

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **September 22, 2014**

T2 BIOSYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-36571
(Commission
File Number)

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

101 Hartwell Avenue, Lexington, Massachusetts 02421
(Address of principal executive offices) (Zip Code)

(718) 491-3400
(Registrant's telephone number, include area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

On September 22, 2014, T2 Biosystems, Inc. issued a press release announcing that it received market authorization from the U.S. Food and Drug Administration for its first two products, the T2Candida® test panel and the T2Dx® instrument for the direct detection of Candida species in whole blood specimens from patients with symptoms of, or medical conditions predisposing the patient to, invasive fungal infections.. A copy of the press release announcing the approval is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

**Exhibit
No.**

Description

99.1 Press Release issued September 22, 2014

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

T2 BIOSYSTEMS, INC.

Date: September 22, 2014

By: /s/ John McDonough
John McDonough
President and Chief Executive Officer

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EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued September 22, 2014

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FOR IMMEDIATE RELEASE

T2 Biosystems Receives FDA Authorization to Market T2Candida and T2Dx for the Detection of Sepsis-Causing Pathogens

— Novel test to identify *Candida*, one of the most lethal forms of common bloodstream infections that cause sepsis, faster than current methods — hours instead of days —

— More than 10 million people tested for *Candida* every year —

LEXINGTON, Mass. — September 22, 2014 — [T2 Biosystems](#), a company developing innovative diagnostic products to improve patient health, today announced that it has received market authorization from the U.S. Food and Drug Administration (FDA) for its first two products, the T2Candida® Panel and the T2Dx® Instrument for the direct detection of *Candida* species in human whole blood specimens from patients with symptoms of, or medical conditions predisposing the patient to, invasive fungal infections. T2Candida and T2Dx, for the first time, provide sensitive detection of specific sepsis-causing pathogens directly from a whole blood specimen in approximately four hours. All other currently FDA-cleared detection systems require cultured blood samples for species-specific identification and take two to five days or more to provide results.

“T2Candida and T2Dx have the potential to quickly change the hospital care paradigm and improve outcomes by offering a new and effective screening option for patients who are at-risk or suspected of having sepsis,” said Eleftherios Mylonakis, M.D., Ph.D., FIDSA, chief, Division of Infectious Diseases, Dean’s Professor of Medical Science, Professor of Medicine, Rhode Island Hospital and The Miriam Hospital, Providence, R.I. “Compared to current blood-culture based diagnostic methods, T2Candida and T2Dx give us an option that provides specific and dependable results in a matter of hours, not days, allowing us to direct the right therapy to our patients — potentially saving their lives.”

In the pivotal trial, T2Candida and T2Dx demonstrated a sensitivity of 91.1 percent and a specificity of 99.4 percent. The mean time to a positive result for T2Candida was 4.4 hours versus 129 hours for blood culture and species identification, the current gold standard. The mean time for a negative result for T2Candida was 4.2 hours, compared to 120 hours for blood culture. Both T2Candida and T2Dx were reviewed under the FDA de novo classification process for devices with low-to-moderate risk that are first-of-a-kind.

Studies have shown that if *Candida* can be diagnosed and treated with targeted therapy beginning within 12 hours of the presentation of symptoms, the associated mortality rate can be reduced from approximately 40 percent to 11 percent. 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 10 days and decreased the average cost of care by approximately \$30,000 per patient.

Due to the high mortality rate and cost of *Candida* infections, many hospitals initiate potentially inappropriate antifungal drugs while waiting for blood culture-based diagnostic results. A negative result from T2Candida may provide timely data allowing physicians to avoid or suspend unnecessary antifungal treatment. This could result in a further reduction of treatment costs, as well as potentially helping to reduce antimicrobial resistant organisms, which the Centers for Disease Control and Prevention has called “one of our most serious health threats.”

T2Candida and T2Dx are the first diagnostic products powered by T2MR®, an innovative and proprietary magnetic resonance-based diagnostic technology platform that offers a fast, sensitive and simple alternative to existing diagnostic methodologies.

To date, more than 100 peer-reviewed publications have featured T2MR in a variety of studies, including the direct detection and measurement of targets in various sample types, such as whole blood, plasma, serum, saliva, sputum and urine.

“The FDA’s market authorization of T2Candida and T2Dx mark a significant milestone for our Company, but more importantly for the more than 800,000 U.S. physicians across the country in need of faster diagnostic results so they can make timely and informed treatment decisions for their patients,” said John McDonough, president and CEO of T2 Biosystems. “We believe the diagnostic capabilities offered by these products can support both improved clinical outcomes, as well as strong health economic benefits, and we look forward to working closely with the medical community to bring this novel diagnostic test to hospitals, physicians and patients.”

About Sepsis

Sepsis is one of the leading causes of death in the U.S. and the most expensive hospital-treated condition, with costs to the healthcare system exceeding \$20 billion each year, according to the U.S. Department of Health and Human Services. T2Candida uses magnetic resonance technology to help detect the presence of five clinically relevant species of *Candida*, the most lethal form of common blood stream infections that cause sepsis, directly from a patient’s blood sample in approximately four hours, versus two to five days or more with current diagnostic methods.

About T2 Biosystems

T2 Biosystems is focused on developing innovative diagnostic products to improve patient health. With two FDA authorized products targeting sepsis and a range of additional products in development, T2 Biosystems is an emerging leader in the field of *in vitro* diagnostics. The Company is utilizing its proprietary T2 Magnetic Resonance platform, or T2MR, to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and

reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. T2MR enables the fast and sensitive detection of pathogens, biomarkers and

other abnormalities in a variety of unpurified patient sample types, including whole blood, eliminating the time-consuming sample prep required in current methods. For more information, please visit www.t2biosystems.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements. These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the performance of the Company's diagnostic products and the ability to work with the medical community to bring such products to hospitals, physicians and patients. These and other important factors discussed under the caption "Risk Factors" in the Company's final prospectus filed with the Securities and Exchange Commission, pursuant to Rule 424(b) of the Securities Act of 1933, as amended, on August 7, 2014, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While the Company may elect to update such forward-looking statements at some point in the future, it disclaims any obligation to do so, even if subsequent events cause its views to change. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this press release.

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