." The T2Sepsis Solution refers to the approach of combining the standard of care for the management of sepsis patients with our products, including the T2Dx Instrument, or the T2Dx, T2Candida, and T2Bacteria, which is commercially available in Europe and other countries that accept the CE mark and available for research use only in the United States. The T2Sepsis Solution is designed to enable clinicians to potentially treat 90% of septic patients within the first twelve hours of developing the symptoms of disease. Currently, high risk patients are typically initially treated with broad spectrum antibiotic drugs that typically cover approximately 60% of patients with infections. Of the remaining 40% of patients, approximately 30% of the patients typically have a bacterial infection and 10% typically have Candida infections. T2Candida and our product candidate, T2Bacteria are designed to identify pathogens commonly not covered by broad spectrum antibiotic drugs, which we believe may enable physicians to effectively treat an additional 30% of patients with sepsis related infections beyond the 60% of patients covered by broad spectrum antibiotic drugs.

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

We have never been profitable and have incurred net losses in each year since inception. Our accumulated deficit at December 31, 2017 was $266.1 million. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and

from selling, general and administrative costs associated with our operations. We have incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution of our FDA-cleared T2Dx and T2Candida. In addition, we will continue to incur significant costs and expenses as we continue to develop other product candidates, improve existing products and maintain, expand and protect our intellectual property portfolio. We may seek to fund our operations through public equity or private equity or debt financings, as well as other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on our business, results of operations and financial condition and our ability to develop, commercialize and drive adoption of the T2Dx, T2Candida, our product candidate, T2Bacteria, and future T2MR-based diagnostics.

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

Management believes that its existing cash and cash equivalents at December 31, 2017, together with the remaining liquidity on the Term Loan Agreement with CRG, will be sufficient to allow the Company to fund its current operating plan through March 2019. However, because certain elements of the Company's operating plan are outside of the Company's control, including the approval of the Company's T2Bacteria Panel and receipt of certain development and regulatory milestone payments under the Company's Co-Development agreements, they cannot be considered probable according to accounting standards. Under ASC 205-40, the future receipt of potential funding from the Company's Co-Development partners and other resources cannot be considered probable at this time because none of the plans are entirely within the Company's control. In addition, the Company is required to maintain a minimum cash balance under its Term Loan Agreement with CRG (Note 6).

These conditions raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date that the financial statements are issued. Management's plans to alleviate the conditions, should it be necessary, include raising additional funding, earning milestone payments pursuant the Company's Co-Development agreements, delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels for the Company to continue as a going concern for a period of 12 months from the date the financial statements are issued. Management has concluded the likelihood that its plan to obtain sufficient funding from one or more of these sources or adequately reduce expenditures will be successful, while reasonably possible, is less than probable.

Our Commercial Products and the Unmet Clinical Need

Our initial FDA-cleared products, the T2Dx and T2Candida, utilize T2MR to detect species-specific Candida directly from whole blood in as few as three hours versus the one to six or more days typically required by blood culture-based diagnostics. This allows the patient to potentially receive the correct treatment in four to six hours versus 24 to 144 hours for blood culture. The T2Candida runs on the T2Dx and provides high sensitivity with a limit of detection as low as 1 CFU/mL, even in the presence of antimicrobial therapy.

Our T2Candida Panel

Our direcT2 pivotal clinical trial was designed to evaluate the sensitivity and specificity of T2Candida on the T2Dx. The direcT2 trial consisted of two patient arms: a prospective arm with 1,501 samples from patients with a possible infection and a seeded arm with 300 samples, also obtained from patients with a possible infection. T2Candida and the T2Dx demonstrated a sensitivity of 91.1 percent and a specificity of 99.4 percent. In addition, the speed to a species-specific positive result with T2Candida was 4.4 hours versus 129 hours with blood culture. A negative result from T2Candida was obtained in just 4.2 hours versus greater than 120 hours with blood culture. The data and other information from the direcT2 pivotal clinical trial was published in January 2015 in Clinical Infectious Diseases.

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 2016, 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 United States 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. 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, which we believe will potentially enable physicians to 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 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.

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$) seven day reduction in median Intensive Care Unit (“ICU”) length of stay per positive patient that was identified as positive for Candida after implementation of the T2Candida test panel and a trend ($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, median 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 average 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 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. T2Candida’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, hospital costs and potentially, the growing resistance to antifungal therapy. This inappropriate therapy is a driving force behind the spread of antimicrobial-resistant pathogens, which the CDC recently called “one of our most serious health threats.”

Our T2Candida auris Panel

On September 6, 2017, we announced that the CDC has agreed to validate the T2Dx Instrument and the T2Cauris investigational use only panel in their laboratory for potentially testing and monitoring the emergence and outbreaks of the superbug Candida auris in hospitals around the country. Candida auris is a multi-drug resistant pathogen recognized by the CDC as a "serious global health threat" because it can be resistant to "all three major classes of antifungal drugs" and difficult to identify. The CDC has also reported that more than one in three patients with Candida auris infections have died. Unlike most other species of Candida, Candida auris can spread quickly in a hospital making rapid identification and hospital environment surveillance a critical component of containing these outbreaks. Existing laboratory methods that detect Candida auris, including blood culture, suffer from prolonged detection times and low accuracy, which exacerbates the challenge in the fight to contain the superbug. Recently, reported cases have surged internationally, and the CDC has reported a significant increase in infected patients in the United States. According to the European Centre for Disease Prevention and Control, hospital outbreaks have occurred in the United Kingdom and Spain. Because Candida auris can be resistant to most treatment options and can spread so quickly, these hospital outbreaks have been difficult to contain by even the most enhanced control measures. We are also conducting a study in Europe that has demonstrated the ability to detect Candida auris directly in patient blood specimens.

Our T2Bacteria Panel

We have also developed a product candidate named T2Bacteria, a multiplex diagnostic panel that detects five major bacterial pathogens associated with sepsis and, in conjunction with T2Candida and standard empiric therapy regimens, may enable the early, appropriate treatment of 90% of sepsis patients. T2Bacteria, which will also run on the T2Dx, is expected to address the same approximately 6.75 million symptomatic high-risk patients as T2Candida and also a new population of patients who are at increased risk for bacterial infections, including an additional two million patients presenting with symptoms of infection in the emergency room setting. The T2Bacteria Panel received authorization to affix a CE mark in July 2017 and is being commercially marketed in Europe and other countries that accept the CE mark.

On August 4, 2017 we completed a pivotal clinical study of the T2Bacteria® Panel, run on the T2Dx® Instrument (T2Dx), which is a qualitative T2 Magnetic Resonance (T2MR®) assay designed for the direct detection of bacterial species in EDTA human whole blood specimens from patients with suspected bacteremia. The T2Bacteria Panel is designed to identify five species of bacteria directly from human whole blood specimens: Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Staphylococcus aureus. Outside of the United States, the CE marked T2Bacteria panel identifies all 5 of these species along with a 6th species, Acinetobacter Baumannii.

The performance characteristics of the T2Bacteria Panel were evaluated through a series of analytical studies as well as a multi-center clinical study. The clinical study evaluated the performance of the T2Bacteria Panel in comparison to the current standard of care, blood culture. All of the data generated in the analytical studies and the clinical study were submitted to the United States Food and Drug Administration, or FDA, in a 510(k) premarket submission on September 8, 2017.

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

T2Bacteria is currently available in the United States for RUO and is CE marked and available in Europe and other countries that accept the CE Mark.

Our Sepsis Solution

We believe our T2 Magnetic Resonance technology, or T2MR, delivers what no conventional technology currently available can: a rapid, sensitive and simple diagnostic platform to enable sepsis applications that can identify specific sepsis pathogens directly from an unpurified blood sample in hours instead of days at a level of accuracy equal to or better than blood culture-based diagnostics. The T2Sepsis Solution refers to the approach of combining the standard of care for the management of sepsis patients with our products, including the T2Dx Instrument, or the T2Dx, T2Candida, and T2Bacteria, which is commercially available in Europe and other countries that accept the CE mark and available for research use only in the United States. The T2Sepsis Solution is designed to enable clinicians to potentially treat 90% of septic patients within the first twelve hours of developing the symptoms of disease. Currently, high risk patients are typically initially treated with broad spectrum antibiotic drugs that typically cover approximately 60% of patients with infections. Of the remaining 40% of patients, approximately 30% of the patients have a bacterial infection and 10% have Candida infections. T2Candida and product candidate, T2Bacteria are designed to identify pathogens commonly not covered by broad spectrum antibiotic drugs, which we believe may enable physicians to effectively treat an additional 30% of septic patients beyond the 60% of patients covered by broad spectrum antibiotic drugs.

We believe the T2Sepsis Solution provides a pathway for more rapid and targeted treatment of infections, potentially reducing the mortality rate by as much as 75% if a patient is treated within 12 hours of suspicion of infection and significantly reducing the cost burden of sepsis. Each year, approximately 500,000 patients in the United States die from sepsis. According to a study published by Critical Care Medicine in 2006, in sepsis patients with documented hypotension, administration of effective antimicrobial therapy within the first hour of detection was associated

with a survival rate of 79.9% and, over the ensuing six hours, each hour of delay in initiation of treatment was associated with an average decrease in survival of 7.6%. According to such study, the survival rate for septic patients who remained untreated for greater than 36 hours was approximately 5%. The toll of sepsis on a patient's health can be severe: more than one-in-five patients die within two years as a consequence of sepsis. Sepsis is also the most prevalent and costly cause of hospital readmissions.

We believe the T2Sepsis Solution addresses a significant unmet need in in vitro diagnostics by providing:

- Limits of Detection as Low as 1 CFU/mL. T2MR is the only technology currently available that can enable identification of sepsis pathogens directly from a patient's blood sample at limits of detection as low as 1 CFU/mL.
- Rapid and Specific Results in as Few as Three Hours. T2MR is the only technology that can enable species-specific results for pathogens associated with sepsis, directly from a patient's blood sample, without the need for blood culture, to deliver an actionable result in three hours.
- Accurate Results Even in the Presence of Antimicrobial Therapy. T2MR is the only technology that can reliably detect pathogens associated with sepsis, including slow-growing pathogens, such as C. glabrata, directly from a patient's blood sample, even in the presence of an antimicrobial therapy.
- Easy-to-Use Platform. T2MR eliminates the need for sample purification or extraction of target pathogens, enabling sample- to-result instruments that can be operated on-site by hospital staff, without the need for highly skilled technicians.

Our T2Dx Instrument

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

By utilizing our proprietary T2MR technology for direct detection, the T2Dx eliminates the need for sample purification and analyte extraction, which are necessary for other optical-detection devices. Eliminating these sample processing steps increases diagnostic sensitivity and accuracy, enables a broad menu of tests to be run on a single platform, and greatly reduces the complexity of the consumables. The T2Dx incorporates a simple user interface and is designed to efficiently process up to seven specimens simultaneously.

Our T2MR Platform

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

We believe that T2MR can also address the significant unmet need associated with Lyme disease, a tick-borne illness that can cause prolonged neurological disease and musculoskeletal disease. For patients with Lyme disease, early diagnosis and appropriate treatment significantly reduces both the likelihood of developing neurological and musculoskeletal disorders, as well as the significant costs associated with treating these complications. Our product candidate, T2Lyme, will identify the bacteria that cause Lyme disease directly from the patient's blood, without the need for blood culture which, for the bacteria associated with Lyme disease, can take several weeks. Our Lyme product candidate is currently in pre-clinical development and we expect to initiate a T2Lyme clinical trial in 2018.

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

Financial Overview

Revenue

We generate revenue from the sale of our products and from activities performed pursuant to research and development agreements.

Revenue earned from activities performed pursuant to research and development agreements is reported as research revenue using the proportional performance method as the work is completed, limited to payments earned, and the related costs are expensed as incurred as research and development expense.

Product revenue is derived from the sale of our instruments and related consumable diagnostic tests, predominantly through our direct sales force in the United States, and distributors in geographic regions outside the United States. We do not offer product return or exchange rights

(other than those relating to defective goods under warranty) or price protection allowances to our customers, including our distributors. Payment terms granted to distributors are the same as those granted to end-user customers and payments are not dependent upon the distributors' receipt of payment from their end-user customers. We recognize product revenue from the sale of our instruments as soon as all applicable revenue recognition criteria have been met. We expect to continue to place our instruments under reagent rental agreements, in hospitals, certain of which may include minimum commitments and/or an incremental charge on the purchase of our consumable diagnostic tests. Under this business model, we believe we will recover the cost of placing our instruments in hospitals through the margins realized from our consumable diagnostic tests. Our consumable diagnostic tests can only be used with our instruments, and accordingly, as the installed base of our instruments grows, we expect the following to occur:

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

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

Cost of Product Revenue

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

We expect cost of product revenue to continue to represent a high percentage of our product revenue as we continue to invest in our manufacturing capabilities, infrastructure and customer service organization and grow our installed customer base. We plan to continue to expand our capacity to support our growth, which will result in higher cost of revenue in absolute dollars. However, we expect cost of product revenue, as a percentage of revenue, to decline as revenue grows in the future.

Research and development expenses

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

We anticipate our overall research and development expenses to continue to be flat to down over the next several quarters in part due to the completion of our T2Bacteria clinical trial. Research and development costs include costs to support research partnerships, clinical trials and new product development. We have committed, and expect to commit, significant resources toward developing additional product candidates, improving existing products, conducting ongoing and new clinical trials and expanding our laboratory capabilities.

Selling, general and administrative expenses

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

Interest expense, net

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

Other income, net

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

Results of Operations for the Years Ended December 31, 2017 and 2016

	Year ended December 31,		
	2017	2016	Change
	(in thousands)		
Revenue:			
Product revenue	$3,440	$1,747	$1,693
Research revenue	1,226	2,333	(1,107)
Total revenue	4,666	4,080	586
Costs and expenses:			
Cost of product revenue	12,028	6,872	5,156
Research and development	23,733	24,009	(276)
Selling, general and administrative	22,757	24,077	(1,320)
Total costs and expenses	58,518	54,958	3,560
Loss from operations	(53,852)	(50,878)	(2,974)
Interest expense, net	(8,907)	(4,098)	(4,809)
Other income, net	331	172	159
Net loss	$(62,428)	$(54,804)	$(7,624)

Product revenue

During the year ended December 31, 2017, product revenue totaled $3.4 million, compared to $1.7 million for the year ended December 31, 2016, an increase of $1.7 million. The increase was driven by higher comparable sales of T2Candida consumables and instruments of $1.0 million and $0.7 million, respectively. Higher sales were the result of increased usage of diagnostic tests in the installed base and growth in our installed T2Dx Instrument base, as well as international sales of T2Dx Instruments.

Research revenue

We recorded research revenue totaling $1.2 million for the year ended December 31, 2017, compared to $2.3 million for the year ended December 31, 2016, a decrease of $1.1 million. The decrease is due to $1.5 million less revenue recognized under our Co-Development Agreement with Canon US Life Sciences and $0.5 million less revenue recognized for projects completed in 2016. The decrease in revenue under our agreement with Canon US Life Sciences is related to differences in timing between work performed and achievement of milestones and related payments. Decreases in research revenue were partially offset by $0.9 million of revenue recognized under our Co-Development Agreement with Allergan Sales.

