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 9, 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 9, 2024, the Company issued a press release providing an update on its new product development pipeline progress. 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 9, 2024, the Company provided an update on its new product development pipeline progress.

The highlights include:

- Finalizing a 510(k) premarket notification application for the T2Resistance® Panel planned to be filed with the U.S. Food and Drug Administration (FDA) during the fourth quarter of 2024.
- The previously submitted a 510(k) premarket notification to expand use of the T2Candida® Panel to detect pediatric Candida infections is pending clearance with the FDA.
- Advanced internal validation and plans to submit a 510(k) premarket notification to the FDA to expand the use of its FDA-cleared T2Bacteria® Panel to detect pediatric bacterial infections.
- The Company maintains its plan to launch the T2Lyme™ Panel as a Laboratory Developed Test (LDT); however, it now plans to build or buy its own laboratory rather than launch through a partnership.
- Pursuing non-dilutive funding to complete the development, validation, and clinical studies for a diagnostic test to detect Candida auris, following the completion of feasibility and early development in collaboration with the U.S. Centers for Disease Control and Prevention (CDC).

Antimicrobial resistance

According to the CDC, antimicrobial resistance is an urgent global public health threat. To address the threat caused by AMR, the Company has developed the T2Resistance Panel, a direct-from-blood molecular diagnostic test that runs on the FDA-cleared T2Dx® Instrument and simultaneously detects 13 antibiotic resistance genes, in just 3-5 hours, without the need to wait days for a positive blood culture.

In March 2024, the results of a new study were published in Journal of Clinical Microbiology highlighting the benefits of the T2Resistance Panel compared to blood culture and standard microbiology methods, including high accuracy (i.e., 94.7% sensitivity, 97.4% specificity), rapid turnaround time (i.e., results available is 4.4 hours vs. 58.3 hours), and clinical impact (i.e., clinical interventions in 41% of patients in the study, or 24 of 59 patients).

Pediatric Sepsis

According to the Children's Hospital Association, sepsis is the leading cause of death in hospitalized children, more than cancer. To address the threat of pediatric sepsis, the Company is pursuing pediatric claims for its T2Candida® Panel and T2Bacteria® Panel, the only FDA-cleared products able to detect sepsis-causing fungal and bacterial pathogens direct-from-blood, in just 3-5 hours, without the need to wait days for a positive blood culture.

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. Additionally, 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.

Lyme Disease

According to the CDC, Lyme disease is the leading vector-borne disease in the U.S., with an estimated 3.4 million tests performed each year at a cost of nearly $500 million. The current diagnostic process is a two-tiered antibody test algorithm that relies on the presence of antibodies, and which is only accurate four to eight weeks after infection. During those weeks, the bacteria may spread throughout the body and become much harder to eradicate and treat effectively, and may lead to chronic, debilitating disease.

To address this critical unmet need, the Company has developed the T2Lyme Panel, a direct-from-blood molecular diagnostic test for the early detection of Borrelia burgdorferi, the bacterium that causes Lyme disease in the United States. Early detection and appropriate treatment are essential, as untreated Borrelia burgdorferi infections may spread throughout the body and lead to chronic, debilitating Lyme disease. The T2Lyme Panel has been designed to be a highly sensitive detection of an infection and is expected to detect Lyme disease within the first 30 days post infection, compared to antibody tests that can take 30-60 days post infection.

Candida auris

According to the World Health Organization, Candida auris is a multidrug-resistant pathogen labeled as a growing threat to public health. A 2023 Wall Street Journal report described Candida auris as a "deadly fungus spreading across the U.S., mostly in healthcare facilities," with a mortality rate of up to 60%. According to the CDC, Candida auris is difficult to identify with standard laboratory methods, which can lead to inappropriate treatment, and some strains are resistant to all three available classes of antifungal therapies.

To address this global threat, the Company intends to expand its direct-from-blood T2Candida Panel to include the detection of Candida auris. The FDA-cleared T2Candida Panel currently covers approximately 90% of Candida species commonly found in bloodstream infections. The addition of Candida auris should provide important coverage for infections caused by this pathogen which are becoming increasingly more prevalent.

