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): November 20, 2019

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))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	**TTOO**	**The Nasdaq Stock Market LLC (Nasdaq Global Market)**

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 November 20, 2019 T2 Biosystems, Inc. (the "Company") issued a press release announcing the granting of a CE-Mark to the T2Resistance™ Panel which will allow the Company to market the T2Resistance Panel within the European Economic Area. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued November 20, 2019

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: November 20, 2019

T2 BIOSYSTEMS, INC.

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

MEDIA RELEASE

T2 Biosystems Announces Granting of CE-Mark for T2Resistance™ Panel

The T2Resistance Panel is the only direct-from-blood diagnostic designed to detect genetic markers associated with antibiotic-resistant bloodstream infections

LEXINGTON, Mass., November 20, 2019 (GLOBE NEWSWIRE)—T2 Biosystems, Inc. (NASDAQ:TTOO), a leader in the development and commercialization of innovative medical diagnostic products for critical unmet needs in healthcare, and CARB-X, a global non-profit partnership dedicated to accelerating R&D innovation to address the rising global threat of drug-resistant bacteria, today announced the granting of a CE-Mark to the T2Resistance™ Panel. With CE-mark, T2 Biosystems has met the requirements of the In-Vitro Diagnostics Directive (98/79/EC) and can market the T2Resistance Panel within the European Economic Area (EEA).

The panel, which was developed with support from CARB-X, was the first diagnostic to graduate from CARB-X's portfolio and is now the first CARB-X-powered product to be approved for use in human whole blood specimens from patients. The T2Resistance Panel identifies 13 of the most serious resistance genes on the antibiotic-resistance threat list published by the Centers for Disease Control and Prevention (CDC), including genes indicating resistance to common empiric antibiotic therapies such as carbapenems, vancomycin, penicillin and more. It is the first diagnostic test that can detect all of these resistance markers directly from whole blood—in three to five hours.

"Fighting antimicrobial resistance not only requires the development of rapid diagnostics, like the T2Resistance Panel, but also requires access to these innovations so they can make a positive impact on as many patients as possible," said John McDonough, chairman and chief executive officer of T2 Biosystems. "We are grateful that with the invaluable help of CARB-X's funding, patients in Europe can start benefitting clinically from the early detection of antibiotic-resistant bloodstream infections."

To receive CARB-X funding, T2 Biosystems had to demonstrate to an advisory panel consisting of global experts in the antimicrobial resistance (AMR) and diagnostic fields that the innovation had the potential to significantly accelerate and improve the detection and diagnosis of serious drug-resistant bacterial infections, and to contribute to the global fight against drug-resistant bacteria.

"We're proud that we were able to help T2 deliver its technology to market as part of our effort to support the development of rapid diagnostics, antibiotics, vaccines and other products from around the world to address drug-resistant bacteria," said Kevin Outterson, Executive Director of CARB-X, which is based at the Boston University School of Law. "This represents a huge step forward for patients, and a critical milestone for CARB-X. Rapid diagnosis of drug-resistant infections is essential to improve appropriate treatment for patients, and to save lives." CARB-X is a consortium led by Boston University and funded by a global partnership.

Drug-resistant infections are responsible for an estimated 700,000 deaths worldwide each year, according to the World Health Organization (WHO). Existing diagnostics to detect antibiotic resistance markers primarily rely on blood cultures, which can take days, and do not provide results when patients need them most. As a result, physicians are often unable to treat infections quickly with the appropriate antibiotics, leading to poor patient outcomes, higher mortality, and the overuse of antibiotics empirically.

“Reaching this milestone demonstrates how essential public-private partnerships like CARB-X are in the global fight against antimicrobial resistant infections,” said Rick Bright, Ph.D., director of the U.S. Biomedical Advanced Research and Development Authority (BARDA). “In founding CARB-X, we and our partners sought to stimulate a more robust pipeline for the innovative products needed to help save lives from some of the toughest infections ever known. At BARDA, we continue to work with T2 on developing their diagnostic to expand the platform’s potential use in rapidly identifying a variety of biodefense-related infections to protect health security.”