Cost of product revenue

During the year ended December 31, 2017, cost of product revenue associated with the sale of our T2Candida Panels and T2Dx Instruments to customers totaled $12.0 million, compared to $6.9 million for the year ended December 31, 2016, an increase of $5.2 million. Cost of product revenue includes a $2.6 million impairment charge related to T2-owned instruments and components. During the fourth quarter of 2017, the Company received communication from the FDA that suggested the approval timeline could be longer than the company initially anticipated. We assessed the recoverability of T2-owned instruments based on delayed T2Bacteria cash flows and recorded the impairment charge. Other increases to the cost of product revenue include $0.4 million of depreciation related to T2 owned instruments, $0.6 million related to idle capacity, $1.1 million of costs related to increased sales of T2Dx

instruments and $0.5 million of costs related to increase consumables sales.

Research and development expenses

Research and development expenses were $23.7 million for the year ended December 31, 2017, compared to $24.0 million for the year ended December 31, 2016, a decrease of approximately $0.3 million. The decrease was primarily due to idle capacity of $1.0 million, related to increased manufacturing production associated with consumables utilized in the T2Bacteria study, decreased pre-clinical expenses of $0.6 million and lower payroll and related expenses of $0.3 million. The decreases in research and development expenses were partially offset by an increase in clinical trial related expenses of $0.9 million, and travel and related expenses of $0.3 million. Increases in these areas were related to the T2Bacteria clinical trial. Decreases in research and development expenses were further offset by a $0.4 million increase in facilities and related costs which include higher depreciation, lab related and engineering prototype expenses.

Selling, general and administrative expenses

Selling, general and administrative expenses were $22.8 million for the year ended December 31, 2017, compared to $24.1 million for the year ended December 31, 2016. The decrease of $1.3 million was due primarily to lower payroll and related expenses of approximately $1.6 million, due to attrition, and decreased travel expenses of $0.3 million related to headcount reductions. The decreases in selling, general and

administrative expenses were partially offset by increased outside services expenditures of $0.3 million and increased facility and other selling, general and administrative expenses of $0.4 million.

Interest expense, net

Interest expense, net, was $8.9 million for the year ended December 31, 2017, compared to $4.1 million for the year ended December 31, 2016. Interest expense, net, increased by $4.8 million due to $2.6 million higher non-cash interest and $2.2 million related to the change in fair value the derivative liability related to the CRG Term Loan Agreement.

Other income, net

Other income, net, was $0.3 million of net income for the year ended December 31, 2017, compared to $0.2 million of net income for the year ended December 31, 2016. Other income, net, increased $0.1 million due primarily to increased dividend and other investment income.

Results of Operations for the Years Ended December 31, 2016 and 2015

	Year ended December 31,		
	2016	2015	Change
	(in thousands)		
Revenue:			
Product revenue	$1,747	$599	$1,148
Research revenue	2,333	2,214	119
Total revenue	4,080	2,813	1,267
Costs and expenses:			
Cost of product revenue	6,872	1,740	5,132
Research and development	24,009	25,362	(1,353)
Selling, general and administrative	24,077	19,094	4,983
Total costs and expenses	54,958	46,196	8,762
Loss from operations	(50,878)	(43,383)	(7,495)
Interest expense, net	(4,098)	(1,967)	(2,131)
Other income, net	172	60	112
Net loss	$(54,804)	$(45,290)	$(9,514)

Product revenue

During the year ended December 31, 2016, product revenue totaled $1.7 million, compared to $0.6 million for the year ended December 31, 2015, an increase of $1.1 million. The increase was driven by an increase in sales volume of our products, primarily the sale of T2Candida consumable diagnostic tests, driven from increased usage of consumable diagnostic tests in the installed base and growth in our installed T2Dx Instrument base, as well as international sales of the T2Dx Instruments, which was 14% of product revenue.

Research revenue

We recorded research revenue totaling $2.3 million for the year ended December 31, 2016, compared to $2.2 million for the year ended December 31, 2015, an increase of $0.1 million. The increase was driven by from activities

performed pursuant to the research and development agreement with Canon US Life Sciences, partially offset by decreased revenue from research and development agreements utilizing T2MR technology with other third parties.

Cost of product revenue

During the year ended December 31, 2016, cost of product revenue associated with the sale of our T2Candida Panels and T2Dx Instruments to customers totaled $6.9 million, compared to $1.7 million for the year ended December 31, 2015, an increase of $5.1 million. The increase was due to continued expansion of manufacturing activities. Cost of product revenue for the year ended December 31, 2016 also included $2.4 million of cost to provide maintenance and technical support services to customers, approximately $1.3 million of costs not allocable to inventory, and $0.6 million of depreciation related to the T2Dx Instruments placed at customer locations pursuant to reagent rental agreements, as compared to $0.8 million, $0.1 million, and $0.1 million, respectively, for the year ended December 31, 2015.

Research and development expenses

Research and development expenses were $24.0 million for the year ended December 31, 2016, compared to $25.4 million for the year ended December 31, 2015, a decrease of approximately $1.4 million. The decrease was primarily due to decreased payroll, payroll-related and

subcontracted research and development expenses of $1.1 million, lower prototype development expenses of $0.4 million, lower travel costs of $0.1 million, and decreased other research and development costs of $0.8 million, which includes lower consulting, facility and lab expenses. Partially offsetting the decrease was an increase of $1.0 million in clinical expenses, primarily related to the T2Bacteria clinical trial.

Selling, general and administrative expenses

Selling, general and administrative expenses were $24.1 million for the year ended December 31, 2016, compared to $19.1 million for the year ended December 31, 2015. The increase of approximately $5.0 million was due primarily to increased payroll and related expenses of $3.4 million as we expanded our sales personnel, including $0.6 million of increased stock compensation expense, increased consulting, audit, public relations and patent fees of $0.8 million, increased travel expenses of $0.5 million related to increased sales personnel, increased other selling, general and administrative expenses of $0.2 million, and increased marketing program expenditures of $0.1 million.

Interest expense, net

Interest expense, net, was $4.1 million for the year ended December 31, 2016, compared to $2.0 million for the year ended December 31, 2015. Interest expense, net, increased by $2.1 million due to higher borrowing levels on our notes payable and a $0.9 million loss on extinguishment of debt resulting from our debt refinancing during the fourth quarter of 2016.

Other income, net

Other income, net, was $0.2 million for the year ended December 31, 2016, compared to $0.1 for the year ended December 31, 2015. Other income, net, increased $0.1 million due primarily to increased dividend and other investment income.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception, and as of December 31, 2017, we had an accumulated deficit of $266.1 million. Having obtained clearance from the FDA and a CE mark in Europe to market the T2Dx and T2Candida, the Company has incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution. In addition, the Company anticipates costs and expenses may increase as the Company continues to develop other product candidates, improve existing products and maintain, expand and protect its intellectual property portfolio. The Company may seek to fund its operations through public equity or private equity or debt financings, as well as other sources. However, the Company may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. The Company’s failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on the Company’s business, results of operations and financial condition and the Company’s ability to develop and commercialize T2Dx, T2Candida, T2Bacteria, and other product candidates.

Historically, the Company has funded its operations primarily through its August 2014 initial public offering, its December 2015 confidentially marketed public offering (“CMPO”), its September 2016 private investment in public equity (“PIPE”) financing, its September 2017 CMPO, private placements of redeemable convertible preferred stock and debt financing arrangements.

Plan of operations and future funding requirements

As of December 31, 2017 we had cash and cash equivalents of $41.8 million. Currently, our funds are primarily held in money market funds invested in U.S. government agency securities. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, costs related to our products, clinical trials, laboratory and related supplies, supplies and materials used in manufacturing, legal and other regulatory expenses and general overhead costs.

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

Going Concern

Our ability to continue operations after December 31, 2018 will depend on our ability to obtain additional funding, as to which no assurances can be given. These conditions raise substantial doubt about our ability to continue as a going concern. There can be no assurance that any financing by us can be realized, or if realized, what the terms of any such financing may be, or that any amount that we are able to raise will be adequate.

Management believes that the existing cash and cash equivalents at December 31, 2017, together with the additional remaining liquidity on our Term Loan Agreement of up to an additional $10.0 million, will be sufficient to fund our current operating plan through March 2019. The borrowing on the Term Loan Agreement is available at any time through September 27, 2018, and is subject to certain conditions including that we receive 510(k) clearance for the marketing of T2BacteriaTM by the FDA by June 30, 2018. Should our current operating plan not materialize Management's plans include raising additional funding, earning milestone payments pursuant the Company’s Co-Development agreements,

delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels for the Company to continue as a going concern for a period of 12 months from the date the financial statements are issued. Management has concluded the likelihood that its plan to obtain sufficient funding from one or more of these sources or adequately reduce expenditures will be successful, while reasonably possible, is less than probable. The Term Loan Agreement also requires us to achieve certain annual revenue targets, whereby we are required to pay double the amount of any shortfall as an acceleration of principal payments, and maintain a minimum liquidity amount. Should we fall short of the revenue target we would seek a waiver of this provision. There can be no assurances that we would be successful in obtaining a waiver.

Cash flows

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

	Year ended December 31,		
	2017	2016	2015
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	$(47,718)	$(46,442)	$(37,465)
Investing activities	(2,476)	(5,487)	(7,894)
Financing activities	18,505	51,755	45,172
Net (decrease) increase in cash and cash equivalents	$(31,689)	$(174)	$(187)

Net cash used in operating activities

Net cash used in operating activities was $47.7 million for the year ended December 31, 2017, and consisted primarily of a net loss of $60.6 million adjusted for non-cash items including depreciation and amortization expense of $2.9 million, stock-based compensation expense of $4.8 million, non-cash interest expense of $2.7 million, change in fair value of a derivative instrument of $2.2 million and an impairment charge of $2.6 million, partially offset by deferred rent of $0.1 million and a net change in operating assets and liabilities of $0.1 million. The net change in operating assets and liabilities was primarily driven by a $0.7 million increase in deferred revenue, $0.3 million decrease in accounts payable, $0.1 increase in accounts receivable and $0.1 million increase in inventory, offset by an increase of $0.7 million in accrued expenses and other liabilities.

Net cash used in operating activities was $46.4 million for the year ended December 31, 2016, and consisted primarily of a net loss of $54.8 million adjusted for non-cash items including depreciation and amortization expense of $2.3 million, stock-based compensation expense of $4.8 million, a net change in operating assets and liabilities of $0.8 million, non-cash interest expense of $0.6 million and non-cash charge on extinguishment of debt of $0.1 million, partially offset by deferred rent of $0.3 million. The net change in operating assets and liabilities was primarily driven by a $0.3 million increase in deferred revenue and an increase of $0.5 million in accounts payable and accrued expenses related to growth in the business.

Net cash used in operating activities was $37.5 million for the year ended December 31, 2015, and consisted primarily of a net loss of $45.3 million adjusted for non-cash items including depreciation and amortization expense of $1.5 million, stock-based compensation expense of $4.2 million and non-cash interest expense of $0.4 million, partially offset by a net change in operating assets and liabilities of $2.0 million and deferred rent of $0.1 million. The net change in operating assets and liabilities was primarily driven by a $2.1 million increase in deferred revenue resulting from payment from our Co-Development Agreement with Canon US Life Sciences, an increase of $0.4 million in

accounts payable and accrued expenses related to growth in the business, partially offset by purchases of inventory of $0.6 million and increased accounts receivable of $0.2 million related to research and product revenue.

Net cash used in investing activities

Net cash used in investing activities was $2.5 million for the year ended December 31, 2017, and consisted of $2.5 million of purchases of property and equipment, including $1.8 million of costs to purchase materials and manufacture T2 owned instruments and components and $0.7 million of purchases of lab equipment, manufacturing equipment and other property and equipment.

Net cash used in investing activities was $5.5 million for the year ended December 31, 2016, and consisted of $5.5 million of purchases of property and equipment, including $4.2 million of costs to purchase materials and manufacture T2 owned instruments and components and $1.3 million of purchases of lab equipment, manufacturing equipment and other property and equipment.

Net cash used in investing activities was $7.9 million for the year ended December 31, 2015, and consisted of $8.0 million of purchases of property and equipment, including $4.4 million of costs to purchase materials and manufacture T2 owned instruments and components, $2.6 million of leasehold improvements and $1.0 million of purchases of lab equipment, manufacturing equipment and other property and equipment. Partially offsetting these outflows was $0.1 million of proceeds from restricted cash accounts related to an operating lease agreement.

Net cash provided by financing activities

Net cash provided by financing activities was $18.5 million for the year ended December 31, 2017, and consisted of $18.6 million of net proceeds from our September 15, 2017 Confidentially Marketed Public Offering ("CMPO"), in which we sold 5,031,250 shares of common stock at the closing price of $4.00 per share and $1.1 million of proceeds from the exercise of stock options and sale of common stock under our 2014 Employee Stock Purchase Plan. Partially offsetting these sources of cash were $1.2 million of repayments of notes payable.

Net cash provided by financing activities was $51.8 million for the year ended December 31, 2016, and consisted of $39.7 million of net proceeds from our September 21, 2016 PIPE financing with Canon, in which we sold 6,055,341 shares of common stock at the closing price of $6.56 per share, $39.2 million of net proceeds from our December 30, 2016 term loan agreement with CRG Servicing LLC, $4.6 million of proceeds under the Facility with Essex, and $1.0 million of proceeds from the exercise of stock options and sale of common stock under our 2014 Employee Stock Purchase Plan. Partially offsetting these sources of cash were $32.4 million of repayments of notes payable and $0.4 million of payments of issuance costs from our December 2015 secondary offering.

Net cash provided by financing activities was $45.2 million for the year ended December 31, 2015, and consisted of $33.7 million of proceeds from the sale of common stock in a public offering, $10.0 million of proceeds from borrowing from our loan agreement with Solar Capital, Ltd., $1.8 million of proceeds from the issuance of common stock from our stock incentive plans, partially offset by repayments of notes payable of $0.3 million.

Borrowing Arrangements

Term Loan Agreement

In December 2016, the Company entered into a Term Loan Agreement (the "Term Loan Agreement") with CRG Servicing LLC ("CRG"). The Company initially borrowed $40.0 million pursuant to the Term Loan Agreement and may borrow up to an additional $10.0 million at any time through and including July 27, 2018, provided that, among other conditions, the Company receives 510(k) clearance for the marketing of T2BacteriaTM by the U.S. Food and Drug Administration ("FDA") on or before April 30, 2018 (the "Approval Milestone"). The Term Loan Agreement has a six-year term with three years (through December 30, 2019) of interest-only payments, which period shall be extended to four years (through December 30, 2020) if the Company achieves the Approval Milestone, after which quarterly principal and interest payments will be due through the December 30, 2022 maturity date. Interest on the amounts borrowed under the Term Loan Agreement accrues at an annual fixed rate of (a) prior to the Approval Milestone, 12.50%, 4.0% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount and (b) following the Approval Milestone, 11.50%, 3.5% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount. In addition, if the Company achieves certain financial performance metrics, the loan will convert to interest-only until the December 30, 2022 maturity, at which time all unpaid principal and accrued unpaid interest will be due and payable. The Company is required to pay CRG a financing fee based on the loan principal amount drawn. The Company is also required to pay a final payment fee of 8% of the principal outstanding upon repayment. In March 2018 the Term Loan Agreement was amended to extend the Approval Milestone to June 30, 2018, the additional $10.0 million funding through September 27, 2018 and reduce the fiscal year 2018 revenue target to $7.0 million.

