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): May 29, 2018

T2 BIOSYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36571**	**20-4827488**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

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

(781) 761-4646
(Registrant's telephone number, including 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

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. ☒

Item 8.01. Other Events.

On May 29, 2018, T2 Biosystems, Inc. issued a press release announcing that it received market clearance from the U.S. Food and Drug Administration (FDA) for the T2Bacteria® Panel for the direct detection of bacterial species in human whole blood specimens from patients with suspected bloodstream infections. The T2Bacteria Panel runs on the T2Dx® Instrument. The FDA-cleared T2Bacteria Panel identifies five of the most common and deadly sepsis-causing species of bacteria*: Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Staphylococcus aureus*.

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 May 29, 2018

SIGNATURES

Pursuant to the requirements 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 hereunto duly authorized.

Date: May 29, 2018

T2 BIOSYSTEMS, INC.

By: /s/ John McDonough
John McDonough
CEO & President

Exhibit 99.1

T2 Biosystems Receives FDA Clearance to Market T2Bacteria Panel for Detection of Sepsis-Causing Pathogens

First FDA-cleared test to identify sepsis-causing bacteria direct from whole blood

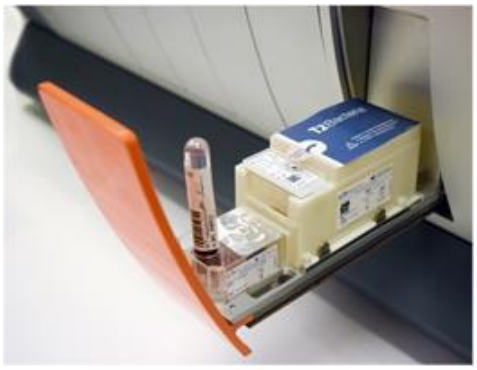
Cuts time to diagnosis from days to hours, allowing greater certainty and new protocols for deadly infections in hospital setting

Company to host conference call to discuss T2Bacteria and provide financial guidance at 8:30 a.m. ET on Tuesday, May 29, 2018

LEXINGTON, Mass., May 29, 2018 (GLOBE NEWSWIRE) — T2 Biosystems, Inc. (NASDAQ:TTOO), an emerging leader in the development and commercialization of innovative diagnostic products for critical unmet needs in healthcare, today announced that it has received market clearance from the U.S. Food and Drug Administration (FDA) for the T2Bacteria® Panel for the direct detection of bacterial species in human whole blood specimens from patients with suspected bloodstream infections. The T2Bacteria Panel, for the first time, provides sensitive detection of specific sepsis-causing bacterial pathogens directly from a whole blood specimen in approximately 5 hours. This was more than 2.5 days faster than blood culture-dependent tests as demonstrated in the over 1,400 patient pivotal trial conducted at 11 hospitals in the United States. All other FDA-cleared diagnostic tests that detect bacteria in blood require a positive blood culture sample prior to bacterial species specific identification, which typically delays results by one to five days. For patients at risk of sepsis, rapid targeted treatment based on the identification of causative pathogens is critical because it is estimated that every hour of speeding up the time to targeted therapy decreases patient mortality by nearly 8%.

“The T2Bacteria Panel’s rapid results and high sensitivity make it a valuable tool for the diagnosis and management of suspected bloodstream infections,” said W. Frank Peacock, MD, FACEP, FACC, professor, associate chair, Baylor College of Medicine. “This is an important breakthrough as bacterial infections are a major cause of poor patient outcomes and high hospital costs. This is a game-changer.”

In addition to the more than tenfold improvement in time to result demonstrated in the pivotal clinical trial, the T2Bacteria Panel also achieved an overall average sensitivity of 90% and an overall average specificity of 98%, while demonstrating no interference from the presence of antibiotics in the bloodstream.



The T2Bacteria Panel is placed into the T2Dx Instrument to identify sepsis-causing bacteria directly from whole blood

“The results from the T2Bacteria pivotal clinical trial were impressive, demonstrating excellent performance and advantages over blood culture,” said Minh-Hong Nguyen, MD, director, Antimicrobial Management Program and director, Transplant Infectious Diseases, UPMC. “T2Bacteria’s detection of bloodstream infections and fast species identification at high sensitivity will expedite life-saving interventions such as the targeting of therapy within hours of blood draw.”

