

**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):
October 24, 2023**

T2 BIOSYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36571
(Commission
File Number)

20-4827488
(I.R.S. Employer
Identification Number)

101 Hartwell Avenue, Lexington, Massachusetts 02421
(Address of principal executive offices and 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 October 24, 2023, the Company issued a press release announcing the results of four new studies supporting the T2Bacteria® Panel, the T2Candida® Panel and the T2Resistance® Panel that were recently presented at the IDWeek conference in Boston, Massachusetts.

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 October 24, 2023, the Company reported the following four new studies supporting the T2Bacteria® Panel, the T2Candida® Panel and the T2Resistance® Panel that were recently presented at the IDWeek conference in Boston, Massachusetts.

Acting on Results: How Culture Independent Diagnostics Impact Patient Care and Stewardship

Audry Hawkins, PharmD, BCIDP, University of Louisville (UofL) Health System and Navaneeth Narayanan, PharmD, MPH, BCIDP, Robert Wood Johnson Hospital

Speakers reviewed the implementation of T2Bacteria and T2Candida, clinical impacts and case studies:

- Reviewed patient selection criteria for T2Bacteria at UofL Health System and shared 3 clinical cases where T2Bacteria facilitated faster optimization of antimicrobial therapy and provided clarity in the setting of negative cultures in highly antimicrobial experienced patients.
- Reviewed T2Candida patient criteria and algorithms for responding to T2Candida results at Robert Wood Johnson Hospital and shared 2 clinical cases where T2Candida facilitated appropriate source evaluation and control in a critically ill patient in the setting of a positive result and facilitated de-escalation of antifungals in the setting of a negative result.

Candidemia: Role of T2Candida® compared to Bact/Alert Virtuo blood culture system in a real-world setting

Birk NK et al., Henry Ford Hospital

The poster presentation found that T2Candida continues to outperform at detecting candidemia blood culture even as blood culture monitoring technology advances.

- Retrospective study comparing all patients with T2Candida and blood culture results collected from January 2018 to January 2019 (VersaTREK; n=522) and March 2019 to March 2020 (Virtuo; n=348) comparing the positivity rate of T2Candida and the two respective blood culture monitoring systems. Positivity rates were significantly higher with T2Candida (8.6%) compared to blood culture (2.7%) in the VersaTREK cohort, $p < 0.001$. Positivity rates were significantly higher with T2Candida (9.8%) compared to blood culture (2.3%) in the Virtuo cohort, $p < 0.001$.

Predictors of 30-Day Mortality Among Critically Ill Patients with Candidemia Identified by T2Candida Panel

Caniff KE et al., Anti-infective Research Laboratory/Wayne State University

Poster on retrospective, multi-center study evaluating predictors of 30-day mortality in patients with known T2Candida positive results including the following conclusions:

- “Empiric antifungal administration and ID consultation are modifiable risk factors that were independently associated with reduced odds of 30-day mortality in patients with candidemia identified by T2Candida Panel, highlighting their importance in clinical management”
- “Real-world use of the T2Candida Panel allowed for rapid identification of candidemia and prompt initiation of definitive therapy”

Rapid Detection of Antibiotic Resistance Genes Direct from Whole Blood Samples by T2 Magnetic Resonance (T2MR®)

Wang J et al., T2Biosystems

T2 Biosystems authored poster on analytical studies evaluating the limit of detection, analytical reactivity/inclusivity, interfering substances, and analytical specificity/exclusivity of the T2Resistance Panel.

- Limit of detection for all 13 genes was < 20 CFU/mL (ranging from 3-18 CFU/mL).
- The panel has broad inclusivity of resistance gene variants, no observed interfering substances from those tested, and no observed cross-reactivity with other species or resistance markers.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued October 24, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report on Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding the detection capabilities of the Company's T2Dx Instrument and sepsis test panels, the clinical and economic benefits of the Company's technology, and the real world performance and benefits of the Company's sepsis products, 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. The preliminary, estimated financial results for the third quarter contained in this Current Report on Form 8-K contain forward-looking statements and are subject to the completion of management's and the audit committee's final reviews and our other financial closing procedures and are therefore subject to change. You should not place undue reliance on such preliminary information and estimates because they may prove to be materially inaccurate. The preliminary information and estimates have not been compiled or examined by our independent auditors and they are subject to revision as we prepare our financial statements for the quarter ended September 30, 2023, including all disclosures required by U.S. generally accepted accounting principles, and as our auditors conduct their audit of these financial statements. While we believe that such preliminary information and estimates are based on reasonable assumptions, actual results may vary, and such variations may be material.

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 Commission on March 31, 2023 and other filings the company makes with Commission 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 Current Report on Form 8-K. 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 on Form 8-K.

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: October 25, 2023

T2 BIOSYSTEMS, INC.

By: /s/ John Sprague

Name: John Sprague

Title: Chief Financial Officer



T2 Biosystems Highlights New Clinical Data Presented at IDWeek 2023 Conference

Data demonstrates speed, accuracy, and clinical benefits of the T2Dx Instrument and T2 Biosystems' sepsis panels, including encouraging early detection data for T2Resistance Panel

LEXINGTON, Mass., October 24, 2023 (GLOBE NEWSWIRE)—T2 Biosystems, Inc. (NASDAQ:TTOO), a leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes, today highlighted four new studies supporting the T2Bacteria® Panel, the T2Candida® Panel and the T2Resistance® Panel that were recently presented at the IDWeek conference in Boston, Massachusetts. The data demonstrates the speed, accuracy and clinical benefits of the T2Dx® Instrument and T2 Biosystems' sepsis panels and early analytical data on the T2Resistance Panel.

“We are encouraged by our latest clinical results as they showcase the critical detection capabilities of both our instrument and sepsis test panels. Adding to our clinical data library and increasing awareness of the clinical and economic benefits of our technology is an important part of our commercial strategy,” said John Sperzel, Chairman and CEO of T2 Biosystems. “In addition, we appreciate the strong display of support from our customers as they continue to highlight real world performance and benefits of our sepsis products in their sepsis patient management.”

Data Highlights

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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, the T2Biothreat™ Panel, and the T2SARS-CoV-2™ Panel and are powered by the proprietary T2 Magnetic Resonance (T2MR®) technology. T2 Biosystems has an active pipeline of future products, including the *Acinetobacter baumannii* test, the *Candida auris* test, and the T2Lyme™ Panel, as well as next-generation products for the detection of bacterial and fungal pathogens and associated antimicrobial resistance markers. For more information, please visit www.t2biosystems.com.

Forward-Looking Statements

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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:

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