The Company may prepay all or a portion of the outstanding principal and accrued unpaid interest under the Term Loan Agreement at any time upon prior notice subject to a certain prepayment fee during the first five years of the term and no prepayment fee thereafter. As security for its obligations under the Term Loan Agreement the Company entered into a security agreement with CRG whereby the Company granted a lien on substantially all of its assets, including intellectual property. The Loan Agreement also contains customary affirmative and negative covenants for a credit facility of this size and type. The Loan Agreement also requires the Company to achieve certain revenue targets, whereby the Company is required to pay double the amount of any shortfall as an acceleration of principal payments,

and maintain a minimum liquidity amount. The Loan Agreement includes customary events of default that could result in the acceleration of the obligations under the Loan Agreement. Under certain circumstances, a default interest rate of an additional 4.00% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default. The Term Loan Agreement is classified as a current liability on the balance sheet at December 31, 2017, based on the Company's consideration of the probability of violating a minimum liquidity covenant included in the Term Loan Agreement. On December 18, 2017, the Term Loan Agreement was amended and the 2017 minimum revenue target was reduced to $3.0 million from $5.0 million.

The Company assessed the terms and features, including the interest-only period dependent on the achievement of the Approval Milestone by April 30, 2018, and acceleration of the obligations under the Loan Agreement under an event of default, of the Term Loan Agreement in order to identify any potential embedded features that would require bifurcation. In addition, under certain circumstances, a default interest rate of an additional 4.0% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default. The Company concluded that these features are not clearly and closely related to the host instrument, and represent a single compound derivative and is required to be re-measured at fair value on a quarterly basis.

During the fourth quarter of 2017, the Company received communication from the FDA that suggested the approval timeline of T2Bacteria would be longer than the Company initially anticipated. The delay resulted in an increase in the probability of not achieving the Approval Milestone by April 30, 2018, as well an increase in the probability of the payment of contingent interest in future periods, based on the contractual payments requirements that exist as of December 31, 2017. As such, in the fourth quarter, the Company recorded a derivative liability related to the Company's debt agreement with CRG of $2.2 million.

In December 2016, pursuant to the Term Loan Agreement, the Company made an initial draw of $39.2 million, net of financing fees. The Company used approximately $28.0 million of the initial proceeds to repay approximately $27.5 million of outstanding debt pursuant to the Loan and Security Agreement and to repay approximately $0.5 million of outstanding debt pursuant to the Promissory Note. Upon the repayment of all amounts owed by the Company under these agreements, all commitments were terminated and all security interests granted by the Company were released. The Company intends to retain the remainder of the initial net proceeds of approximately $11.2 million for general corporate purposes and working capital. As of December 31, 2017, we were in compliance with all covenants.

Equipment Lease Credit Facility

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

In April 2016 and June 2016, the Company completed the first two draws under the Credit Facility of $2.1 million and $2.5 million, respectively. The Company will make monthly payments of $67,000 under the first draw and $79,000 under the second draw. The borrowings under the Credit Facility are treated as capital leases. The amortization of the assets conveyed under the Credit Facility is included as a component of depreciation expense.

Contractual Obligations and Contingent Liabilities

The following summarizes our significant contractual obligations as of the date of issuance of this annual report on Form 10-K:

	Payments Due by Fiscal Year Ended December 31,				
	Total	2018	2019-2020	2021-2022	Thereafter
	(in thousands)				
Operating leases [1]	$8,449	$2,173	$ 4,350	$ 1,926	$ —
Notes payable [2][3][4]	68,322	67,266	1,056	-	—
Total obligations	$76,771	$69,439	$ 5,406	$ 1,926	$ —

[1] Represents the leases of approximately 62,800 square feet for office, laboratory and manufacturing space in Lexington and Wilmington, Massachusetts under noncancelable operating leases, which includes the lease amendment entered into on March 7, 2017 for office and laboratory space at our headquarters in Lexington, MA.

[2] Represents borrowing under our Term Loan Agreement, which currently bears interest at an annual rate of 12.5% and has principal repayment dates through September 2022, and our Credit Facility, which has principal repayment dates through May 2019. The balance for these debt instruments includes estimated interest payment obligations.

[3] This does not include prepayment penalties.

[4] The Term Loan Agreement with CRG is classified as a current liability on the balance sheet at December 31, 2017, based on the Company's consideration of the probability of violating a minimum liquidity covenant included in the Term Loan Agreement. The contractual terms of the agreement require payments of $3.5 million, $13.4 million

and $48.6 million during the years ended December 31, 2018, 2019-2020 and 2021-2022, respectively.

Contingent Liabilities and Commitments, Including Tax Matters

We have net deferred tax assets of $77.7 million as of December 31, 2017, which have been fully offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. The deferred tax assets are primarily composed of federal net operating loss ("NOL"), tax carryforwards and research and development tax credit carryforwards. As of December 31, 2017, we had federal NOL carryforwards of $229.1 million available to reduce future taxable income, if any. These federal NOL carryforwards are available to offset future taxable income, if any, through 2037. In general, if we experience, or have experienced, a greater than 50% aggregate change in ownership of certain significant stockholders over a three-year period, or a Section 382 ownership change, utilization of our pre-change NOL carryforwards are subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization and may be substantial. If we experience a Section 382 ownership change in connection as a result of future changes in our stock ownership, some of which changes are outside of our control, the tax benefits related to the NOL carryforwards may be limited or lost. We have not conducted an assessment to determine whether there may have been a Section 382 or 383 ownership change.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Significant Judgements

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

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

Revenue Recognition

We generate revenue from product sales, which includes the sale of instruments, consumable diagnostic tests and related services, and research and development agreements with third parties. Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collection is reasonably assured. If any of the revenue recognition criteria described have not been met, we defer revenue until such time each of the revenue recognition criteria have been satisfied.

Product revenue is generated by the sale of instruments and consumable diagnostic tests. We either directly sell instruments to customers and international distributors or retain title and place the instrument at the customer site pursuant to a reagent rental agreement. When the instrument is directly purchased by a customer, we recognize revenue when all applicable revenue recognition criteria are met. When the instrument is placed under a reagent rental agreement, our customers generally agree to fixed term agreements, which can be extended, minimum purchase commitments and/or pay an incremental charge on each consumable diagnostic test purchased, which varies based on the volume of test cartridges purchased. Revenue from the sale of consumable diagnostic tests, which includes the incremental charge, is generally recognized upon shipment as a component of product revenue in our consolidated statements of operations and comprehensive loss.

Direct sales of instruments include warranty, maintenance and technical support services for one year following the installation of a purchased instrument ("Maintenance Services"). After the completion of the initial Maintenance Services period, customers have the option to renew the Maintenance Services for additional one year periods in exchange for additional consideration. In addition, we may provide training to customers. We defer revenue from the initial sale of the instrument equal to the relative fair value of other deliverables, including one year of Maintenance Services, and recognize the amounts ratably over the service delivery period.

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

accrue warranty costs associated with the estimated defect rates of the consumable diagnostic tests.

We do not offer rights of return for instruments or consumable diagnostic tests.

For multiple-element arrangements, we identify the deliverables included within each agreement and evaluate which deliverables represent separate units of accounting. The determination that multiple elements in an arrangement meet the criteria for separate units of accounting requires us to exercise our judgment. We account for those components as separate elements when the following criteria are met: (1) the delivered items have value to the customer on a stand-alone basis; and, (2) if there is a general right of return relative to the delivered items, delivery or performance of the undelivered items is considered probable and within its control.

The consideration received is allocated among the separate units of accounting based on a selling price hierarchy. The selling price hierarchy is based on: (1) vendor specific objective evidence (“VSOE”), if available; (2) third party evidence of selling price if VSOE is not available; or (3) best estimated selling price (“BESP”) if neither VSOE nor third party evidence is available. We generally expect that we will not be able to establish selling price using third-party evidence due to the nature of our products and the markets in which we compete, and, as such, we typically will determine selling price using VSOE or BESP.

When we establish selling price using BESP, consideration is given to both market and Company-specific factors, including the cost to produce the deliverable and the anticipated margin on that deliverable, as well as the characteristics of markets in which the deliverable is sold.

Revenue earned from activities performed pursuant to research and development agreements is reported as research revenue in the consolidated statements of operations and comprehensive loss, and is recognized using the proportional performance method as the work is completed, limited to payments earned, and the related costs are expensed as incurred as research and development expense. The timing of receipt of cash from our research and development agreements generally differs from when revenue is recognized.

Stock-based compensation

We issue stock-based awards to employees and non-employees, generally in the form of stock options and restricted stock awards. We account for our stock-based awards in accordance with FASB ASC Topic 718, Compensation — Stock Compensation, or ASC 718. ASC 718 requires all stock-based payments to employees, including grants of employee stock options and modifications to existing stock options, to be recognized in the consolidated statements of operations and comprehensive loss based on their grant date fair values. We account for stock-based awards to non-employees in accordance with FASB ASC Topic 505-50, Equity-Based Payments to Non-Employees, which requires the fair value of the award to be remeasured at fair value as the award vests. We recognize the compensation cost of stock-based awards to employees and non-employees on a straight-line basis over the vesting period. See below for a detailed description of how we estimate fair value for purposes of option grants and the methodology used in measuring stock-based compensation expense.

We estimate the fair value of our stock-based awards to employees and non-employees using the Black-Scholes-Merton option pricing model, which requires the input of highly subjective assumptions, including (a) the expected volatility of our stock, (b) the expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of company specific historical and implied volatility data resulting from our limited public market trading history, we have based our estimate of expected volatility primarily on the historical volatility of a group of similar companies that are publicly traded. For these analyses, we have selected companies with comparable characteristics to ours, including enterprise value, risk profiles and position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. We compute the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of our stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. We have estimated the expected life of our employee stock options using the "simplified" method, whereby the expected life equals the average of the vesting term and the original contractual term of the option. The risk-free interest rates for periods within the expected life of the option are based on the U.S. Treasury yield curve in effect during the period in which the options were granted.

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

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

Inventories

Inventories are stated at the lower of cost or net realizable value. The Company determines the cost of its inventories, which includes amounts related to materials, direct labor, and manufacturing overhead, on a first-in, first-out basis.

We perform an assessment of the recoverability of capitalized inventory during each reporting period, and writes down any excess and obsolete inventories to their realizable value in the period in which the impairment is first identified. Shipping and handling costs incurred for inventory purchases are capitalized and recorded upon sale in cost of product revenues in the consolidated statements of operations and comprehensive loss or are included in the value of T2-owned instruments and components, a component of property and equipment, net, and depreciated.

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

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

Income Taxes

During 2017 we recorded no income tax benefit due to the full valuation allowance recorded against the Company's deferred tax assets. The Tax Cuts and Jobs Act reduced the federal tax rate from 35% to 21% and we re-measured certain deferred tax assets and liabilities based on the rates at which they are anticipated to reverse in the future. The provisional amount recorded related to the re-measurement of our deferred tax balance was a tax expense of $32.9 million which was offset by an adjustment to the valuation allowance against our deferred taxes of $32.9 million.

During 2016 and 2015 we recorded no income tax benefit due to the full valuation allowance recorded against the Company's deferred tax assets.

Impairment of Long Lived Assets

We review long lived assets, including capitalized T2 owned instruments and components, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indications of impairment exist, projected future undiscounted cash flows associated with the asset or asset group are compared to the carrying amount to determine whether the asset's value is recoverable. During this review, we reevaluate the significant assumptions used in determining the original cost and estimated lives of long lived assets. Although the assumptions may vary from asset to asset, they generally include operating results, changes in the use of the asset, cash flows and other indicators of value. Management then determines whether the remaining useful life continues to be appropriate or whether there has been an impairment of long lived assets based primarily upon whether expected future undiscounted cash flows are sufficient to support the assets' recovery. If impairment exists, we would adjust the carrying value of the asset to fair value, generally determined by a discounted cash flow analysis. If the carrying value of the asset exceeds such projected undiscounted cash flows, the asset will be written down to its estimated fair value. We recorded an impairment expense of $2.6 million during the year ended December 31, 2017.

Fair Value of Derivative

Our Term Loan Agreement with CRG contains certain provisions that change the underlying cash flows of the instrument, including an interest-only period dependent on the achievement of the Approval Milestone by April 30, 2018, and acceleration of the obligations under the Loan Agreement under an event of default. In addition, under certain circumstances, a default interest rate of an additional 4.0% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default. We concluded that these features are not clearly and closely related to the host instrument, and represent a single compound derivative and is required to be re-measured at fair value on a quarterly basis.

During the fourth quarter of 2017, we received communication from the FDA that suggested the approval timeline of T2Bacteria might be longer than we initially anticipated. The delay resulted in an increase in the probability of not achieving the Approval Milestone by April 30, 2018, as well an increase in the probability of the payment of contingent interest in future periods, based on the contractual payments requirements that exist as of December 31, 2017. As such, in the fourth quarter, we recorded a derivative liability related to the Company's debt agreement with CRG of $2.2 million. The estimated fair value of the derivative liability was determined using a probability-weighted discounted cash flow model that includes principal and interest payments under the following scenarios: FDA approval by April 30, 2017 (40%), FDA approval after April 30, 2017 (20%) and no FDA approval (40%). Should our assessment of these probabilities change, including amendments of projected revenue targets, there could be a change

to the fair value of the derivative liability.

Recent Accounting Standards

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

Accounting Standards Adopted

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory ("ASU 2015-11"). The standard simplifies the subsequent measurement of inventory by requiring inventory to be measured at the lower of cost and net realizable value for entities using the first-in-first out method of valuing inventory. ASU 2015-11 eliminates other measures required by current guidance to determine net realizable value. ASU 2015-11 is effective for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years and early adoption is permitted. The Company's adoption of this standard did not have a material effect on its consolidated financial statements.

In March 2016, the FASB released ASU No. 2016-09 Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09") which is intended to simplify income tax accounting for excess tax benefits, accounting for forfeitures, and employer statutory withholding. Under the current guidance, excess tax benefits that result from an award vesting or settling are recognized in additional paid-in capital in the

period that they reduce cash taxes payable. This requires the provision to be computed on a with and without option basis and may result in net operating loss and credit carryforwards on the balance sheet being less than what is available on the tax return. Under the new guidance, the income tax effects of awards will be recognized as a component of income tax expense when the awards vest or are settled (regardless if cash taxes are reduced). For interim reporting purposes, companies will account for excess tax benefits and tax deficiencies as discrete items in the period during which they occurred. The guidance is effective for public entities for fiscal years beginning after December 15, 2016, and interim periods within those years. Early adoption is permitted, however all of the guidance included in the update must be applied when adopted. The Company must use a modified retrospective transition method for adopting and record the cumulative effect of all unrecognized benefits and any change in valuation allowances at the end of the prior tax period as an adjustment to retained earnings. The Company's adoption of this standard did not have a material effect on its consolidated financial statements and prior periods have not been adjusted. As a result, the Company established a net operating loss deferred tax asset of $1.2 million to account for prior period excess tax benefits through retained earnings, however an offsetting valuation allowance of $1.2 million will also be established through retained earnings because it is not more likely than not that the deferred tax asset will be realized due to historical and expected future losses, such that there is no impact on the Company's consolidated financial statements. The Company also elected to maintain the use of estimated forfeitures in the calculation of stock based compensation.

In March 2016, the FASB issued ASU No. 2016-06, Derivatives and Hedging (Topic 815): Contingent Put and Call Options in Debt Instruments ("ASU 2016-06"), which applies to all issuers of or investors in debt instruments with embedded call or put options. ASU 2016-06 clarifies the requirements for assessing whether contingent call or put options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts. Entities performing the assessment under the guidance of ASU 2016-06 are required to assess the embedded call or put options solely in accordance with the four-step decision process. In addition, ASU 2016-06 clarifies what steps are required when assessing whether the economic characteristics and risks of call or put options are clearly and closely related to the economic characteristics and risks of their debt hosts. ASU 2016-06 is effective for financial statements issued for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years using the modified retrospective method for existing debt instruments. The Company's adoption of this standard did not have a material effect on its consolidated financial statements.

