# 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 14, 2022**

# 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 7.01 Regulation FD Disclosure.**

On October 14, 2022, the Company issued a press release announcing the publication of three new, peer-reviewed studies. 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 9.01 Financial Statements and Exhibits**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release issued October 14, 2022 |
| 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: October 14, 2022

**T2 BIOSYSTEMS, INC.**

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

**Exhibit 99.1**

**T2 Biosystems Highlights Multiple New Studies Demonstrating Improved Rapid Detection Across Several Patient Populations**

*Studies demonstrate that T2Bacteria and T2Candida panels enable sensitive and specific diagnosis to enhance the standard of care*

LEXINGTON, Mass., October 14, 2022 (GLOBE NEWSWIRE)—T2 Biosystems, Inc. (NASDAQ:TTOO), a leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes, announced today the publication of three new, peer-reviewed studies that demonstrate the clinical value of the use of the T2 Biosystems' products, also referred to as T2 Magnetic Resonance Technology (T2MR®). T2 Biosystems' sepsis products are CE marked, and include the only FDA cleared products able to quickly and accurately detect sepsis-causing pathogens within adult patient blood samples without the need to wait hours for a positive blood culture. The studies were conducted in Europe and published in the *Journal of Clinical Microbiology*, *Microbiology Spectrum* and the *Journal of Fungi.*

"We are pleased with the growing number of publications with clinical evidence supporting the value proposition of our sepsis panels. Given the mounting evidence of additional clinical utility, we are exploring expansion of product claims through future regulatory submissions," stated John Sperzel, Chairman and CEO of T2 Biosystems. "The growing awareness of the benefits of our technology can help T2 Biosystems positively impact the lives of more patients, advance the standard of care, and drive continued product adoption."

**Study Highlights**

**Combining T2Bacteria and T2Candida Panels for Diagnosing Intra-Abdominal Infections: A Prospective Multicenter Study (2022)**

**Authors:** Anders Krifors, Måns Ullberg, Markus Castegren, Johan Petersson, Ernesto Sparrelid, Volkan Özenci and Ola Blennow

**Journal:** *Journal of Fungi 2022*, 8, 832

A study conducted at the Karolinska University Hospital in Stockholm, Sweden, that combined T2Bacteria and T2Candida to diagnose Intra-Abdominal Infection (IAI) in surgical patients admitted to the ICU or high dependency unit found:

- Ability to detect more infections: T2Bacteria and T2Candida detected more clinically confirmed cases of IAI than blood culture.
- Faster Targeted Therapy: 15% of blood culture negative and T2Bacteria positive cases were receiving inappropriate antimicrobial therapy at the time of sampling.
- Fast and accurate detections: T2Bacteria and T2Candida were fast and accurate in diagnosing on-panel bloodstream infections and were able to detect culture-negative IAI and intra-abdominal candidiasis (IAC).

**Effective Rapid Diagnosis of Bacterial and Fungal Bloodstream Infections by T2 Magnetic Resonance Technology in the Pediatric Population (2022)**

**Authors**: B. Lucignano, V. Cento, M. Agosta, F. Ambrogi, S. Albitar-Nehme, L. Mancinelli, G. Mattana, M. Onori, F. Galaverna, L. Di Chiara, T. Fragasso, R. Bianchi, F. Tortora, C. Auriti, A. Dotta, C. Cecchetti, S. Perdichizzi, M. Raponi, A. Onetti Muda, S. Nerini Molteni, A. Villani, F. Locatelli, C. Federico Perno, P. Bernaschia

**Journal:** *American Society for Microbiology, Journal of Clinical Microbiology*

A 754 patient retrospective research study conducted at the Bambino Gesù hospital in Rome, Italy, that analyzed the diagnosis of bacterial and fungal bloodstream infections in the pediatric population found:

- Faster Targeted Therapy: Patients suspected of bacterial or fungal bloodstream infections that were tested with T2Bacteria or T2Candida received targeted therapy 61.3 hours or 121.8 hours faster compared to blood culture, respectively.
- Higher Detection Rate: T2Bacteria and T2Candida detected 79 additional probable or possible bacterial bloodstream infections and 6 additional probable or possible fungal bloodstream infections in pediatric patients that were missed by blood culture.

**Rapid Detection of Bacterial and Fungal Pathogens Using the T2MR versus Blood Culture in Patients with Severe COVID-19 (2022)**

**Authors:** Tamara Seitz, Johannes Holbik, Julian Hind, Georg Gibas, Mario Karolyi, Erich Pawelka, Marianna Traugott, Christoph Wenisch, Alexander Zoufalya

**Journal:** *Microbiology Spectrum*

A study conducted at the Klink Favoriten hospital in Vienna, Austria, reported several highlights regarding usage of T2 Biosystems' products to detect COVID-19 superinfections in ICU patients.

- Faster Targeted Therapy: the median time to therapy change with T2 panels was more than 52 hours faster compared to blood culture. The authors noted "without the additional use of T2MR, 13.3% of candidemia and 10% of bacterial superinfections would have been missed."
- Faster Time to Detection: Positive results for COVID-19 with T2Bacteria were available in 4.3 hours, compared to a mean time of 41.5 hours for the standard of care. Positive results for COVID-19 with T2Candida were available in 5 hours compared to a mean time of 85.6 hours for the standard of care. A negative result for T2MR was available in 4.7 hours compared to a mean time of 177.3 hours for the standard of care.
- Sensitivity and Specificity: T2 Biosystems' products detected 100% of species on the panel.
- Impact on Infections: T2 Panel targets covered and detected 71.4% of all pathogens causing infection.

**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, T2Bacteria® Panel, T2Candida® Panel, T2Resistance® Panel, and T2SARS-CoV-2™ Panel and are powered by the Company's proprietary T2 Magnetic Resonance (T2MR®) technology. T2 Biosystems has an active pipeline of future products, including the T2Cauris™ Panel, T2Lyme™ Panel, as well as additional products for the detection of bacterial and fungal pathogens and associated antimicrobial resistance markers, and biothreat pathogens. 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 value proposition of T2 Biosystems' products, the benefits of T2 Biosystems' technology, or the impact that growing awareness of the technology can have on the lives of patients, the standard of care, and product adoption, 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, 2021, filed with the U.S. Securities and Exchange Commission, or SEC, on March 23, 2022, 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.

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