In addition to the T2Resistance Panel, T2 Biosystems is the company behind the T2Bacteria® Panel, which was the first in-vitro diagnostic test to receive approval for a New Technology Add-on Payment (NTAP) by the United States Centers for Medicare & Medicaid Services (CMS). The panel is the only test cleared by the United States Food and Drug Administration (FDA) to identify sepsis-causing bacterial pathogens directly from whole blood without the need to wait for blood culture; the test’s counterpart for fungal bloodstream infections is the T2Candida® Panel, the first and only FDA-cleared direct-from-whole blood diagnostic for detection of fungal pathogens that are associated with sepsis. Both panels provide results in three to five hours instead of days. The products are two of several panels that are approved or in development that are run on the Company’s T2Dx® Instrument, which is powered by miniaturized magnetic resonance (T2MR®) technology.

This ***news release*** *is supported by the Cooperative Agreement Number IDSEP160030 from ASPR/BARDA and awards from Wellcome Trust, the German Federal Ministry of Education and Research, as administrated by CARB-X. The content is solely the responsibility of the authors and does not necessarily represent the official views of the Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response, other funders, or CARB-X.*

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About T2 Biosystems

T2 Biosystems, a leader in the development and commercialization of innovative medical diagnostic products for critical unmet needs in healthcare, is dedicated to improving patient care and reducing 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, which was recently announced as the first and only in-vitro diagnostic test to receive approval for a New Technology Add-on Payment (NTAP) by CMS, are powered by the proprietary T2 Magnetic Resonance (T2MR®) technology. T2 Biosystems has an active pipeline of future products, including products for the detection of additional species and antibiotic resistance markers of sepsis pathogens, and tests for Lyme disease.

About CARB-X

Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) is a global non-profit partnership dedicated to accelerating early development antibacterial R&D to address the rising global threat of drug-resistant bacteria. CARB-X is led by Boston University and funding is provided by the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the US Department of Health and Human Services, the Wellcome Trust, a global charity based in the UK working to improve health globally, Germany's Federal Ministry of Education and Research (BMBF), the Bill & Melinda Gates Foundation, and with in-kind support from National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH). CARB-X is investing up to $500 million from 2016-2021 to support innovative antibiotics and other therapeutics, vaccines, and rapid diagnostics. CARB-X supports the world's largest and most innovative pipeline of preclinical products against drug-resistant infections. CARB-X is headquartered at Boston University School of Law. https://carb-x.org/. Follow us on Twitter @CARB_X.

About BARDA and NIAID

The US Department of Health and Human Services works to enhance and protect the health and well-being of all Americans, providing for effective health and human services and fostering advances in medicine, public health, and social services. Within HHS, ASPR's mission is to save lives and protect Americans from 21st century health security threats. ASPR leads the nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies. BARDA provides a comprehensive, integrated, portfolio approach to the advanced research and development, innovation, acquisition, and manufacturing of medical countermeasures – vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products for public health emergency threats. These threats include chemical, biological, radiological, and nuclear agents, pandemic influenza, and emerging infectious diseases. NIH is the primary US federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. NIAID conducts and supports research — at NIH, throughout the United States, and worldwide — to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses.

About Wellcome Trust

Wellcome exists to improve health for everyone by helping great ideas to thrive. We're a global charitable foundation, both politically and financially independent. We support scientists and researchers, take on big problems, fuel imaginations and spark debate. The Wellcome Trust is a charity registered in England and Wales, no. 210183. Its sole trustee is The Wellcome Trust Limited, a company registered in England and Wales, no. 2711000 (whose registered office is at 215 Euston Road, London NW1 2BE, UK)

About BMBF

Education and research are the foundations for our future. The promotion of education, science and research by the Federal Ministry of Education and Research (BMBF) represents an important contribution to securing Germany's prosperity. Education and research are a Federal Government policy priority, which is reflected in the development of the funding it is making available to these fields.

About Boston University

Founded in 1839, Boston University is an internationally recognized institution of higher education and research. With more than 33,000 students, it is the fourth-largest independent university in the United States. BU consists of 17 schools and colleges, along with a number of multi-disciplinary centers and institutes integral to the University's research and teaching mission. In 2012, BU joined the Association of American Universities (AAU), a consortium of 62 leading research universities in the United States and Canada. For further information, please contact Jeremy Thompson at jeremy22@bu.edu. www.bu.edu.

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 additional patients, timing of testing patients, anticipated product benefits, strategic priorities, product expansion or opportunities, growth expectations or targets, timing of FDA filings or clearances and anticipated operating expenses, 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, 2018, filed with the U.S. Securities and Exchange Commission, or SEC, on March 14, 2019, 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, no one should 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.