Accounting Standards Issued, Not Adopted

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments ("ASC 2016-15"), which provides guidance on the classification of certain specific cash flow issues including debt prepayment or extinguishment costs, settlement of certain debt instruments, contingent consideration payments made after a business combination, proceeds from the settlement of certain insurance claims and distributions received from equity method investees. The standard requires the use of a retrospective approach to all periods presented, but may be applied prospectively if retrospective application would be impracticable. The guidance is effective for public entities for fiscal years beginning after December 15, 2017, and interim periods within those years, and early application is permitted. The Company is currently evaluating the impact of its pending adoption of ASU 2016-15 on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases ("ASU 2016-02"), which applies to all leases. Under ASU 2016-02, a right-of-use asset and lease obligation will be recorded for all leases, whether operating or financing leases, while the statement of operations will reflect lease expense for operating leases and amortization and interest expense for financing leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 and interim periods within those years, which is the year ended December 31, 2019 for the Company. Entities are required to use a modified retrospective approach of adoption for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. Full retrospective application is prohibited. The Company is evaluating the new guidance and the expected effect on the Company's consolidated financial statements.

In June 2014, the FASB issued amended guidance, ASU No. 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"), which is applicable to revenue recognition that will be effective for the Company for the year ending December 31, 2018, as a result of the deferral of the effective date adopted by the FASB in July 2015. The new guidance must be adopted using either a full retrospective approach for all periods presented or a modified retrospective approach. Early adoption prior to the original adoption date (annual reporting periods beginning after December 15, 2016) of ASU 2014-09 is not permitted. The new guidance applies a more principles-based approach to revenue recognition. The Company will adopt the new standard, effective January 1, 2018, under the modified retrospective method.

The Company established an implementation team to assess the potential impacts of the new standard and prepare for adoption. The implementation team has reviewed current accounting policies and practices and identified potential differences resulting from the application of the new standard. Findings and progress of the project have been regularly communicated to the Audit Committee and senior management.

The qualitative assessment of the standard provided below are estimates of the expected effects of the adoption of ASC 606. This represents our best estimate of the effects of adopting ASC 606 at the time of the preparation of this Annual Report on Form 10-K. The actual impact of ASC 606 is subject to change from these estimates and such change may be significant, pending the completion of our assessment in the first quarter of 2018.

The implementation team is in the process of completing an analysis of our revenue generating arrangements, including direct sales of instruments and consumables, sales of instruments and consumables to distributors, reagent rental agreements and research agreements. A detailed policy for each revenue stream has been drafted. The Company is in the process of implementing appropriate changes to controls, processes, and systems to support recognition and disclosure under the new standard. In addition, the Company continues to monitor changes, modifications, clarifications or interpretations, which may impact the results of adoption, undertaken by the FASB.

The impact of adopting the new standard is not expected to be material to 2017 and 2016 revenue. The most significant impacts of the new standard, upon adoption, are expected to be around the timing of revenue recognition. Specifically, under the new standard:

- Consideration allocated to the instrument in a direct sale will be recognized upon shipment and consideration allocated to installation will be recognized upon installation. Currently, revenue recognition for both obligations occurs upon installation.
- Revenue recognition on sales to distributors may be accelerated based on management's judgement regarding use of the sell-in or sell-through method. Currently, the Company recognizes revenue with new distributors based on the sell-through method, which requires deferral of revenue until product is sold to an end customer.

The Company does not expect the adoption of the new standard to a have material impact on our consolidated balance sheet. The Company does expect significant changes to its financial statement disclosures.

Emerging Growth Company Status

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

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of December 31, 2017, we had cash and cash equivalents of $41.8 million held primarily in money market funds consisting of U.S. government agency securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate one percent change in interest rates would not have a material effect on the fair market value of our portfolio. As of December 31, 2017, we had no outstanding debt exposed to variable interest rates.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA
Report of Independent Registered Public Accounting Firm

The Stockholders and the Board of Directors of T2 Biosystems, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of T2 Biosystems, Inc. (the Company) as of December 31, 2017 and 2016, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2017, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, will require additional capital to fund its current operating plan, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. In addition, the Company has classified certain debt obligations with long-term contractual maturities as current liabilities due to likely future debt covenant violations. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The 2017 consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2008

Boston, Massachusetts

March 19, 2018

T2 Biosystems, Inc.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$41,799	$73,488
Accounts receivable	467	327
Prepaid expenses and other current assets	708	820
Inventories	1,344	803
Total current assets	44,318	75,438
Property and equipment, net	10,015	13,589
Restricted cash	260	260
Other assets	268	281
Total assets	$54,861	$89,568
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$648	$962
Accrued expenses and other current liabilities	6,218	4,908
Derivative liability	2,238	—
Notes payable	40,696	1,269
Deferred revenue	1,736	2,445
Current portion of lease incentives	246	301
Total current liabilities	51,782	9,885
Notes payable, net of current portion	1,008	39,504
Lease incentives, net of current portion	731	792
Other liabilities	—	49
Commitments and contingencies (see Note 12)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized; 35,948,900 and 30,482,712 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	36	30
Additional paid-in capital	267,421	242,997
Accumulated deficit	(266,117)	(203,689)
Total stockholders' equity	1,340	39,338
Total liabilities and stockholders' equity	$54,861	$89,568

See accompanying notes to financial statements.

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T2 Biosystems, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

	Year ended December 31,		
	2017	2016	2015
Revenue:			
Product revenue	$3,440	$1,747	$599
Research revenue	1,226	2,333	2,214
Total revenue	4,666	4,080	2,813
Costs and expenses:			
Cost of product revenue	12,028	6,872	1,740
Research and development	23,733	24,009	25,362
Selling, general and administrative	22,757	24,077	19,094
Total costs and expenses	58,518	54,958	46,196
Loss from operations	(53,852)	(50,878)	(43,383)
Interest expense, net	(8,907)	(4,098)	(1,967)
Other income, net	331	172	60
Net loss and comprehensive loss	(62,428)	(54,804)	(45,290)
Net loss per share — basic and diluted	$(1.94)	$(2.11)	$(2.21)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	32,131,512	26,015,751	20,501,748

See accompanying notes to financial statements.

T2 Biosystems, Inc.

Consolidated Statements of Stockholders' Equity

(In thousands, except share and per share data)

	Common Stock Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2014	20,041,645	$ 20	$ 156,576	$ (103,595)	$ 53,001
Stock-based compensation expense	—	—	4,168	—	4,168
Issuance of common stock from secondary public offering, net of offering costs of $2,732	3,691,049	4	33,252	—	33,256
Issuance of common stock from exercise of stock options and employee stock purchase plan	442,687	—	1,804	—	1,804
Net loss	—	—	—	(45,290)	(45,290)
Balance at December 31, 2015	24,175,381	24	195,800	(148,885)	46,939
Stock-based compensation expense	—	—	4,848	—	4,848
Offering costs on issuance of common stock from secondary public offering	—	—	(215)	—	(215)
Issuance of common stock from exercise of stock options and employee stock purchase plan	251,990	—	1,018	—	1,018
Issuance of common stock for private investment	6,055,341	6	39,717	—	39,723
Issuance of warrants	—	—	1,829	—	1,829
Net loss	—	—	—	(54,804)	(54,804)
Balance at December 31, 2016	30,482,712	30	242,997	(203,689)	39,338
Stock-based compensation expense	—	—	4,790	—	4,790
Issuance of common stock from vesting of restricted stock, exercise of stock options and employee stock purchase plan	434,938	1	1,058	—	1,059
Issuance of common stock from secondary public offering, net of offering costs of $252	5,031,250	5	18,576	—	18,581
Net loss	—	—	—	(62,428)	(62,428)
Balance at December 31, 2017	35,948,900	$ 36	$ 267,421	$ (266,117)	$ 1,340

See accompanying notes to financial statements.

T2 Biosystems, Inc.

Consolidated Statements of Cash Flows

(In thousands)

	Year ended December 31,		
	2017	2016	2015
Operating activities			
Net loss	$(62,428)	$(54,804)	$(45,290)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,940	2,280	1,465
Stock-based compensation expense	4,790	4,848	4,168
Noncash interest expense	2,710	564	354
Loss on extinguishment of debt	—	112	—
Impairment of T2 owned instruments and components	2,571	—	—
Change in fair value of derivative instrument	2,238	—	—
Deferred rent	(115)	(250)	(119)
Changes in operating assets and liabilities:			
Accounts receivable	(140)	42	(168)
Prepaid expenses and other assets	125	68	190
Inventories, net	(110)	(120)	(568)
Accounts payable	(314)	(61)	177
Accrued expenses and other liabilities	724	580	260
Deferred revenue	(709)	299	2,066
Net cash used in operating activities	(47,718)	(46,442)	(37,465)
Investing activities			
Purchases and manufacture of property and equipment	(2,476)	(5,487)	(7,974)
Decrease in restricted cash	—	—	80
Net cash used in investing activities	(2,476)	(5,487)	(7,894)
Financing activities			
Proceeds from issuance of common stock in public offering, net of offering costs	18,640	(385)	33,677
Proceeds from issuance of common stock and stock options exercises, net	1,059	1,018	1,804
Proceeds from private investment in public equity	—	39,723	—
Proceeds from notes payable, net of issuance costs	—	43,803	10,000
Repayments of note payable	(1,194)	(32,404)	(309)
Net cash provided by financing activities	18,505	51,755	45,172
Net decrease in cash and cash equivalents	(31,689)	(174)	(187)
Cash and cash equivalents at beginning of period	73,488	73,662	73,849
Cash and cash equivalents at end of period	$41,799	$73,488	$73,662

See accompanying notes to financial statements.

T2 Biosystems, Inc.

Consolidated Statements of Cash Flows (Continued)

(In thousands)

	Year ended December 31, 2017	2016	2015
Supplemental disclosures of cash flow information			
Cash paid for interest	$ 3,959	$ 2,732	$ 1,506
Supplemental disclosures of noncash activities			
Accrued property and equipment	$ 189	$ 82	$ 247
Transfer from T2 owned equipment to inventory	$ 431	$ —	$ —
Leasehold improvements paid by landlord	$ —	$ —	$ 1,268
Transfer from other liabilities to accrued expenses and other current liabilities	$ 585	$ —	$ —
Public offering costs unpaid at year end	$ 59	$ —	$ 420

See accompanying notes to financial statements.

T2 Biosystems, Inc.

Notes to Consolidated Financial Statements

1. Nature of Business

T2 Biosystems, Inc. (the "Company") was incorporated on April 27, 2006 as a Delaware corporation with operations based in Lexington, Massachusetts. The Company is an in vitro diagnostics company that has developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. The Company is using its T2 Magnetic Resonance technology, 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. The Company's 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, the Company received market clearance from the U.S. Food and Drug Administration ("FDA") for its first two products, the T2Dx Instrument (the "T2Dx") and T2Candida Panel ("T2Candida"). On June 30, 2017, the Company received a CE Mark for its T2Bacteria Panel ("T2Bacteria"). On September 8, 2017, the Company filed a 510(k) premarket submission for the T2Bacteria Panel with the U.S. Food and Drug Administration (FDA).

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

Liquidity and Going Concern

At December 31, 2017, the Company has cash and cash equivalents of $41.8 million and an accumulated deficit of $266.1 million. The future success of the Company is dependent on its ability to successfully commercialize its products, obtain regulatory clearance for and successfully launch its future product candidates, obtain additional capital and ultimately attain profitable operations. Historically, the Company has funded its operations primarily through its August 2014 initial public offering, its December 2015 confidentially marketed public offering ("CMPO"), its September 2016 private investment in public equity ("PIPE") financing, its September 2017 CMPO, private placements of redeemable convertible preferred stock and debt financing arrangements.

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

Having obtained clearance from the FDA and a CE mark in Europe to market the T2Dx and T2Candida, the Company has incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution. In addition, the Company anticipates costs and expenses to increase as the Company continues to develop other product candidates, improve existing products and maintain, expand and protect its intellectual property portfolio. The Company may seek to fund its operations through public equity or private equity or debt financings, as well as other sources. However, the Company may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. The Company's failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on the Company's business, results of operations and financial condition and the Company's ability to develop and commercialize T2Dx, T2Candida, T2Bacteria, and other product candidates.

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

Management believes that its existing cash and cash equivalents at December 31, 2017, together with funding available under the Term Loan Agreement, will be sufficient to allow the Company to fund its current operating plan through March 2019. However, as certain elements of the Company's operating plan are outside of the Company's control, including the approval of the Company's T2Bacteria Panel and receipt of certain development and regulatory milestone payments under the Company's Co-Development agreements, they cannot be considered probable. Under ASC 205-40, the future receipt of potential funding from the Company's Co-Development partners and other resources cannot be considered probable at this time because none of the plans are entirely within the Company's control. In addition, the Company is required to maintain a minimum cash balance under its Term Loan Agreement with CRG Servicing LLC ("CRG") (Note 6).

These conditions raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date that the financial statements are issued. Management's plans to alleviate the conditions that raise substantial doubt include raising additional funding, earning milestone payments pursuant the Company's Co-Development agreements, delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels for the Company to continue as a going concern for a period of 12 months from the date the financial statements are issued. Management has concluded the likelihood that its plan to obtain sufficient funding from one or more of these sources or adequately reduce expenditures will be successful, while reasonably possible, is less than probable. Accordingly, the Company has concluded that substantial doubt exists about the Company's ability to continue as a going concern for a period of at least twelve months from the date of issuance of these consolidated financial statements.

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

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

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

Use of Estimates

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

Segment Information

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

Off Balance Sheet Risk and Concentrations of Credit Risk

The Company has no significant off-balance sheet risks, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Cash and cash equivalents are financial instruments that potentially subject the Company to concentrations of credit risk. At December 31, 2017 and 2016, substantially all of the Company's cash was deposited in accounts at one financial institution, with a significant amount invested in money market funds that are invested in short-term U.S. government agency securities. The Company maintains its cash deposits, which at times may exceed the federally insured limits, with a large financial institution and, accordingly, the Company believes such funds are subject to minimal credit risk.

For the year ended December 31, 2017, the Company derived approximately 19% of its total revenue from one customer and 10% of its total revenue from a second customer. For the year ended December 31, 2016, the Company derived approximately 45% of its total revenue from one customer and 10% of its total revenue from a second customer. For the year ended December 31, 2015, the Company derived approximately 50% of its total revenue from one customer and 25% of its total revenue from a second customer.

Cash Equivalents

Cash equivalents include all highly liquid investments maturing within 90 days from the date of purchase. Cash equivalents consist of money market funds invested in short-term U.S. government agency securities as of December 31, 2017 and 2016.

Accounts Receivable

The Company's accounts receivable consists of amounts due from commercial customers and from research and development arrangements with partners. At each reporting period, management reviews all outstanding balances to determine if the facts and circumstances of each customer relationship indicate the need for a reserve. The Company does not require collateral and did not have an allowance for doubtful accounts at December 31, 2017 or 2016.

Inventories

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

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

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

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

	December 31, 2017	December 31, 2016
Raw materials	$ 539	$ 389
Work-in-process	562	351
Finished goods	243	63
Total inventories, net	$ 1,344	$ 803

Fair Value Measurements

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

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

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

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

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

The fair value hierarchy prioritizes valuation inputs based on the observable nature of those inputs. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment

of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability (Note 3).

