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): December 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 December 9, 2024, T2 Biosystems, Inc. (the "Company") issued a press release announcing its plans to license its proprietary technology to expand its leadership in direct-from-whole-blood detection of sepsis-causing pathogens. 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 December 9, 2024, the Company announced that it plans to license its proprietary technology to expand its leadership in direct-from-whole-blood detection of sepsis-causing pathogens.

The Company's expanded business model is intended to generate non-dilutive capital through licensing agreements that provide access to the Company's patented direct-from-whole-blood technology, create a new royalty revenue stream, and accelerate the broad adoption of direct-from-whole-blood diagnostics to detect sepsis-causing pathogens and antibiotic resistance. The Company's FDA-cleared products are powered by its proprietary sample processing and Magnetic Resonance (T2MR®) detection. Through its research and development efforts, T2 Biosystems has determined that its patented sample processing may be adapted to other detection methods, including fluorescence, potentially enabling other diagnostic platforms to also detect sepsis-causing pathogens and antibiotic resistance directly-from-whole-blood.

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 he Company's ability integrate its direct-from-whole-blood capabilities into other companies'

commercially available instruments; its ability to generate non-dilutive capital, create a royalty revenue stream, and accelerate the widespread adoption of blood culture-independent diagnostics, 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 December 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: December 9, 2024

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

T2 Biosystems Announces Plans to License its Proprietary Technology to Expand its Leadership in Direct-From-Whole-Blood Detection of Sepsis-Causing Pathogens

Intends to accelerate broad adoption of direct-from-whole-blood diagnostics, generate non-dilutive capital, and create a new royalty revenue stream

LEXINGTON, Mass., December 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 announced plans to license its proprietary technology to expand its leadership in direct-from-whole-blood detection of sepsis-causing pathogens. T2 Biosystems' proprietary technology is a key component of its FDA-cleared products, including the first and only products able to detect sepsis-causing pathogens directly from whole blood.

T2 Biosystems' expanded business model is intended to generate non-dilutive capital through licensing agreements that provide access to the Company's patented direct-from-whole-blood technology, create a new royalty revenue stream, and accelerate the broad adoption of direct-from-whole-blood diagnostics to detect sepsis-causing pathogens and antibiotic resistance. The Company's FDA-cleared products are powered by its proprietary sample processing and Magnetic Resonance (T2MR®) detection. Through its research and development efforts, T2 Biosystems has determined that its patented sample processing may be adapted to other detection methods, including fluorescence, potentially enabling other diagnostic platforms to also detect sepsis-causing pathogens and antibiotic resistance directly-from-whole-blood.

"We believe our proprietary technology is a valuable asset and that by licensing our intellectual property to allow other diagnostic firms to integrate our direct-from-whole-blood capabilities into their commercially available instruments, we can generate non-dilutive capital, create a royalty revenue stream, and enable widespread market access to accelerate the broad adoption of blood culture-independent diagnostics," stated John Sperzel, Chairman and CEO at T2 Biosystems. "This new strategy further leverages our robust patent portfolio and scientific expertise to accelerate our mission to improve patient outcomes, lower mortality rates, and reduce healthcare cost by enabling clinicians to make faster, targeted antimicrobial decisions."

In September 2024, T2 Biosystems succeeded in defending against the opposition of a key patent that covers the Company's novel sample preparation method, which is a key part its proprietary direct-from-whole-blood pathogen detection method. The opposition was filed with the European Patent Office (EPO) by bioMerieux and a strawman representing another multibillion-dollar global diagnostics company against one of T2 Biosystems' previously granted European patents, which covers a novel method for amplifying a target nucleic acid characteristic of a pathogen in a whole blood sample.

T2 Biosystems intellectual property was used to develop the T2Dx® Instrument, the T2Bacteria® Panel, and the T2Candida® Panel, which are the first and only FDA-cleared diagnostics able to detect sepsis-causing bacterial and fungal pathogens directly-from-whole-blood, in just 3-5 hours, without the need to wait days for a positive blood culture. The Company has developed significant clinical data to support its direct-from-whole-blood value proposition, built an installed base of nearly 200 instruments, established a number of influential key reference accounts, built relationships with key opinion leaders who advocate for our products and technology, and recently entered into an exclusive U.S. commercial agreement with Cardinal Health (NYSE: CAH). The Company has achieved record sepsis test growth in 2024, and additional revenue streams will allow continued focus on core priorities of accelerating sepsis test sales on the T2Dx Instrument and reducing operational costs. Accordingly, the Company believes now is the optimal time to license its proprietary technology to accelerate broad adoption of direct-from-whole-blood detection of sepsis-causing pathogens and antibiotic resistance.

The Company's competitors that market FDA-cleared products to detect sepsis-causing pathogens and antibiotic resistance are currently dependent on positive blood culture results. When these firms market that their products provide species identification results in 1-3 hours, or antibiotic susceptibility results in 7 hours, it is important to understand that these turnaround times are only after waiting 1-5 days for a positive blood culture. Further, if blood culture produces false negative results due to poor sensitivity, these blood culture-dependent diagnostics provide little to no value. The potential to add direct-from-whole-blood detection to other diagnostic platforms may provide a more comprehensive sepsis solution to hospitals and their patients.

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

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 Company's ability integrate its direct-from-whole-blood capabilities into other companies' commercially available instruments; its ability to generate non-dilutive capital, create a royalty revenue stream, and accelerate the widespread adoption of blood culture-independent diagnostics; and all other 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.

Investor Contact:

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