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 likelihood that the Company will submit a 510(k) premarket notification for the T2Resistance Panel to the FDA during the fourth quarter of 2024; the likelihood that the Company will be successful in receiving approval and commercializing the T2Resistance Panel, T2Lyme Panel and expanding the T2Candida Panel for the detection of pediatric sepsis and Candida auris; the likelihood that the T2Lyme Panel will be able to detect Borrelia burgdorferi in the first 30 days following infection; the likelihood that the Company will successful in building or buying its own laboratory for the testing of the T2Lyme Panel; the ability for the Company to launch multiple new products in 2024 and 2025; the likelihood that all four of our pipeline products will allow

clinicians to achieve faster targeted treatment, reduce cost, and improve patient outcome; the likelihood that the Company will receive non-dilutive funding to complete the development, validation, and clinical studies for the addition of Candida auris to the T2Candida Panel, 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 9, 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 9, 2024

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

T2 Biosystems Provides Updates on its New Product Development Pipeline Progress

Company plans to launch multiple direct-from-blood diagnostics over the next 15 months for antimicrobial resistance, pediatric Candida infections, Lyme disease, and Candida auris

LEXINGTON, Mass., September 9, 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 provided an update on its new product development pipeline progress. The Company's product pipeline is focused on direct-from-blood diagnostic tests for antimicrobial resistance (AMR), pediatric *Candida* infections, Lyme disease, and *Candida auris*.

Pipeline Progress Highlights

- Finalizing a 510(k) premarket notification application for the T2Resistance® Panel planned to be filed with the U.S. Food and Drug Administration (FDA) during the fourth quarter of 2024.
- The previously submitted 510(k) premarket notification to expand use of the T2Candida® Panel to detect pediatric *Candida* infections is pending clearance with the FDA.
- Advanced internal validation and plans to submit a 510(k) premarket notification to the FDA to expand the use of its FDA-cleared T2Bacteria® Panel to detect pediatric bacterial infections.
- The Company maintains its plan to launch the T2Lyme™ Panel as a Laboratory Developed Test (LDT); however, it now plans to build or buy its own laboratory rather than launch through a partnership.
- Pursuing non-dilutive funding to complete the development, validation, and clinical studies for a diagnostic test to detect *Candida auris*, following the completion of feasibility and early development in collaboration with the U.S. Centers for Disease Control and Prevention (CDC).

"Our team is making excellent progress developing novel diagnostics to rapidly detect pathogens directly-from blood, including antimicrobial resistance, pediatric *Candida* infections, Lyme disease, and *Candida auris,* and we expect to launch multiple new products in 2024 and 2025," stated John Sperzel, Chairman and CEO of T2 Biosystems. "Three of our pipeline products have received FDA Breakthrough Device designation, including the T2Resistance Panel, the T2Lyme Panel, and the *Candida auris* test, and we believe all four of our pipeline products will allow clinicians to achieve faster targeted treatment, reduce cost, and improve patient outcomes."

Antimicrobial resistance

According to the CDC, antimicrobial resistance is an urgent global public health threat. To address the threat caused by AMR, the Company has developed the T2Resistance Panel, a direct-from-blood molecular diagnostic test that runs on the FDA-cleared T2Dx® Instrument and simultaneously detects 13 antibiotic resistance genes, in just 3-5 hours, without the need to wait days for a positive blood culture.

In March 2024, the results of a new study were published in *Journal of Clinical Microbiology* highlighting the benefits of the T2Resistance Panel compared to blood culture and standard microbiology methods, including high accuracy (i.e., 94.7% sensitivity, 97.4% specificity), rapid turnaround time (i.e., results available is 4.4 hours vs. 58.3 hours), and clinical impact (i.e., clinical interventions in 41% of patients in the study, or 24 of 59 patients).

The Company plans to submit a 510(k) premarket notification to the FDA during the fourth quarter of 2024 and expects to receive a prioritized FDA review given the T2Resistance Panel previously received FDA Breakthrough Device designation.