For certain financial instruments, including accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses, the carrying amounts approximate their fair values as of December 31, 2017 and 2016 because of their short-term nature. At December 31, 2017 and 2016, the carrying value of the Company's debt approximated fair value, which was determined using Level 3 inputs, using market quotes from brokers and is based on current rates offered for similar debt (Note 6).

Property and Equipment

Property and equipment are recorded at cost and depreciated over their estimated useful lives using the straight line method. Property and equipment includes raw materials, work-in-process and finished instruments that are Company-owned or expected to remain Company-owned when placed in service. Company-owned instruments are instruments that are manufactured and placed with customers in connection with reagent rental agreements, or are used for internal purposes. Repairs and maintenance costs are expensed as incurred, whereas major improvements are capitalized as additions to property and equipment.

Revenue Recognition

The Company generates revenue from product sales, which includes the sale of instruments, consumable diagnostic tests and related services, and research and development agreements with third parties. The Company recognizes revenue in accordance with FASB ASC Topic 605, Revenue Recognition ("ASC 605"). Accordingly, the Company recognizes revenue when all of the following criteria have been met:

i. Persuasive evidence of an arrangement exists

ii. Delivery has occurred or services have been rendered

iii. The seller's price to the buyer is fixed or determinable

iv. Collectability is reasonably assured

If any of the above criteria have not been met, the Company defers revenue until such time each of the criteria have been satisfied.

Product revenue is generated by the sale of instruments and consumable diagnostic tests predominantly through its direct sales force in the United States, and distributors in geographic regions outside the United States. The Company does not offer product return or exchange rights (other than those relating to defective goods under warranty) or price protection allowances to its customers, including its distributors. Payment terms granted to distributors are the same as those granted to end-user customers and payments are not dependent upon the distributors' receipt of payment from their end-user customers. The Company either sells instruments to customers and international distributors, or retains title and places the instrument at the customer site pursuant to a reagent rental agreement. When the instrument is directly purchased by a customer, the Company recognizes revenue when all applicable revenue recognition criteria are met. When the instrument is placed under a reagent rental agreement, the Company's customers generally agree to fixed term agreements, which can be extended, certain of which may include minimum purchase commitments and/or incremental charges on each consumable diagnostic test purchased, which varies based on the volume of test cartridges purchased. Revenue from the sale of consumable diagnostic tests, which includes the incremental charge, is recognized upon delivery as a component of product revenue in the Company's consolidated statements of operations and comprehensive loss.

Direct sales of instruments to U.S. customers include warranty, maintenance and technical support services for one year following the installation of the purchased instrument ("Maintenance Services"). After the completion of the initial Maintenance Services period, customers have the option to renew the Maintenance Services for additional one year periods in exchange for additional consideration. In addition, the Company may provide training to customers. The Company defers revenue from the initial sale of the instrument equal to the contract value of the one year of Maintenance Services and recognizes the amounts ratably over the service delivery period.

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

The Company does not offer rights of return for instruments or consumable diagnostic tests.

Shipping and handling costs incurred associated with products sold to customers are recorded as a cost of product revenue in the consolidated statement of operations and comprehensive loss. Shipping and handling costs billed to customers in connection with a product sale are recorded as a component of product revenue in the consolidated statements of operations and comprehensive loss.

For multiple-element arrangements, the Company identifies the deliverables included within each agreement and evaluates which deliverables represent separate units of accounting. The determination that multiple elements in an arrangement meet the criteria for separate units of accounting requires the Company's management to exercise judgment. The Company accounts for those components as separate elements

when the following criteria are met: (1) the delivered items have value to the customer on a stand-alone basis; and, (2) if there is a general right of return relative to the delivered items, delivery or performance of the undelivered items is considered probable and within its control.

The consideration received is allocated among the separate units of accounting based on a selling price hierarchy. The selling price hierarchy is based on: (1) vendor specific objective evidence ("VSOE"), if available; (2) third party evidence of selling price if VSOE is not available; or (3) best estimated selling price ("BESP") if neither VSOE nor third party evidence is available. The Company generally expects that it will not be able to establish selling price using third-party evidence due to the nature of our products and the markets in which the Company competes, and, as such, the Company typically will determine selling price using VSOE or BESP.

When the Company establishes selling price using BESP, consideration is given to both market and Company-specific factors, including the cost to produce the deliverable and the anticipated margin on that deliverable, as well as the characteristics of markets in which the deliverable is sold.

Revenue earned from activities performed pursuant to research and development agreements is reported as research revenue in the consolidated statements of operations and comprehensive loss, using the proportional performance method as the work is completed, limited to payments earned, and the related costs are expensed as incurred as research and development expense. The timing of receipt of cash from the Company's research and development agreements generally differs from when revenue is recognized.

Product Recall

In July 2016, the Company initiated a voluntary recall and replacement of its T2Candida cartridges at certain customer sites because T2Candida was experiencing higher than normal invalid test rates as the T2Candida cartridges aged. As of June 30, 2016, as a result of this voluntary recall, the Company deferred revenue totaling $149,000 and recorded additional costs of product revenue of $41,000 related to returned products, which are no longer usable. As of December 31, 2017 there were no balances remaining related to this voluntary recall. As of December 31, 2016, the Company had approximately $37,000 of deferred revenue and $3,000 of warranty reserve remaining, both related to this voluntary recall. The impact of the voluntary recall on T2Candida cartridges in inventory was not material to the consolidated financial statements.

Cost of Product Revenue

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

Research and Development Costs

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

Impairment of Long Lived Assets

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

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non owner sources. Comprehensive loss consists of net loss and other comprehensive loss, which includes certain changes in equity that are excluded from net loss. The Company's comprehensive loss equals reported net loss for all periods presented.

Stock-Based Compensation

The Company has a stock based compensation plan which is more fully described in Note 8. The Company records stock based compensation for options granted to employees and to members of the board of directors for their services on the board of directors, based on the grant date fair value of awards issued, and the expense is recorded on a straight line basis over the applicable service period, which is generally four years. The Company accounts for non employee stock based compensation arrangements based upon the fair value of the consideration received or the equity instruments issued, whichever is more reliably measurable. The measurement date for non employee awards is generally the date that the performance of services required for the non employee award is complete. Stock based compensation costs for non employee awards is recognized as services are provided, which is generally the vesting period, on a straight line basis.

The Company records the expense for stock option grants that vest upon achievement of performance-based milestones using the accelerated attribution method over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the relative satisfaction of the performance conditions as of the reporting date.

The Company expenses restricted stock awards based on the fair value of the award on the date of issuance, on a straight line basis over the associated service period of the award.

The Company uses the Black Scholes Merton option pricing model to determine the fair value of stock options. The use of the Black Scholes Merton option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk free interest rates and expected dividend yields of the common stock. The expected term was determined according to the simplified method, which is the average of the vesting tranche dates and the contractual term. Due to the lack of company specific historical and implied volatility data resulting from our limited public market trading history, we have based our estimate of expected volatility primarily on the historical volatility of a group of similar companies that are publicly traded. For these analyses, companies with comparable characteristics are selected, including enterprise value and position within the industry, and with historical share price information sufficient to meet the expected life of the stock based awards. The Company computes the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of its stock based awards. The risk free interest rate is determined by reference to U.S. Treasury zero coupon issues with remaining maturities similar to the expected term of the options. The Company has not paid, and does not anticipate paying, cash dividends on shares of common stock; therefore, the expected dividend yield is assumed to be zero. The Company has elected an accounting policy to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates.

Income Taxes

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

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

The Tax Cuts and Jobs Act ("the Act") was enacted on December 22, 2017. The Act reduces the US federal corporate tax rate from 35% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign

subsidiaries that were previously tax deferred and creates new taxes on certain foreign sourced earnings. On December 22, 2017, the Securities and Exchange Commission issued guidance under Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act ("SAB 118") directing taxpayers to consider the impact of the U.S. legislation as "provisional" when it does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete its accounting for the change in tax law.

Guarantees

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

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

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

As of December 31, 2017 and 2016, the Company had not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

Net Loss Per Share

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

Recent Accounting Standards

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

Accounting Standards Adopted

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory ("ASU 2015-11"). The standard simplifies the subsequent measurement of inventory by requiring inventory to be measured at the lower of cost and net realizable value for entities using the first-in-first out method of valuing inventory. ASU 2015-11 eliminates other measures required by current guidance to determine net realizable value. ASU 2015-11 is effective for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years and early adoption is permitted. The Company's adoption of this standard did not have a material effect on its consolidated financial statements.

In March 2016, the FASB released ASU No. 2016-09 Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09") which is intended to simplify income tax accounting for excess tax benefits, accounting for forfeitures, and employer statutory withholding. Under the current guidance, excess tax benefits that result from an award vesting or settling are recognized in additional paid-in capital in the period that they reduce cash taxes payable. This requires the provision to be computed on a with and without option basis and may result in net operating loss and credit carryforwards on the balance sheet being less than what is available on the tax return. Under the new guidance, the income tax effects of awards will be recognized as a component of income tax expense when the awards vest or are settled (regardless if cash taxes are reduced). For interim reporting purposes, companies will account for excess tax benefits and tax deficiencies as discrete items in the period during which they occurred. The guidance is effective for public entities for fiscal years beginning after December 15, 2016, and interim periods within those years. Early adoption is permitted, however all of the guidance included in the update must be applied when adopted. The Company must use a modified retrospective transition method for adopting and record the cumulative effect of all unrecognized benefits and any change in valuation allowances at the end of the prior tax period as an adjustment to retained earnings. The Company's adoption of this standard did not have a material effect on its consolidated financial statements and prior periods have not been adjusted. As a result, the Company established a net operating loss deferred tax asset of $1.2 million to account for prior period excess tax benefits through retained earnings, however an offsetting valuation allowance of $1.2 million will also be established through retained earnings because it is not more likely than not that the deferred tax asset will be realized due to historical and expected future losses, such that there is no impact on the Company's consolidated financial statements. The Company also elected to maintain the use of estimated forfeitures in the calculation of stock based compensation.

In March 2016, the FASB issued ASU No. 2016-06, Derivatives and Hedging (Topic 815): Contingent Put and Call Options in Debt Instruments ("ASU 2016-06"), which applies to all issuers of or investors in debt instruments with embedded call or put options. ASU 2016-06 clarifies the requirements for assessing whether contingent call or put options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts. Entities performing the assessment under the guidance of ASU 2016-06 are required to assess the embedded call or put options solely in accordance with the four-step decision process. In addition, ASU 2016-06 clarifies what steps are required when assessing whether the economic characteristics and risks of call or put options are clearly and closely related to the economic characteristics and risks of their debt hosts. ASU 2016-06 is effective for financial statements issued for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years using the modified retrospective method for existing debt instruments. The Company's adoption of this standard did not have a material effect on its consolidated financial statements.

Accounting Standards Issued, Not Adopted

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments ("ASC 2016-15"), which provides guidance on the classification of certain specific cash flow issues including debt prepayment or extinguishment costs, settlement of certain debt instruments, contingent consideration payments made after a business combination, proceeds from the settlement of certain insurance claims and distributions received from equity method investees. The standard requires the use of a retrospective approach to all periods presented, but may be applied prospectively if retrospective application would be impracticable. The guidance is effective for public entities for fiscal years beginning after December 15, 2017, and interim periods within those years, and early application is permitted. The Company is currently evaluating the impact of its pending adoption of ASU 2016-15 on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases ("ASU 2016-02"), which applies to all leases. Under ASU 2016-02, a right-of-use asset and lease obligation will be recorded for all leases, whether operating or financing leases, while the statement of operations will reflect lease expense for operating leases and amortization and interest expense for financing leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 and interim periods within those years, which is the year ended December 31, 2019 for the Company. Entities are required to use a modified retrospective approach of adoption for leases that exist or are entered into after the beginning of the earliest

comparative period in the financial statements. Full retrospective application is prohibited. The Company is evaluating the new guidance and the expected effect on the Company's consolidated financial statements.

In June 2014, the FASB issued amended guidance, ASU No. 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"), which is applicable to revenue recognition that will be effective for the Company for the year ending December 31, 2018, as a result of the deferral of the effective date adopted by the FASB in July 2015. The new guidance must be adopted using either a full retrospective approach for all periods presented or a modified retrospective approach. Early adoption prior to the original adoption date (annual reporting periods beginning after December 15, 2016) of ASU 2014-09 is not permitted. The new guidance applies a more principles-based approach to revenue recognition. The Company will adopt the new standard, effective January 1, 2018, under the modified retrospective method.

The Company established an implementation team to assess the potential impacts of the new standard and prepare for adoption. The implementation team has reviewed current accounting policies and practices and identified potential differences resulting from the application of the new standard. Findings and progress of the project have been regularly communicated to the Audit Committee and senior management.

The qualitative assessment of the standard provided below are estimates of the expected effects of the adoption of ASC 606. This represents our best estimate of the effects of adopting ASC 606 at the time of the preparation of this Annual Report on Form 10-K. The actual impact of ASC 606 is subject to change from these estimates and such change may be significant, pending the completion of our assessment in the first quarter of 2018.

The implementation team is in the process of completing an analysis of our revenue generating arrangements, including direct sales of instruments and consumables, sales of instruments and consumables to distributors, reagent rental agreements and research agreements. A detailed policy for each revenue stream has been drafted. The Company is in the process of implementing appropriate changes to controls, processes, and systems to support recognition and disclosure under the new standard. In addition, the Company continues to monitor changes, modifications, clarifications or interpretations, which may impact the results of adoption, undertaken by the FASB.

The impact of adopting the new standard is not expected to be material to 2017 and 2016 revenue. The most significant impacts of the new standard, upon adoption, are expected to be around the timing of revenue recognition. Specifically, under the new standard:

- Consideration allocated to the instrument in a direct sale will be recognized upon shipment and consideration allocated to installation will be recognized upon installation. Currently, revenue recognition for both obligations occurs upon installation.
- Revenue recognition on sales to distributors may be accelerated based on management's judgement regarding use of the sell-in or sell-through method. Currently, the Company recognizes revenue with new distributors based on the sell-through method, which requires deferral of revenue until product is sold to an end customer.

The Company does not expect the adoption of the new standard to a have material impact on our consolidated balance sheet. The Company does expect significant changes to its financial statement disclosures.

3. Fair Value Measurements

The Company measures the following financial assets at fair value on a recurring basis. There were no transfers between levels of the fair value hierarchy during any of the periods presented. The following tables set forth the Company's financial assets and liabilities carried at fair value categorized using the lowest level of input applicable to each financial instrument as of December 31, 2017 and 2016 (in thousands):

	Balance at December 31, 2017	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash	$ 3,463	$ 3,463	$ —	$ —
Money market funds	38,336	38,336	—	—
Restricted cash	260	260	—	—

	$ 42,059	$ 42,059	$ —	$ —
Liabilities:				
Derivative liability	$ 2,238	$ —	$ —	$ 2,238
	$ 2,238	$ —	$ —	$ 2,238

	Balance at December 31, 2016	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash	$ 16,887	$ 16,887	$ —	$ —
Money market funds	56,601	56,601	—	—
Restricted cash	260	260	—	—
	$ 73,748	$ 73,748	$ —	$ —

The Company’s Term Loan Agreement with CRG (Note 6) contains certain provisions that change the underlying cash flows of the instrument, including an interest-only period dependent on the achievement of the Approval Milestone by April 30, 2018, and acceleration of the obligations under the Loan Agreement under an event of default. In addition, under certain circumstances, a default interest rate of an additional 4.0% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default. The Company concluded that these features are not clearly and closely related to the host instrument, and represent a single compound derivative and is required to be re-measured at fair value on a quarterly basis.