The T2Bacteria Panel, like the previously FDA-cleared T2Candida® Panel, runs on the Company’s proprietary, FDA-cleared T2Dx® Instrument. The FDA-cleared T2Bacteria Panel identifies five of the most common and deadly sepsis-causing species of bacteria: *Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa,* and *Staphylococcus aureus.*

Bacterial and fungal bloodstream infections are a leading cause of sepsis, a life-threatening illness that affects 1.6 million U.S. patients each year, resulting in over 250,000 deaths or almost 50% of all deaths of U.S. hospitalized patients. Studies have shown that the mortality rate for bloodstream infections can be reduced significantly with appropriate targeted therapy within 12 hours.

“The FDA’s market clearance of the T2Bacteria Panel is a significant milestone for our company, but more importantly, for millions of patients at risk of sepsis from bloodstream infections,” said John McDonough, president and chief executive officer of T2 Biosystems. “This breakthrough technology provides potentially life-saving answers for patients and economic savings to hospitals that bear the enormous burden of sepsis-related care and mortality.”

Conference Call and Webcast

Management will host a conference call today with the investment community at 8:30 a.m. Eastern Time to discuss key T2Bacteria commercial launch activities in more detail and provide updated 2018 full-year financial guidance. Interested parties may access the live call via telephone by dialing 1-877-407-9208 (U.S.) or 1-201-493-6784 (International). To listen to the live call via T2 Biosystems’ website, go to www.t2biosystems.com, in the Investors/Events & Presentations section. A webcast replay of the call will be available following the conclusion of the call, also in the Investors/Events & Presentations section of the website.

About Bloodstream Infections

Treating bloodstream infections earlier may prevent progression to sepsis, one of the leading causes of death in the U.S. and the most expensive hospital-treated condition, with costs exceeding $27 billion. Sepsis claims more lives annually than breast cancer, prostate cancer, and AIDS combined and is the most prevalent and costly cause of hospital readmissions. The pathogens that cause sepsis infections are difficult to detect and can be deadly even at very small concentrations in the bloodstream. With sepsis, one hour of delayed treatment increases mortality risk by nearly 8%. The T2Bacteria Panel uses magnetic resonance technology to help detect the presence of five clinically relevant species of bacteria directly from a patient’s blood sample in approximately five hours, versus one to five days or more with current diagnostic methods, potentially enabling more rapid treatment that may prevent the progression of a bloodstream infection to sepsis.

About T2 Biosystems:

T2 Biosystems, an emerging leader in the development and commercialization of innovative medical diagnostic products for critical unmet needs in healthcare, improves patient care and reduces the cost of care by helping clinicians effectively treat patients faster than ever before. T2 Biosystems’ products include the T2Dx Instrument, T2Candida Panel and T2Bacteria Panel and are powered by the proprietary T2 Magnetic Resonance (T2MR®) technology. T2 Biosystems has an active pipeline of future products, including detection of additional species and antibiotic resistance markers of sepsis pathogens and tests for Lyme disease. 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, including, without limitation, statements regarding product pipeline, anticipated product benefits, goals and strategic priorities, product expansion or opportunities, growth expectations or targets and FDA clearance, as well as statements that

include the words “expect,” “intend,” “plan,” “believe,” “project,” “forecast,” “estimate,” “may,” “should,” “anticipate” and similar statements of a future or forward-looking nature. 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, (i) any inability to (a) realize anticipated benefits from commitments, contracts or products; (b) successfully execute strategic priorities; (c) bring products to market; (d) expand product usage or adoption; (e) obtain customer testimonials; (f) accurately predict growth assumptions; (g) realize anticipated revenues; (h) incur expected levels of operating expenses; or (i) increase the number of high-risk patients at customer facilities; (ii) failure of early data to predict eventual outcomes; (iii) failure to make or obtain anticipated FDA filings or clearances within expected time frames or at all; or (iv) the factors discussed under Item 1A. “Risk Factors” in the Company’s Annual Report on Form 10-K for the year-ended December 31, 2017, filed with the U.S. Securities and Exchange Commission (SEC) on March 19, 2018, and other filings the Company makes with the SEC from time to time. These and other important factors 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, unless required by law, it disclaims any obligation to do so, even if subsequent events cause its views to change. Thus, one should not assume that the Company’s silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. 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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