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 16, 2024

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 Capital 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 7.01 Regulation FD Disclosure.

On September 16, 2024, the Company issued a press release announcing that it has received clearance from the U.S. Food and Drug Administration (FDA) to market its FDA-cleared T2Candida® Panel for pediatric patients. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 and Exhibit 99.1 of this Current Report on Form 8-K is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section.

Item 8.01 Other Events

On September 16, 2024, the Company announced that it has received clearance from the FDA to market its FDA-cleared T2Candida® Panel for pediatric patients.

The T2Candida Panel is the only FDA-cleared diagnostic test able to detect sepsis-causing Candida species directly-from-blood, in just 3-5 hours, without the need to wait days for a positive blood culture. The T2Candida Panel runs on the FDA-cleared T2Dx® Instrument and simultaneously detects five Candida species including, *Candida albicans, Candida tropicalis, Candida parapsilosis, Candida krusei,* and *Candida glabrata*. According to the U.S. Centers for Disease Control and Prevention (CDC), the five species detected by the T2Candida Panel account for up to 95% of all *Candida* bloodstream infections in the U.S.

According to the Journal of Fungi, a peer-reviewed scientific journal that provides an advanced forum for studies related to pathogenic fungi, *Candida* species are a major contributor to morbidity and mortality in hospitalized children. Moreover, children with invasive candidiasis present a significant burden to the U.S. healthcare system, with a mean increased hospital length of stay of 21 days and approximately $92,000 in excess hospital costs.

A Journal of Clinical Microbiology (2022) study conducted at the Bambino Gesù hospital in Rome, Italy found that pediatric patients suspected of fungal bloodstream infections that were tested with the T2Candida Panel received species identification results 121.8 hours faster compared to blood culture. The study also found a higher detection rate with the T2Candida Panel, as six additional probable or possible fungal bloodstream infections in pediatric patients were detected by the T2Candida Panel that were missed by blood culture. In addition, a prospective observational study published in Clinical Infectious Diseases (2022) evaluated the performance of four pre-blood culture tests for detecting the presence of invasive candidiasis in pediatric patients and found that the T2Candida Panel had the highest sensitivity and specificity of all four assays among five hundred patients enrolled. The T2Candida Panel was the only test recommended for individual use as a tool for the diagnosis of invasive candidiasis in at-risk children and adolescents.

Forward-Looking Statements

This Current Report on Form 8-K ("Current Report") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding the ability of the T2Candida Panel to detect Candida species in pediatric patients; the ability of the T2Candida Panel to detect Candida species in pediatric patients significantly faster and with greater sensitivity than blood culture; and the likelihood that the expansion of the T2Candida pediatric testing claim will allow clinicians to improve outcomes and reduce cost by achieving faster targeted antifungal treatment for their pediatric patients, as well as statements that include the words "expect," "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, 2023, filed with the U.S. Securities and Exchange Commission, or SEC, on April 1, 2024, and other filings the Company makes with the SEC from time to time, including our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this Current Report. Any such forward-looking statements represent management's estimates as of the date of this Current Report. 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 Current Report.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued September 16, 2024
104	Cover Page Interactive Data File (embedded within the inline XBRL document

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: September 16, 2024

T2 BIOSYSTEMS, INC.

By: /s/ John Sprague
John Sprague
Chief Financial Officer

T2 Biosystems Receives FDA Clearance to Market the T2Candida Panel for Pediatric Patients

Expands available market to include over 200 children's hospitals in the United States

LEXINGTON, Mass., September 16, 2024 (GLOBE NEWSWIRE)— T2 Biosystems, Inc. (NASDAQ:TTOO) (the "Company"), a leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes, today announced that it has received clearance from the U.S. Food and Drug Administration (FDA) to market its FDA-cleared T2Candida® Panel for pediatric patients. The Company expects to immediately begin marketing and selling the T2Candida Panel under the expanded pediatric claim.

The T2Candida Panel is the only FDA-cleared diagnostic test able to detect sepsis-causing *Candida* species directly-from-blood, in just 3-5 hours, without the need to wait days for a positive blood culture. The T2Candida Panel runs on the FDA-cleared T2Dx® Instrument and simultaneously detects five *Candida* species including, *Candida albicans*, *Candida tropicalis*, *Candida parapsilosis*, *Candida krusei*, and *Candida glabrata*. According to the U.S. Centers for Disease Control and Prevention (CDC), the five species detected by the T2Candida Panel account for up to 95% of all *Candida* bloodstream infections in the U.S.

"This FDA clearance marks another important milestone in our commitment to expand the clinical utility of our sepsis test panels and allows our commercial team to immediately begin marketing and selling our test to over 200 children's hospitals in the U.S.," stated John Sperzel, Chairman and CEO of T2 Biosystems. "Studies show that the T2Candida Panel detects *Candida* species significantly faster, and with greater sensitivity, when compared to blood culture-based diagnostics, and we believe the new pediatric testing claim will allow clinicians to improve outcomes and reduce cost by achieving faster targeted antifungal treatment for their pediatric patients."

According to the Journal of Fungi, a peer-reviewed scientific journal that provides an advanced forum for studies related to pathogenic fungi, *Candida* species are a major contributor to morbidity and mortality in hospitalized children. Moreover, children with invasive candidiasis present a significant burden to the U.S. healthcare system, with a mean increased hospital length of stay of 21 days and approximately $92,000 in excess hospital costs.

A *Journal of Clinical Microbiology* (2022) study conducted at the Bambino Gesù hospital in Rome, Italy found that pediatric patients suspected of fungal bloodstream infections that were tested with the T2Candida Panel received species identification results 121.8 hours faster compared to blood culture. The study also found a higher detection rate with the T2Candida Panel, as six additional probable or possible fungal bloodstream infections in pediatric patients were detected by the T2Candida Panel that were missed by blood culture. In addition, a prospective observational study published in *Clinical Infectious Diseases* (2022) evaluated the performance of four pre-blood culture tests for detecting the presence of invasive candidiasis in pediatric patients and found that the T2Candida Panel had the highest sensitivity and specificity of all four assays among five hundred patients enrolled. The T2Candida Panel was the only test recommended for individual use as a tool for the diagnosis of invasive candidiasis in at-risk children and adolescents.

About T2 Biosystems

T2 Biosystems, a leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes, 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 are powered by the proprietary T2 Magnetic

Resonance (T2MR®) technology and include the T2Dx® Instrument, the T2Bacteria® Panel, the T2Candida® Panel, the T2Resistance® Panel, and the T2Biothreat™ Panel. T2 Biosystems has an active pipeline of future products, including the U.S. T2Resistance Panel, the T2Lyme™ Panel, and the expended T2Candida Panel to add the detection of *Candida auris*. For more information, please visit www.t2biosystems.com.

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Investor Contact:

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