During the fourth quarter of 2017, the Company received communication from the FDA that suggested the approval timeline of T2Bacteria could be longer than the Company initially anticipated. The delay resulted in an increase in the probability of not achieving the Approval Milestone by April 30, 2018, as well an increase in the probability of the payment of contingent interest in future periods, based on the contractual payments that exist as of December 31, 2017. As such, in the fourth quarter, the Company recorded a derivative liability related to the Company's debt agreement with CRG of $2.2 million. The estimated fair value of the derivative liability was determined using a probability-weighted discounted cash flow model that includes principal and interest payments under the following scenarios: FDA approval by April 30, 2017 (40%), FDA approval after April 30, 2017 (20%) and no FDA approval (40%). Should the Company's assessment of these probabilities change, including amendments of certain revenue targets, there could be a change to the fair value of the derivative liability.

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

Balance at December 31, 2016	$—
Change in fair value of derivative liability, recorded as interest expense	2,238
Balance at December 31, 2017	$2,238

4. Restricted Cash

The Company is required to maintain a security deposit for its operating lease agreement for the duration of the lease agreement and for its credit cards as long as they are in place. At both December 31, 2017 and 2016, the Company had certificates of deposit for $260,000, which represented collateral as security deposits for its operating lease agreement for its facility and its credit card.

5. Supplemental Balance Sheet Information

Property and Equipment

Property and equipment consists of the following (in thousands)

	Estimated Useful Life (Years)	December 31, 2017	December 31, 2016
Office and computer equipment	3	$ 409	$ 409
Software	3	743	708
Laboratory equipment	5	4,224	4,516
Furniture	5-7	200	200
Manufacturing equipment	5	910	897
Manufacturing tooling and molds	0.5	255	154
T2-owned instruments and components	5	7,370	9,119
Leasehold improvements	Lesser of useful life or lease term	3,437	3,353
Construction in progress	n/a	1,591	1,299
		19,139	20,655
Less accumulated depreciation and amortization		(9,124)	(7,066)

Property and equipment, net	$ 10,015	$ 13,589

Construction in progress is primarily comprised of equipment and leasehold improvement construction projects that have not been placed in service. T2-owned instruments and components is comprised of raw materials and work-in-process inventory that are expected to be used or used to produce Company-owned instruments, based on our business model and forecast, and completed instruments that will be used for internal research and development or reagent rental agreements with customers. Completed T2-owned instruments are placed in service once installation procedures are completed and are depreciated over five years. Depreciation expense for T2-owned instruments placed at customer sites pursuant to reagent rental agreements is recorded as a component of cost of product revenue and totaled $1.0 million and $0.6 million for the years ended December 31, 2017 and December 31, 2016, respectively. Depreciation expense for T2-owned instruments used for internal research and development is recorded as a component of research and development expense.

Depreciation and amortization expense of $2.9 million, $2.3 million and $1.5 million was charged to operations for the years ended December 31, 2017, 2016 and 2015, respectively.

During the fourth quarter of 2017, the Company received communication from the FDA that suggested the approval timeline would be longer than the company initially anticipated. The Company assessed the recoverability of T2-owned instruments based on delayed T2Bacteria cash flows and recorded an impairment charge of $2.6 million, related to T2-owned instruments and components, which is recorded in the cost of product revenue in the Consolidated Statements of Operations and Comprehensive Loss. The fair value used in the impairment calculation was based on the best estimated selling price of the underlying T2-owned instruments, less the estimated cost to sell the instruments.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2017	December 31, 2016
Accrued payroll and compensation	$ 2,793	$ 2,479
Accrued research and development expenses	818	846
Accrued professional services	1,018	884
Other accrued expenses	1,589	699
Total accrued expenses	$ 6,218	$ 4,908

The Company classified $0.6 million, related to a fee associated with the Company's Term Loan Agreement (Note 6), from other liabilities to accrued expenses and other current liabilities, as of December 31, 2017, to match the classification of the associated debt.

6. Notes Payable

Future principal payments on the notes payable as of December 31, 2017 are as follows (in thousands):

Year ended December 31,	
2018	$47,483
2019	1,015
2020	-
2021	-
2022	-
Total before unamortized discount and issuance costs	48,498
Less: paid-in-kind interest	(4,347)
Less: unamortized discount and issuance costs	(2,448)
Total notes payable	$41,703

The Term Loan Agreement with CRG is classified as a current liability on the balance sheet at December 31, 2017, based on the Company's consideration of the probability of violating a minimum liquidity covenant included in the Term Loan Agreement. The contractual terms of the agreement require payments of $5.8 million, $23.0 million and $17.2 million during the years ended December 31, 2020, 2021 and 2022, respectively.

Term Loan Agreement

In December 2016, the Company entered into a Term Loan Agreement (the "Term Loan Agreement") with CRG. The Company initially borrowed $40.0 million pursuant to the Term Loan Agreement and may borrow up to an additional $10.0 million at any time through and including July 27, 2018, provided that, among other conditions, the Company receives 510(k) clearance for the marketing of T2BacteriaTM by the U.S. Food and Drug Administration ("FDA") on or before April 30, 2018 (the "Approval Milestone"). The Term Loan Agreement has a six-year term with three years (through December 30, 2019) of interest-only payments, which period shall be extended to four years (through

December 30, 2020) if the Company achieves the Approval Milestone, after which quarterly principal and interest payments will be due through the December 30, 2022 maturity date. Interest on the amounts borrowed under the Term Loan Agreement accrues at an annual fixed rate of (a) prior to the Approval Milestone, 12.50%, 4.0% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount and (b) following the Approval Milestone, 11.50%, 3.5% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount. In addition, if the Company achieves certain financial performance metrics, the loan will convert to interest-only until the December 30, 2022 maturity, at which time all unpaid principal and accrued unpaid interest will be due and payable. The Company is required to pay CRG a financing fee based on the loan principal amount drawn. The Company is also required to pay a final payment fee of 8% of the principal outstanding upon repayment. In March 2018 the Term Loan Agreement was amended to extend the Approval Milestone to June 30, 2018, the additional $10.0 million funding through September 27, 2018 and reduce the fiscal year 2018 revenue target to $7.0 million.

The Company may prepay all or a portion of the outstanding principal and accrued unpaid interest under the Term Loan Agreement at any time upon prior notice subject to a certain prepayment fee during the first five years of the term and no prepayment fee thereafter. As security for its obligations under the Term Loan Agreement the Company entered into a security agreement with CRG whereby the Company granted a lien on substantially all of its assets, including intellectual property. The Loan Agreement also contains customary affirmative and negative covenants for a credit facility of this size and type, including a requirement to maintain a minimum cash balance. The Loan Agreement also requires the Company to achieve certain revenue targets, whereby the Company is required to pay double the amount of any shortfall as an acceleration of principal payments. The revenue target for fiscal year 2018 is $7.0 million. The Loan Agreement includes a subjective acceleration clause whereby an event of default, including a material adverse change in the business, operations, or conditions (financial or otherwise), could result in the acceleration of the obligations under the Loan Agreement. Under certain circumstances, a default interest rate of an additional 4.00% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default. CRG has

not exercised its right under this clause, as there have been no such events. On December 18, 2017, the Term Loan Agreement was amended and the 2017 minimum revenue target was reduced to $3.0 million from $5.0 million.

The Company assessed the terms and features of the Term Loan Agreement, including the interest-only period dependent on the achievement of the Approval Milestone by April 30, 2018, and acceleration of the obligations under the Loan Agreement under an event of default, of the Term Loan Agreement in order to identify any potential embedded features that would require bifurcation. In addition, under certain circumstances, a default interest rate of an additional 4.0% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default. The Company concluded that these features are not clearly and closely related to the host instrument, and represent a single compound derivative and is required to be re-measured at fair value on a quarterly basis.

During the fourth quarter of 2017, the Company received communication from the FDA that suggested the approval timeline of T2Bacteria would be longer than the Company initially anticipated. The delay resulted in an increase in the probability of not achieving the Approval Milestone by April 30, 2018, as well an increase in the probability of the payment of contingent interest in future periods, based on the contractual payments requirements that exist as of December 31, 2017. As such, in the fourth quarter, the Company recorded a derivative liability related to the Company’s debt agreement with CRG of $2.2 million (Note 3).

In December 2016, pursuant to the Term Loan Agreement, the Company made an initial draw of $39.2 million, net of financing fees. The Company used approximately $28.0 million of the initial proceeds to repay approximately $27.5 million of outstanding debt pursuant to the Loan and Security Agreement and to repay approximately $0.5 million of outstanding debt pursuant to the Promissory Note. Upon the repayment of all amounts owed by the Company under these agreements, all commitments were terminated and all security interests granted by the Company were released.

In connection with the Term Loan Agreement entered into in December 2016, the Company issued to CRG four separate warrants to purchase a total of 528,958 shares of the Company’s common stock. The warrants are exercisable any time prior to December 30, 2026 at a price of $8.06 per share, with typical provisions for termination upon a change of control or a sale of all or substantially all of the assets of the Company. The warrants are classified within stockholders’ equity, and the proceeds were allocated between the debt and warrants based on their relative fair value. The fair value of the warrants was determined by the Black Scholes Merton option pricing model. The fair value of the warrants at December 30, 2016 was $1.8 million.

Equipment Lease Credit Facility

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

In April 2016 and June 2016, the Company completed the first two draws under the Credit Facility of $2.1 million and $2.5 million, respectively. The Company will make monthly payments of $67,000 under the first draw and $79,000 under the second draw. The borrowings under the Credit Facility are treated as capital leases. The amortization of the assets conveyed under the Credit Facility is included as a component of depreciation expense.

7. Stockholders' Equity

Common Stock

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding. As of December 31, 2017, a total of 3,785,083 shares and 1,207,825 shares of common stock were reserved for issuance upon (i) the exercise of outstanding stock options and (ii) the issuance of stock awards under the Company's 2014 Incentive Award Plan and 2014 Employee Stock Purchase Plan, respectively.

Private Investment in Public Equity Financing

On September 21, 2016, Canon U.S.A., Inc. ("Canon") became a related party when the Company sold 6,055,341 shares of its common stock (the "Canon Shares") to Canon at $6.56 per share, the closing price on this date, for an aggregate cash purchase price of $39.7 million. As of September 21, 2016, the Canon Shares represented 19.9% of the outstanding shares of common stock of the Company. In connection with the director to the Company's board of directors. On March 20, 2017, the Company filed with the SEC a registration statement on Form S-3 for purposes of registering the resale of the Canon Shares.

Confidentially Marketed Public Offering

On September 15, 2017, the Company sold 5,031,250 shares of its common stock in a CMPO at $4.00 per share, for an aggregate gross cash purchase price of $20.1 million, or proceeds of $18.8 million after underwriters discount and expenses

8. Stock-Based Compensation

Stock Incentive Plans

2006 Stock Incentive Plan

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

2014 Stock Incentive Plan

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

The number of shares reserved for future issuance under the 2014 Plan is the sum of (1) 823,529, (2) any shares that were granted under the 2006 Plan which are forfeited, lapse unexercised or are settled in cash subsequent to the effective date of the 2014 Plan and (3) an annual increase on the first day of each calendar year beginning January 1, 2015 and ending on January 1, 2024, equal to the lesser of (A) 4% of the shares outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of shares determined by the Board of Directors. As of December 31, 2017 there were 1,026,422 shares available for future grant under the Plan.

Stock Options

During the years ended December 31, 2017, 2016, and 2015, the Company granted options with an aggregate fair value of $2.7 million and $7.0 million, and $10.1 million, respectively, which are being amortized into compensation expense over the vesting period of the options as the services are being provided.

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

		Weighted-Average	
		Weighted-Average Remaining	

	Number of Shares	Exercise Price Per Share	Contractual Term (In years)	Aggregate Intrinsic Value
Outstanding at December 31, 2016	4,042,627	$ 8.20	7.05	$ 4,091
Granted	903,200	5.07		
Exercised	(223,352)	2.36		553
Forfeited	(587,040)	9.12		
Canceled	(350,352)	11.96		
Outstanding at December 31, 2017	3,785,083	7.31	6.88	1,989
Exercisable at December 31, 2017	2,327,392	7.19	5.75	1,923
Vested or expected to vest at December 31, 2017	3,598,126	7.35	6.77	1,977

Included in the stock options outstanding at December 31, 2016 are 146,066 options to purchase common stock granted to certain executive officers of the Company that vest upon the achievement of certain performance conditions, which include the attainment of specified operating result and regulatory targets, by December 31, 2017. Included in the stock options forfeited during the year ended December 31, 2017 are 40,000 options to purchase common stock upon the achievement of certain performance conditions. There are 106,066 performance based options included in the outstanding balance at December 31, 2017. The operating results and regulatory target were not achieved by December 31, 2017, so no expense was recorded.

The weighted average fair values of options granted in the years ended December 31, 2017, 2016, and 2015 were $2.95, $4.68, and $8.42 per share, respectively, and were calculated using the following estimated assumptions:

	Year ended December 31,		
	2017	2016	2015
Weighted-average risk-free interest rate	1.99%	1.42%	1.69%
Expected dividend yield	0.00%	0.00%	0.00%
Expected volatility	60%	61%	56%
Expected terms	6.0 years	6.0 years	6.0 years

The total fair values of stock options that vested during the years ended December 31, 2017, 2016, and 2015 were $3.5 million, $4.9 million, and $4.0 million, respectively.

As of December 31, 2017, there was $5.3 million of total unrecognized compensation cost related to non vested stock options granted under the Stock Incentive Plans. Total unrecognized compensation cost will be adjusted for future changes in the estimated forfeiture rate. The Company expects to recognize that cost over a remaining weighted average period of 2.3 years as of December 31, 2017.

Restricted Stock Units

During the year ended December 31, 2017 the Company awarded shares of restricted stock units to certain employees at no cost to them, which cannot be sold, assigned, transferred or pledged during the restriction period. The restricted stock and restricted stock units vest through the passage of time, assuming continued employment. Restricted stock units are not included in issued and outstanding common stock until the shares are vested and released. The fair value of the award at the time of the grant is expensed on a straight line basis. The granted restricted stock units had an aggregate fair value of $2.9 million, which are being amortized into compensation expense over the vesting period of the options as the services are being provided.

The following is a summary of restricted stock unit activity under the Plan (in thousands, except share and per share amounts):

	Number of Shares	Weighted-Average Grant Date Fair Value
Nonvested at December 31, 2016	272,195	$ 5.83
Granted	552,925	5.17
Exercised	(116,173)	5.83
Forfeited	(102,450)	5.79
Canceled	—	—
Nonvested at December 31, 2017	606,497	5.23

During the year ended December 31, 2017, 116,173 restricted stock units vested.

As of December 31, 2017, there was $2.5 million of total unrecognized compensation cost related to non vested stock options granted under the Stock Incentive Plans. Total unrecognized compensation cost will be adjusted for future changes in the estimated forfeiture rate. The Company expects to recognize that cost over a remaining weighted average period of 1.4 years as of December 31, 2017.

Employee Stock Purchase Plan

The 2014 Employee Stock Purchase Plan (the “2014 ESPP”) period is semi-annual and allows participants to purchase the Company’s common stock at 85% of the lower of (i) the market value per share of common stock on the first day of the offering period or (ii) the market value per share of the common stock on the purchase date. Each participant can purchase up to a maximum of $25,000 per calendar year in fair market value. The first plan period began on August 7, 2014. Stock-based compensation expense from the 2014 ESPP for the years ended December 31, 2017, 2016 and 2015 was approximately $0.2 million, $0.3 million and $0.2 million, respectively.

