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): March 18, 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 March 18, 2024, the Company issued a press release announcing the publication of a new study highlighting the clinical benefits and performance of real-world use of the T2Resistance® Panel in *The Journal of Clinical Microbiology*. 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 March 18, 2024, the Company announced the publication of a new study highlighting the clinical benefits and performance of real-world use of the T2Resistance Panel in The Journal of Clinical Microbiology.

Highlights from the two-center prospective trial of 59 patients, intended to determine the clinical sensitivity, time to detection and the performance of T2Resistance as compared to blood culture and conventional microbiological methods, include:

- High Accuracy: The T2Resistance Panel demonstrated 94.7% clinical sensitivity and 97.4% specificity (adjudicated).
- Rapid Turnaround Time: The T2Resistance Panel results were available in 4.4 hours compared to 58.3 hours with blood culture-based methods.
- Clinical Impact: Across 59 patients in the study, there were 49 clinical interventions, resulting in 17 antibiotic escalations and 32 discontinuations of unnecessary antibiotics.

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 growing dataset will be a catalyst for increased adoption in countries that accept the CE Mark where the T2Resistance Panel is currently available and the international clinical experience

with direct-from-blood detection of resistance genes will be an important precursor to our launch in the U.S. market, 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, 2022, filed with the U.S. Securities and Exchange Commission, or SEC, on March 31, 2023, 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 March 18, 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: March 18, 2024

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

T2 Biosystems Announces New Publication Highlighting the Clinical Benefits and Performance of the T2Resistance Panel

Study demonstrates T2Resistance Panel utilization enables faster targeted therapy based on direct-from-blood detection of resistance genes

LEXINGTON, Mass., March 18, 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 the publication of a new study highlighting the clinical benefits and performance of real-world use of the T2Resistance® Panel in The *Journal of Clinical Microbiology*. The European study demonstrated high accuracy for the T2Resistance Panel, faster detection times, and the impact of faster test results on clinical interventions based on T2 sepsis test results.

"This publication is the strongest demonstration to date of the clinical impact the T2Resistance Panel in a real-world hospital setting," said John Sperzel, Chairman and CEO of T2 Biosystems. "We believe the growing dataset will be a catalyst for increased adoption in countries that accept the CE Mark where the T2Resistance Panel is currently available. We also believe the international clinical experience with direct-from-blood detection of resistance genes is an important precursor to our launch in the U.S. market, where we have already received Breakthrough Device designation from the U.S. Food and Drug Administration (FDA), and plan to submit a 510(k) premarket notification to the FDA later this year."

Highlights from the two-center prospective trial of 59 patients, intended to determine the clinical sensitivity, time to detection and the performance of T2Resistance as compared to blood culture and conventional microbiological methods, include:

- High Accuracy: The T2Resistance Panel demonstrated 94.7% clinical sensitivity and 97.4% specificity (adjudicated).
- Rapid Turnaround Time: The T2Resistance Panel results were available in 4.4 hours compared to 58.3 hours with blood culture-based methods.
- Clinical Impact: Across 59 patients in the study, there were 49 clinical interventions, resulting in 17 antibiotic escalations and 32 discontinuations of unnecessary antibiotics.

The publication, *A prospective observational pilot study of the T2Resistance panel in the T2Dx system for detection of resistance genes in bacterial bloodstream infections* Walsh et al., noted in summary, "T2R (T2Resistance) markers were highly sensitive for the detection of drug resistance genes in patients with bacterial BSIs (Blood Stream Infections), when compared with standard molecular resistance detection systems and phenotypic identification assays while significantly reducing by approximately 90% the time to detection of resistance compared to standard methodology and impacting clinical decisions for antimicrobial therapy."

About the T2Resistance Panel

The T2Resistance Panel, which runs on T2 Biosystems' FDA-cleared T2Dx® Instrument, is a direct-from-blood test panel that detects 13 antibiotic resistance genes from both Gram-positive and Gram-negative bacterial pathogens (KPC, OXA-48, CTX-M-14/15, AmpC (CMY/DHA), NDM/IMP/VIM, mecA/C, vanA/B) in 3-5 hours without the need to wait for blood culture. The T2Resistance® Panel is commercially available in Europe under a CE mark and was granted "Breakthrough Device" designation from the FDA, which provides for a prioritized FDA review process.

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 include the T2Dx® Instrument, the T2Bacteria® Panel, the T2Candida® Panel, the T2Resistance® Panel, and the T2Biothreat™ Panel, and are powered by the proprietary T2 Magnetic Resonance (T2MR®) technology. T2 Biosystems has an active pipeline of future products, including the U.S. T2Resistance Panel, the *Candida auris* test, and the T2Lyme™ Panel. 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 the likelihood that the growing dataset will be a catalyst for increased adoption in countries that accept the CE Mark where the T2Resistance Panel is currently available and the international clinical experience with direct-from-blood detection of resistance genes will be an important precursor to our launch in the U.S. market, 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, 2022, filed with the U.S. Securities and Exchange Commission, or SEC, on March 31, 2023, 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.

Investor Contact:
Philip Trip Taylor, Gilmartin Group
ir@T2Biosystems.com
415-937-5406