

T2 Biosystems, Inc.
Form 10-K
March 15, 2017
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the year ended December 31, 2016

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

For the transition period from to

Commission File Number: 001-36571

T2 Biosystems, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

20-4827488
(I.R.S. Employer Identification No.)

101 Hartwell Avenue, Lexington, MA
(Address of principal executive offices)

02421
(Zip code)

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

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

Title of Each Class:	Name of Each Exchange on which Registered:
Common Stock, par value \$0.001 per share	The NASDAQ Stock Market LLC (NASDAQ Global Market)

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required

to submit and post such files). Yes No

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

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

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

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

As of June 30, 2016, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates was approximately \$154.2 million based on the closing price for the common stock of \$7.89 on that date. Shares of common stock held by each executive officer, director, and their affiliated stockholders have been excluded from this calculation as such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant's common stock on March 3, 2017 was 30,576,110. The common stock is listed on the NASDAQ Global Market (trading symbol "TTOO").

DOCUMENTS INCORPORATED BY REFERENCE

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

Table of Contents

TABLE OF CONTENTS

	Page
<u>PART I.</u>	
<u>Item 1.</u> <u>Business</u>	4
<u>Item 1A.</u> <u>Risk Factors</u>	32
<u>Item 1B.</u> <u>Unresolved Staff Comments</u>	61
<u>Item 2.</u> <u>Property</u>	61
<u>Item 3.</u> <u>Legal Proceedings</u>	61
<u>Item 4.</u> <u>Mine Safety Disclosures</u>	61
<u>PART II.</u>	
<u>Item 5.</u> <u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	62
<u>Item 6.</u> <u>Selected Consolidated Financial Data</u>	63
<u>Item 7.</u> <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	65
<u>Item 7A.</u> <u>Quantitative and Qualitative Disclosures about Market Risk</u>	83
<u>Item 8.</u> <u>Financial Statements and Supplementary Data</u>	84
<u>Item 9.</u> <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	114
<u>Item 9A.</u> <u>Controls and Procedures</u>	114
<u>Item 9B.</u> <u>Other Information</u>	115
<u>PART III.</u>	
<u>Item 10.</u> <u>Directors, Executive Officers and Corporate Governance</u>	115
<u>Item 11.</u> <u>Executive Compensation</u>	115
<u>Item 12.</u> <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	115
<u>Item 13.</u> <u>Certain Relationships and Related Transactions, and Director Independence</u>	115

<u>Item 14.</u>	<u>Principal Accountant Fees and Services</u>	115
<u>Item 15.</u>	<u>Exhibits, Financial Statement and Schedules</u>	116

Table of Contents

FORWARD-LOOKING STATEMENTS

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

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or of these terms or other similar expressions. The forward-looking statements in this Annual Report on Form 10-K are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described under the sections in this Annual Report on Form 10-K entitled “Item 1A.—Risk Factors”. These forward looking statements are subject to numerous risks, including, without limitation, the following:

our expectation to incur losses in the future;

the market acceptance of our T2MR technology;

our ability to timely and successfully develop and commercialize our existing products and future product candidates;

the length of our anticipated sales cycle;

our ability to gain the support of leading hospitals and key thought leaders and publish the results of our clinical trials in peer-reviewed journals;

our ability to successfully manage our growth;

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

the performance of our diagnostics;

our ability to compete in the highly competitive diagnostics market;

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

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

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

These forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report on Form 10-K. Unless required by U.S. federal securities laws, we do not intend to update any of these forward-

Table of Contents

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.

Table of Contents

PART I.

Item 1. BUSINESS

Overview

We are an in vitro diagnostics company that has developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. We are using our T2 Magnetic Resonance technology, or T2MR, to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. T2MR enables rapid detection of pathogens, biomarkers and other abnormalities in a variety of unpurified patient sample types, including whole blood, plasma, serum, saliva, sputum and urine, and can detect cellular targets at limits of detection as low as one colony forming unit per milliliter, or CFU/mL. Our initial development efforts target sepsis and Lyme disease, which are areas of significant unmet medical need in which existing therapies could be more effective with improved diagnostics.

On September 22, 2014, we received market clearance from the U.S. Food and Drug Administration, or the FDA, for our first two products, the T2Dx Instrument, or the T2Dx and the T2Candida Panel, which have the ability to rapidly identify the five clinically relevant species of Candida, a fungal pathogen known to cause sepsis. In the United States, we have built a direct sales force that is primarily targeting the top 450 hospitals with the highest concentration of patients at risk for Candida infections. In Europe, we have partnered with distributors that target large hospitals in their respective European markets.

Three additional diagnostic applications in development are called T2Bacteria, T2Resistance and T2Lyme, which are focused on bacterial sepsis infections and Lyme disease, respectively. In late 2015 we initiated the collection of patient blood samples to support the clinical trial for T2Bacteria, and in early 2017, we initiated a multi-site clinical trial for T2Bacteria. We expect that existing reimbursement codes will support our sepsis and Lyme disease product candidates, and that the anticipated economic savings associated with our sepsis products will be realized directly by hospitals.