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

	Year ended December 31,		
	2017	2016	2015
Weighted-average risk-free interest rate	1.03%	0.50%	0.19%
Expected dividend yield	0.00%	0.00%	0.00%
Expected volatility	68%	67%	57%
Expected terms	0.5 years	0.5 years	0.5 years

The 2014 ESPP provides initially for the granting of up to 220,588 shares of the Company's common stock to eligible employees. In addition, on the first day of each calendar year beginning January 1, 2015 and ending on January 1, 2024, the number of common shares available under the Plan shall be increased by the number of shares equal to the lesser of (1) 1% of the common shares outstanding on the final day of the immediately preceding calendar year and (2) such smaller number of common shares as determined by the Board of Directors. At December 31, 2017, there were 181,403 shares available under the 2014 ESPP.

Stock Based Compensation Expense

The following table summarizes the stock-based compensation expense for stock options granted to employees and non-employees, as well as stock-compensation expense for the 2014 ESPP that was recorded in the Company's results of operations for the years presented (in thousands):

	Year ended December 31,		
	2017	2016	2015
Cost of product revenue	$125	$123	$—
Research and development	1,384	1,127	1,213
Selling, general and administrative	3,196	3,480	2,840
Total stock-based compensation expense	$4,705	$4,730	$4,053

For the years ended December 31, 2017 and December 31, 2016, $0.1 million and $0.1 million of stock-based compensation expense was capitalized, respectively, as part of inventory or T2-owned instruments and components.

9. Warrants

In connection with the Term Loan Agreement entered into in December 2016, the Company issued to CRG four separate warrants to purchase a total of 528,958 shares of the Company's common stock. The warrants are exercisable any time prior to December 30, 2026 at a price of $8.06 per share, with typical provisions for termination upon a change of control or a sale of all or substantially all of the assets of the Company. The warrants are classified within stockholders' equity, and the proceeds were allocated between the debt and warrants based on their relative fair value. The fair value of the warrants was determined by the Black Scholes Merton option pricing model. The fair value

of the warrants at date of issuance was $1.8 million.

10. Net Loss Per Share

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

	Year ended December 31,		
	2017	2016	2015
Numerator:			
Net loss	$(62,428)	$(54,804)	$(45,290)
Denominator:			
Weighted-average number of common shares outstanding — basic and diluted	32,131,512	26,015,751	20,501,748
Net loss per share applicable to common stockholders — basic and diluted	$(1.94)	$(2.11)	$(2.21)

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

	Year ended December 31,		
	2017	2016	2015
Options to purchase common shares	3,785,083	4,042,627	3,484,298
Restricted stock units	606,497	272,195	—
Warrants to purchase common stock	528,958	528,958	—
Total	4,920,538	4,843,780	3,484,298

11. Income Taxes

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

	Year Ended December 31,		
	2017	2016	2015
Tax at statutory rates	35.0 %	35.0 %	35.0 %
State income taxes	6.5	5.2	6.6
Permanent differences	(2.5)	(1.2)	(1.3)
Research and development credits	1.5	1.3	1.5
US tax rate change	(52.7)	—	—
Change in valuation allowance	12.2	(40.3)	(41.8)
Effective tax rate	0.0 %	0.0 %	0.0 %

The significant components of the Company's deferred tax asset consist of the following at December 31, 2017 and 2016 (in thousands):

	December 31,	
	2017	2016
Deferred tax assets:		
Net operating loss carryforwards	$62,670	$69,411
Tax credits	6,924	5,269
Other temporary differences	2,723	1,636
Start-up expenditures	3,214	5,088
Stock option expenses	2,127	2,779
Total deferred tax assets	77,658	84,183
Deferred tax asset valuation allowance	(77,546)	(83,924)
Net deferred tax assets	112	259
Deferred tax liabilities:		
Prepaid expenses	(112)	(259)

Net deferred taxes	$—	$—

The Tax Cuts and Jobs Act was enacted in the United States on December 22, 2017. The Act reduces the US federal corporate tax rate from 35% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred, and creates new taxes on certain foreign sourced earnings. In December 2017, the SEC issued SAB 118, which directs taxpayers to consider the impact of the U.S. legislation as "provisional" when it does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete its accounting for the change in tax law. As of December 31, 2017, we recognized a provisional amount of $0 for the transition tax.

We re-measured certain deferred tax assets and liabilities based on the rates at which they are anticipated to reverse in the future, which is generally 21%. However, we are still examining certain aspects of the Act and refining our calculations, which could potentially affect the measurement of these balances or potentially give rise to new deferred tax amounts. The provisional amount recorded related to the re-measurement of our deferred tax balance was a tax expense of $32.9 million which was offset by an adjustment to the valuation allowance against our deferred taxes of $32.9 million.

In 2017 and 2016, the Company did not record a benefit for income taxes related to its operating losses incurred. ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Based upon the level of historical U.S. losses and future projections over the period in which the net deferred tax assets are deductible, at this time, management believes it is more likely than not that the Company will not realize the benefits of these deductible differences, and as a result the Company continues to maintain a valuation allowance for the full amount of the 2017 deferred tax assets. The valuation allowance decreased $6.4 million, and increased $22.1 million and $18.9 million for the years ended December

31, 2017, 2016 and 2015, respectively. The decrease in the 2017 valuation allowance is primarily attributable to the reduction in the US corporate tax rate enacted in Q4 2017. The increase in 2016 and 2015 is primarily related to each year's taxable loss.

As of December 31, 2017, the Company had federal and state net operating losses of $229.1 million and $237.9 million, respectively, which are available to offset future taxable income, if any, through 2037. The Company also had federal and state research and development tax credits of $4.4 million and $3.2 million, respectively, which expire at various dates through 2037. Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed several financings since its inception which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code, or could result in a change in control in the future. The Company has not conducted an assessment to determine whether there may have been a Section 382 or 383 ownership change.

The Company has no unrecognized tax benefits. Interest and penalty charges, if any, related to uncertain tax positions would be classified as income tax expenses in the accompanying consolidated statements of operations. At December 31, 2017 and 2016, the Company had no accrued interest or penalties related to uncertain tax positions.

The Company files income tax returns in the U.S. federal tax jurisdiction and various state jurisdictions. Since the Company is in a loss carryforward position, the Company is generally subject to examination by the U.S. federal, state and local income tax authorities for all tax years in which a loss carryforward is available. The Company does not have any international operations as of December 31, 2017. The statute of limitations for assessment by federal and state tax jurisdictions in which the Company has business operations is open for tax years ending December 31, 2014, 2015, and 2016. The tax years under examination vary by jurisdiction.

12. Commitments and Contingencies

Operating Leases

In August 2010, the Company entered into a five-year, non-cancelable operating lease for office and laboratory space at its headquarters in Lexington, MA. The lease commenced on January 1, 2011, with the Company providing a security deposit of $400,000. In accordance with the operating lease agreement, the Company reduced its security deposit to $240,000 in May 2015, which is recorded as restricted cash in the consolidated balance sheets. In July 2014, the Company entered into an amendment to expand the office and laboratory space leased. In May 2015, the Company entered into an amendment to extend the term from December 31, 2015 to December 31, 2017. In March 2017, the Company entered into an amendment to extend the term from December 31, 2017 to December 31, 2021. The rent expense, inclusive of the escalating rent payments, is recognized on a straight-line basis over the lease term.

In May, 2013, the Company entered into a two-year operating lease for additional office, laboratory and manufacturing space in Wilmington, MA. The Company entered into an amendment in September 2015 to extend this lease term through December 31, 2017. In August 2017, the Company entered into an amendment to extend the term from December 31, 2017 to December 31, 2018

In November, 2014 the Company entered into an agreement to rent additional office space in Lexington, MA. The term of the agreement is two years, commencing December 2014. In April 2015, the Company entered into an amendment to extend the term of this agreement. The amendment extends the agreement term from December 31,

2016 to December 31, 2017. In connection with this agreement, the Company paid a security deposit totaling $50,000, which is recorded as a component of prepaid assets in the consolidated balance sheets. In May 2015, the Company entered into an amendment to expand existing manufacturing facilities in Lexington, MA. The lease amendment term is June 1, 2015 to December 31, 2017. In September 2017, the Company entered into an amendment to extend the term from December 31, 2017 to December 31, 2021

In November, 2014, the Company entered into a lease for additional laboratory space in Lexington, MA. The lease term commenced April 1, 2015 and extends for six years. The rent expense, inclusive of the escalating rent payments, is recognized on a straight-line basis over the lease term. As an incentive to enter into the lease, the landlord paid approximately $1.4 million of the $2.2 million space build-out costs. The incentive is recorded as a component of lease incentives on the consolidated balance sheets and is amortized as a reduction in rent expense on a straight-line basis over the term of the lease. In connection with this lease agreement, the Company paid a security deposit of $281,000, which is recorded as a component of other assets in the consolidated balance sheets.

Future minimum non-cancelable lease payments under the Company's operating leases as of December 31, 2017 are as follows (in thousands):

Year ending December 31,	
2018	$2,173
2019	2,149
2020	2,201
2021	1,926
	$8,449

Rent expense for the years ended December 31, 2017, 2016, and 2015 was $1.9 million, $1.8 million, and $1.6 million, respectively.

License Agreement

In 2006, the Company entered into a license agreement with a third party, pursuant to which the third party granted the Company an exclusive, worldwide, sublicenseable license under certain patent rights to make, use, import and commercialize products and processes for diagnostic, industrial and research and development purposes. The Company agreed to pay an annual license fee ranging from $5,000 to $25,000 for the royalty bearing license to certain patents. For the years ended December 31, 2017, 2016 and 2015, the Company incurred $30,000, $31,000 and $34,000, respectively, for regulatory milestones, license fees and reimbursed patent costs under the agreement. The Company also issued a total of 84,678 shares of common stock pursuant to the agreement in 2006 and 2007, which were recorded at fair value at the date of issuance.The Company is required to pay royalties on net sales of products and processes that are covered by patent rights licensed under the agreement at a percentage ranging in the low single digits, subject to reductions and offsets in certain circumstances, as well as a royalty on net sales of products that the Company sublicenses at a low double digit percentage of specified gross revenue. Royalties that became due under this agreement for the years ended December 31, 2017 and 2016 were immaterial.

13. 401(k) Savings Plan

In March, 2008, the Company established a retirement savings plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers substantially all employees of the Company who meet minimum age and service requirements, and allows participants to defer a portion of their annual compensation on a pretax basis. Company contributions to the 401(k) Plan may be made at the discretion of the board of directors. Company contributions to the 401(k) Plan were $190,000 and $237,000 for the years ended December 31, 2017 and 2016, respectively. No contributions were made during the year ended December 31, 2015.

14. Co-Development Agreements

Canon US Life Sciences

On September 21, 2016, Canon became a related party when the Company sold the Canon Shares for an aggregate cash purchase price of $39.7 million, which represented 19.9% of the outstanding shares of common stock of the Company. On February 3, 2015, the Company entered into a Co-Development Partnership Agreement (the "Co-Development Agreement") with Canon U.S. Life Sciences, Inc. ("Canon US Life Sciences") to develop a diagnostic test panel to rapidly detect Lyme disease. Under the terms of the Co-Development Agreement, the Company received an upfront payment of $2.0 million from Canon US Life Sciences and the agreement includes an additional $6.5 million of consideration upon achieving certain development and regulatory milestones for total aggregate payments

of up to $8.5 million. In October 2015, the Company achieved a specified technical requirement and received $1.5 million related to the achievement of the milestone. The Company is eligible to receive an additional $5.0 million under the arrangement, in two milestone payments of $2.0 million and $3.0 million, related to the achievement of additional development and regulatory milestones. All payments under the Co-Development Agreement are non-refundable once received. The Company will retain exclusive worldwide commercialization rights of any products developed under the Co-Development Agreement, including sales, marketing and distribution and Canon US Life Sciences will not receive any commercial right and will be entitled to only receive royalty payments on the sales of all products developed under the Co-Development Agreement. Either party may terminate the Co-Development Agreement upon the occurrence of a material breach by the other party (subject to a cure period).

The Company evaluated the deliverables under the Co-Development Agreement and determined that the Co-Development Agreement included one unit of accounting, the research and development services, as the joint research and development committee deliverable was deemed to be de minimus . The Company is recognizing revenue for research and development services as a component of research revenue in the consolidated financial statements as the services are delivered using the proportional performance method of accounting, limited to payments earned. Costs incurred to deliver the services under the Co-Development Agreement are recorded as research and development expense in the consolidated financial statements.

The Company recorded revenue of $0.3 million, $1.8 million and $1.4 million for the years ended December 31, 2017, 2016, and 2015, respectively, under the Co-Development Agreement, and expects to record revenue over the next two years, provided development and regulatory milestones are achieved.

Allergan Sales, LLC

On November 1, 2016, the Company entered into a Co-Development, Collaboration and Co-Marketing Agreement (the "Allergan Agreement") with Allergan Sales, LLC ("Allergan Sales") to develop (1) a direct detection diagnostic test panel that adds one additional bacteria species to the existing T2Bacteria product candidate (the "T2Bacteria II Panel"), and (2) a direct detection diagnostic test panel for testing drug resistance directly in whole blood (the "T2GNR Panel" and, together with the T2Bacteria II Panel, the "Developed Products"). In addition, both the Company and Allergan Sales will participate in a joint research and development committee and Allergan Sales will receive the right to cooperatively market the T2Candida, T2Bacteria, and the Developed Products under the Allergan Agreement to certain agreed-upon customers.

Under the terms of the Allergan Agreement, the Company received an upfront payment of $2.0 million from Allergan Sales and will receive additional milestone payments upon achieving certain developmental milestones for total aggregate payments of up to $4.0 million. All payments under the Allergan Agreement are non-refundable once received. The Company will retain exclusive worldwide commercialization rights of any products developed under the Allergan Agreement, including distribution, subject to Allergan Sales' right to co-market the Developed Products. Allergan Sales, at its election, may co-market T2Candida, T2Bacteria and the Developed Products worldwide to certain agreed-upon customers and will receive royalty based on its sales for a period of time.

The Company evaluated the deliverables under the Allergan Agreement and determined that the Allergan Agreement included two units of accounting, the research and development services for the T2Bacteria II Panel and the research and development services for the T2GNR Panel, as the joint research and development committee and right to cooperatively market deliverables were deemed to be de minimus . The Company is recognizing revenue for research and development services as a component of research revenue in the consolidated financial statements as the services are delivered using the proportional performance method of accounting, limited to payments earned. Costs incurred to deliver the services under the Allergan Agreement are recorded as research and development expense in the consolidated financial statements.

The Company recorded revenue of $0.9 million during the year ended December 31, 2017 under the Allergan Agreement and expects to record revenue over the next two years, provided development and regulatory milestones are achieved. The Company did not record revenue during the year ended December 31, 2016 under the Allergan Agreement.