Pediatric Sepsis

According to the Children's Hospital Association, sepsis is the leading cause of death in hospitalized children, more than cancer. To address the threat of pediatric sepsis, the Company is pursuing pediatric claims for its T2Candida® Panel and T2Bacteria® Panel, the only FDA-cleared products able to detect sepsis-causing fungal and bacterial pathogens direct-from-blood, in just 3-5 hours, without the need to wait days for a positive blood culture.

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. Additionally, 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 Company previously submitted a 510(k) premarket notification to the FDA to expand the use of its FDA-cleared T2Candida Panel to include pediatric testing, and the indication is pending FDA clearance. The Company also plans to submit a 510(k) premarket notification to the FDA to expand the use of its FDA-cleared T2Bacteria Panel to include pediatric testing.

Lyme Disease

According to the CDC, Lyme disease is the leading vector-borne disease in the U.S., with an estimated 3.4 million tests performed each year at a cost of nearly $500 million. The current diagnostic process is a two-tiered antibody test algorithm that relies on the presence of antibodies, and which is only accurate four to eight weeks after infection. During those weeks, the bacteria may spread throughout the body and become much harder to eradicate and treat effectively, and may lead to chronic, debilitating disease.

To address this critical unmet need, the Company has developed the T2Lyme Panel, a direct-from-blood molecular diagnostic test for the early detection of *Borrelia burgdorferi*, the bacterium that causes Lyme disease in the United States. Early detection and appropriate treatment are essential, as untreated *Borrelia burgdorferi* infections may spread throughout the body and lead to chronic, debilitating Lyme disease. The T2Lyme Panel has been designed to be a highly sensitive detection of an infection and is expected to detect Lyme disease within the first 30 days post infection, compared to antibody tests that can take 30-60 days post infection.

The Company has made an important strategic decision regarding the commercialization of the T2Lyme Panel. The Company maintains its plan to launch the T2Lyme Panel as a Laboratory Developed Test (LDT); however, it now plans to build or buy its own laboratory rather than to do so through a partnership. While this is expected to delay the intended launch of the test beyond the third quarter of 2024, the Company believes this strategy will be in the best long-term interest of its stockholders as it is expected to ultimately result in higher profit margins, give the Company complete control of its Lyme business, and also provide the potential to use the Lyme laboratory for other tests developed by the Company.

While the Company plans to launch the T2Lyme Panel as an LDT, it intends to submit a 510(k) premarket notification to the FDA and, it will expect to receive a prioritized FDA review given the T2Lyme Panel previously received FDA Breakthrough Device designation.

Candida auris

According to the World Health Organization, *Candida auris* is a multidrug-resistant pathogen labeled as a growing threat to public health. A 2023 Wall Street Journal report described *Candida auris* as a "deadly fungus spreading across the U.S., mostly in healthcare facilities," with a mortality rate of up to 60%. According to the CDC, *Candida auris* is difficult to identify with standard laboratory methods, which can lead to inappropriate treatment, and some strains are resistant to all three available classes of antifungal therapies.

To address this global threat, the Company intends to expand its direct-from-blood T2Candida Panel to include the detection of *Candida auris*. The FDA-cleared T2Candida Panel currently covers approximately 90% of *Candida* species commonly found in bloodstream infections. The addition of *Candida auris* should provide important coverage for infections caused by this pathogen which are becoming increasingly more prevalent.

T2 Biosystems previously collaborated with the CDC to complete feasibility and early development of a diagnostic test to detect *Candida auris*, and the Company believes it is possible to receive non-dilutive funding to complete the development, validation, and clinical studies. The FDA previously granted the T2 *Candida auris* test Breakthrough Device designation, so the Company is having interactive dialog with the FDA and expects to receive a prioritized review upon submission of a 510(k) premarket notification to the FDA.

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.

Forward-Looking Statements

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reduce cost, and improve patient outcome; the likelihood that the Company will receive non-dilutive funding to complete the development, validation, and clinical studies for the addition of *Candida auris* to the T2Candida Panel, 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 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.

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