Sepsis is one of the leading causes of death in the United States, claiming more lives annually than breast cancer, prostate cancer, and AIDS combined, and it is the most expensive hospital-treated condition. Most commonly afflicting immunocompromised, critical care, and elderly patients, sepsis is a severe inflammatory response to a bacterial or fungal infection with a mortality rate of approximately 30%. According to data published by the U.S. Department of Health and Human Services for 2013, the cost of sepsis was over \$23 billion in the United States, or approximately 5% of the total aggregate costs associated with domestic hospital stays. Sepsis is typically caused by one or more of five Candida species or over 25 bacterial pathogens, and effective treatment requires the early

detection and identification of these specific target pathogens in a patient's bloodstream. Today, sepsis is typically diagnosed through a series of blood cultures followed by post-blood culture species identification. These methods have substantial diagnostic limitations that lead to a high rate of false negative test results, a delay of up to several days in administration of targeted treatment, and the incurrence of unnecessary hospital expense. In addition, the Survey of Physicians' Perspectives and Knowledge About Diagnostic Tests for Bloodstream Infections in 2015 reported that negative blood culture results are only trusted by 36% of those physicians. Without the ability to rapidly identify pathogens, physicians typically start treatment of at-risk patients with broad-spectrum antibiotics, which can be ineffective and unnecessary and have contributed to the spread of antimicrobial resistance. According to a study published by Critical Care Medicine in 2006, in sepsis patients with documented hypotension, administration of effective antimicrobial therapy within the first hour of detection was associated with a survival rate of 79.9% and, over the ensuing six hours, each hour of delay in initiation of treatment was associated with an average decrease in survival of 7.6%.

We believe our sepsis products, which include T2Candida and our product candidate, T2Bacteria, will redefine the standard of care in sepsis management while lowering healthcare costs by improving both the precision and the speed of detection of sepsis-causing pathogens. According to a study published in the Journal of Clinical Microbiology in 2010, targeted therapy for patients with bloodstream infections can be delayed up to 72 hours due to the wait time for blood culture results. In another study published in Clinical Infectious Diseases in 2012, the delayed administration of appropriate antifungal therapy was associated with higher mortality among patients with septic shock attributed to Candida infection and, on that basis, the study concluded that more rapid and accurate diagnostic techniques are needed.

Table of Contents

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

Candida is the fourth leading hospital-acquired bloodstream infection, afflicting more than 135,000 patients per year in the United States, and the most lethal form of common bloodstream infections that cause sepsis, with an average mortality rate of approximately 40%. This high mortality rate is largely due to a delay in providing targeted therapy to the patient due to the elapsed time from Candida infection to positive diagnosis. According to a study published in Antimicrobial Agents and Chemotherapy, the Candida mortality rate can be reduced to 11% with the initiation of targeted therapy within 12 hours of presentation of symptoms. Additionally, a typical patient with a Candida infection averages 40 days in the hospital, including nine days in intensive care, resulting in an average cost per hospital stay of more than \$130,000 per patient. In a study published in the American Journal of Respiratory and Critical Care Medicine, providing targeted antifungal therapy within 24 hours of the presentation of symptoms decreased the length of hospital stay by approximately ten days and decreased the average cost of care by approximately \$30,000 per patient. Furthermore, in April 2015, Future Microbiology published the results of an economic study regarding the use of T2Candida conducted by IMS Health, a healthcare economics agency. In that economic study, IMS demonstrated that an average hospital admitting 5,100 patients at risk for Candida infections could save approximately \$5.8 million annually due to decreased hospital stays for patients, reduction in use of antifungal drugs and other associated savings. The economic study further showed T2Candida can potentially reduce the costs of care by \$26,887 per Candida patient and that rapid detection of Candida reduces patient deaths by 60.6%. Results from a data analysis of T2Candida for the detection and monitoring of Candida infection and sepsis were published comparing aggregated results from the use of T2Candida to blood culture-based diagnostics for the detection of invasive candidiasis and candidemia. The analysis included samples acquired from more than 1,900 patients. Out of 55 prospective patient cases that were tested with T2Candida and blood culture and determined to be positive or likely to be positive for a Candida infection, T2Candida detected 96.4% of the patients (53 cases) compared to detection of 60% of the patients (33 cases) with blood culture. During 2016, a number of T2Candida users presented data on their experiences with the T2Candida Panel which demonstrated both the clinical and economic benefits of use of the T2Candida Panel in the diagnostic regimen. The Henry Ford Health System in Detroit, Michigan reported data on a pre- and post-T2Candida implementation analysis that covered 6 months of clinical experience. The data showed a statistically significant ($p = 0.009$) seven day reduction in median Intensive Care Unit, or ICU, length of stay per positive patient that was identified as positive for Candida after implementation of the T2Candida test panel and a trend ($p = 0.164$) of total hospital length of stay reduction of four days. The data also showed significant reductions in use of antifungal drugs for negative patients tested with T2Candida. The overall economic savings resulting from these clinical benefits was projected to be approximately \$2.3 million on an annualized basis. The Lee Health System in Fort Myers, Florida compared patient and economic experience before and after T2Candida implementation. The data demonstrated that in the post-T2Candida cohort, average length of stay for patients with Candida infections was reduced by 7 days when

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

Table of Contents