15. Quarterly Financial Data (unaudited)

	Year ended December 31, 2017 (In thousands, except per share data)			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenue:				
Product revenue	$631	$ 735	$ 739	$ 1,335
Research revenue	310	221	369	326
Total revenue	$941	$ 956	$ 1,108	$ 1,661
Costs and expenses:				
Cost of product revenue	1,627	1,989	2,106	6,306
Research and development	6,585	7,112	5,880	4,156
Selling, general and administrative	5,874	5,759	5,559	5,565
Total costs and expenses	14,086	14,860	13,545	16,027
Loss from operations	$(13,145)	$ (13,904)	$ (12,437)	$ (14,366)
Net loss	$(14,703)	$ (15,456)	$ (14,076)	$ (18,193)

Per share data:				
Net loss per common share—basic and diluted	$(0.48)	$(0.50)	$(0.45)	$(0.51)

	Year ended December 31, 2016 (In thousands, except per share data)			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenue:				
Product revenue	$437	$ 151	$ 580	$ 579
Research revenue	659	839	504	331
Total revenue	$1,096	$ 990	$ 1,084	$ 910
Costs and expenses:				
Cost of product revenue	1,026	1,781	1,894	2,171
Research and development	6,589	6,369	5,200	5,851
Selling, general and administrative	6,204	6,143	5,935	5,795
Total costs and expenses	13,819	14,293	13,029	13,817
Loss from operations	$(12,723)	$(13,303)	$(11,945)	$(12,907)
Net loss	$(13,426)	$(14,046)	$(12,783)	$(14,549)
Per share data:				
Net loss per common share—basic and diluted	$(0.55)	$(0.58)	$(0.51)	$(0.48)

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

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Management conducted an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of December 31, 2017. Based on the evaluation of our disclosure controls and procedures as December, 2017, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, the Company's disclosure controls and procedures were not effective due to a material weaknesses in our internal control over financial reporting as described below in Management's Annual Report on Internal Control over Financial Reporting.

Management's Annual Report on Internal Control over Financial Reporting

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

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2017. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control—Integrated Framework (2013). Based on our assessment, the Company's management identified a material weakness in our internal control over financial reporting relating to the accounting for instruments which are classified as either inventory and property and equipment depending on their future use. Specifically, the Company concluded that a deficiency exists in the design and execution of the review control over the accounting of instrument valuation, including the recoverability analyses for the Company's

instruments. Management determined that its accounting process for the review of these accounts lacked adequate levels of monitoring and review to appropriately identify and correct errors in the calculation in a timely manner.

The control deficiency described above resulted in certain material and immaterial misstatements in the preliminary financial statement accounts that were corrected prior to the issuance of the annual consolidated financial statements. The errors noted were all related to and corrected in the fourth quarter. The control deficiency creates a possibility that a material misstatement to our consolidated financial statements will not be prevented or detected on a timely basis, and therefore we concluded that the deficiency represents a material weakness in our internal control over financial reporting and our internal control over financial reporting for instruments in inventory and fixed assets is not effective as of December 31, 2017.

We are developing and implementing new control processes and procedures to address this weakness. We are undertaking steps to design and implement sufficient controls over accounting for inventory. These steps include increasing oversight by our management in the calculation and reporting of instrument valuation, including the recoverability analyses related to instruments reported in the Company’s balance sheet in both inventory and property and equipment.

Changes in Internal Control Over Financial Reporting

Except as noted above, during the quarter ended December 31, 2017, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION
None.

PART III.

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE
The information required by this Item is incorporated in this Annual Report by reference from the information under the captions “Board of Directors Information,” “Executive Officers” and “Section 16(a) Beneficial Ownership Reporting Compliance” contained in the Proxy Statement to be filed in connection with our 2018 Annual Meeting of Stockholders, or the Proxy Statement.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics for our directors, officers and employees, which is available on our website at www.t2biosystems.com in the Investor Relations section under “Corporate Governance.” If we make any substantive amendments to the code of business conduct and ethics or grant any waiver from a provision of the code of business conduct and ethics to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website. The information on, or that can be accessed from, our website is not incorporated by reference into this Annual Report.

Item 11. EXECUTIVE COMPENSATION
The information required by this Item is incorporated in this Annual Report by reference from the information under the captions “Executive Compensation,” “Compensation Committee Interlocks and Insider Participation” and “Report of the Compensation Committee” contained in the Proxy Statement.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIA L OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS
The information required by this Item is incorporated in this Annual Report by reference from the information under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” contained in the Proxy Statement.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE
The information required by this Item is incorporated in this Annual Report by reference from the information under the captions “Certain Relationships and Related Transactions,” and “Board of Directors Information” contained in the Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES
The information required by this Item is incorporated in this Annual Report by reference from the information under the captions “Principal Accountant Fees and Services” and “Report of the Audit Committee” contained in the Proxy Statement.

Item 15. EXHIBITS, FINANCIAL STATEMENTS AND SCHEDULES
a.Documents filed as part of this Annual Report.

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

Report of Ernst & Young LLP, Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2017 and 2016

Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2017, 2016 and 2015

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2017, 2016 and 2015

Consolidated Statements of Cash Flows for the years ended December 31, 2017, 2016 and 2015

Notes to Consolidated Financial Statements

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

3.List of Exhibits required by Item 601 of Regulation S-K. See Item 15(b) below.

b.Exhibits.

INDEX TO EXHIBITS

Exhibit Number		Description of Exhibit
3.1	*	Restated Certificate of Incorporation of the Company, as amended (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36571) filed on August 12, 2014)
3.2	*	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 of the Company's Form 8-K (File No. 001-36571) filed on August 12, 2014)
4.1	*	Form of Common Stock Certificate of the Company (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A (File No. 333-197193) filed on July 28, 2014)
4.2	*	Fourth Amended and Restated Investors' Rights Agreement, dated as of March 22, 2013, as amended (incorporated by reference to Exhibit 4.2 of the Company's Registration Statement on Form S-1/A (File No. 333-197193) filed on July 28, 2014
10.1	#*	Amended and Restated 2006 Employee, Director and Consultant Stock Plan, as amended, and form of option agreements thereunder (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-197193 filed on July 2, 2014)
10.2	#	Amended and Restated 2014 Incentive Award Plan and form of option agreements thereunder
10.3	#*	Non-Employee Director Compensation Program, as amended (incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q (File No. 001-36571) filed on August 5, 2015)
10.4	#*	Form of Indemnification Agreement for Directors and Officers (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1/A (File No. 333-197193 filed on July 28, 2014)
10.5	#*	Employment Letter Agreement, dated as of March 14, 2008, by and between the Company and John McDonough, as amended (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1/A (File No. 333-197193) filed on July 28, 2014)
10.6	#*	Employment Letter Agreement, dated as of July 22, 2014, by and between the Company and Tom Lowery, Jr. (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1/A (File No. 333-197193) filed on July 28, 2014)
10.7	#*	Consulting Agreement, dated as of July 20, 2006 by and between the Company and Robert S. Langer, as amended on March 20, 2013 and July 24, 2014 (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1/A (File No. 333-197193) filed on July 28, 2014)
	*†	

10.8		Exclusive License Agreement, dated as of November 7, 2006, as amended on December 2, 2008 and February 21, 2011, by and between The General Hospital Corporation d/b/a Massachusetts General Hospital and the Company (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 (File No. 333-197193) filed on July 2, 2014)
10.9	*	Commercial Lease, dated as of May 6, 2013, as amended on September 24, 2013, by and between the Company and Columbus Day Realty, Inc. (incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1 (File No. 333-197193) filed on July 2, 2014)
10.10	*	Lease, dated as of August 6, 2010, by and between the Company and King 101 Hartwell LLC, as amended by the First Amendment to Lease on November 30, 2011 and the Second Amendment to Lease on July 11, 2014 (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1/A (File No. 333-197193) filed on July 16, 2014)
10.11	#*	2014 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-1/A (File No. 333-197193) filed on July 28, 2014)
10.12	*†	Supply Agreement by and between the Company and SMC Ltd., effective as of October 10, 2014 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K/A (File No. 001-36571) filed on January 21, 2015)
10.13	*†	Co-Development Partnership Agreement by and between the Company and Canon U.S. Life Sciences, Inc., dated as of February 3, 2015 (incorporated by reference to Exhibit 10.22 of the Company's Form 10-K (File No. 001-36571) filed on March 4, 2015)

10.14	*	Third Amendment to Lease with King 101 Hartwell LLC on May 27, 2015 (incorporated by referenced to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on May 29, 2015)
10.15	*†	Master Lease Agreement and between the Company and Essex Capital Corporation, dated as of October 31, 2015 (incorporated by reference to Exhibit 10.27 of the Company's Form 10-K (File No. 001-36571) filed on March 9, 2016)
10.16	#*	Employment Letter Agreement, dated June 30, 2016, by and between the Company and Dr. Joanne Spadoro, Ph. D. (incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q (File No. 001-36571) filed on November 8, 2016)
10.17	#*	Change of Control Severance Agreement, dated July 7, 2016, by and between the Company and Dr. Joanne Spadoro, Ph. D. (incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q (File No. 001-36571) filed on November 8, 2016)
10.18	*	Stock Purchase Agreement, dated September 21, 2016, by and among Canon U.S.A., Inc. and the Company (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on September 22, 2016)
10.19	*	Voting and Standstill Agreement, dated September 21, 2016, by and among Canon U.S.A., Inc. and the Company (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K (File No. 001-36571) filed on September 22, 2016)
10.20	*	Registration Rights Agreement, dated September 21, 2016, by and among Canon U.S.A., Inc. and the Company (incorporated by reference to Exhibit 10.3 of the Company's Form 8-K (File No. 001-36571) filed on September 22, 2016)
10.21	†	Co-Development, Collaboration and Co-Marketing Agreement, dated November 1, 2016, by and between the Company and Allergan Sales, LLC
10.22	†	Term Loan Agreement, dated December 30, 2016, by and among the Company, CRG Servicing LLC, as administrative and collateral agent, and the lenders from time to time party thereto and the subsidiary guarantors from time to time party thereto
10.23	*	Security Agreement, dated December 30, 2016, by and among the Company, the other grantors from time to time party thereto and CRG Servicing LLC, as administrative and collateral agent
10.24	*	Warrant to Purchase Shares of Common Stock of T2 Biosystems, Inc., dated December 30, 2016, by and between the Company and CRG Partners III (Cayman) L.P.
10.25	*	Warrant to Purchase Shares of Common Stock of T2 Biosystems, Inc., dated December 30, 2016, by and between the Company and CRG Partners III - Parallel Fund "A" L.P.
10.26	*	Warrant to Purchase Shares of Common Stock of T2 Biosystems, Inc., dated December 30, 2016, by and between the Company and CRG Partners III L.P.
10.27	*	Warrant to Purchase Shares of Common Stock of T2 Biosystems, Inc., dated December 30, 2016, by and between the Company and CRG Partners III Parallel Fund "B" (Cayman) L.P.
10.28	*	

		Fourth Amendment to Lease, dated March 2, 2017, by and between the Company and King 101 Harwell LLC (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on March 3, 2017)
10.29*		Amendment No. 1 to Term Loan Agreement, dated March 1, 2017, by and among the Company, CRG Servicing LLC, as administrative and collateral agent, and the lenders party thereto (incorporated by reference to Exhibit 10.3 of the Company's Form 10-Q (File No. 001-36571) filed on May 8, 2017)
10.30*		Amendment to Co-Development, Collaboration and Co-Marketing Agreement, by and between the Company and Allergan Sales, LLC, dated June 1, 2017 (incorporated by reference to Exhibit 10.3 of the Company's Form 10-Q (File No. 001-36571) filed on August 4, 2017)
10.31*†		Amendment to Supply Agreement, by and between the Company and SMC Ltd., dated August 29, 2017 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on August 29, 2017)
10.32*		Second Amendment to Supply Agreement, by and between the Company and SMC Ltd., dated December 22, 2017 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on December 27, 2017)
10.33*		Lease Indenture Agreement, dated September 21, 2017, by and between 91 Hartwell Ave. Trust and the Company (incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q (File No. 001-36571) filed on November 3, 2017)
10.34*#		T2 Biosystems, Inc. Inducement Award Plan and form of stock option agreement, form of restricted stock agreement and form of restricted stock unit agreement thereunder (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on March 7, 2018)
10.35#		Employment Offer Letter, dated as of March 7, 2016, by and between the Company and Alex Barclay

10.36#	Change of Control Severance Agreement, dated February 1, 2017, as amended on March 6, 2018, by and between the Company and Alex Barclay
10.37#	Amendment to Change of Control Severance Agreement, by and between the Company and Alex Barclay, dated March 6, 2018
10.38#	Employment Offer Letter, dated as of January 30, 2018, by and between the Company and John M. Sprague
10.39#	Change of Control Severance Agreement, dated January 30, 2018, by and between the Company and John M. Sprague
10.40	Amendment No. 2 to Commercial Lease, dated as of September 21, 2015,, by and between the Company and Columbus Day Realty, Inc.
10.41	Amendment No. 3 to Commercial Lease, dated as of August 10, 2017, by and between the Company and Columbus Day Realty, Inc.
10.42	Amendment No. 2 to Term Loan Agreement, dated December 18, 2017, by and among the Company, CRG Servicing LLC, as administrative and collateral agent, and the lenders party thereto
10.43	Amendment No. 3 to Term Loan Agreement, dated March 16, 2018, by and among the Company, CRG Servicing LLC, as administrative and collateral agent, and the lenders party thereto
10.44#	Amendment Number Three to Consulting Agreement, by and between the Company and Robert S. Langer, dated as of October 13, 2017
10.45#	Employment Offer Letter, dated as of April 16, 2017, by and between the Company and Darlene Deptula-Hicks
10.46#	Change of Control Severance Agreement, dated April 16, 2017, by and between the Company and Darlene Deptula-Hicks
21.1	Subsidiaries of the Registrant
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
24.1	Power of Attorney (included on the signature page hereto).
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of the principal executive and financial officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350.
	Interactive Data Files regarding (a) our Consolidated Balance Sheets as of December 31, 2016 and 2015 (b) our Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31,

101 2016, 2015 and 2014, (c) our Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for the Years Ended December 31, 2016, 2015 and 2014, (d) our Consolidated Statements of Cash Flows for the Years Ended December 31, 2016, 2015 and 2014 and (e) the Notes to such Consolidated Financial Statements.

* Previously filed.
# Indicates management contract or compensatory plan.
† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, or the Securities Act.
** As provided in Rule 406T of Regulation S-T, this information is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act and Section 18 of the Securities Exchange Act of 1934.
The exhibits listed in the accompanying "Exhibit Index" are filed, furnished or incorporated by reference as part of this Annual Report, as indicated.

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 19, 2018.

T2 BIOSYSTEMS, INC.

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

March 19, 2018

By: /s/ JOHN M. SPRAGUE
Name: John M. Sprague
Title: Chief Financial Officer
(principal financial officer and principal accounting officer)
March 19, 2018

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John McDonough and John Sprague, jointly and severally, his attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Signature	Title	Date
/ S / JOHN MCDONOUGH John McDonough	President, Chief Executive Officer and Director (principal executive officer)	March 19, 2018
/ s / JOHN M. SPRAGUE John M. Sprague	Chief Financial Officer (principal accounting officer)	March 19, 2018
/ S / STANLEY N. LAPIDUS Stanley N. Lapidus	Director	March 19, 2018
/ S / ADRIAN M. JONES Adrian M. Jones	Director	March 19, 2018
/ S / MICHAEL J. CIMA, PH.D. Michael J. Cima, Ph.D.	Director	March 19, 2018
/ S / JOHN W. CUMMING John W. Cumming	Director	March 19, 2018
/ S / DAVID B. ELSBREE David B. Elsbree	Director	March 19, 2018
/ S / SEYMOUR LIEBMAN Seymour Liebman	Director	March 19, 2018

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