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):
January 7, 2025

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)	(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 2.02 Results of Operations and Financial Condition

On January 7, 2025, the Company issued a press release announcing its financial results for its fiscal quarter and full year ended December 31, 2024. A copy of the Company's press release is furnished with this report as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 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. Furthermore, such information, including Exhibit 99.1 attached hereto, shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly stated by specific reference in such a filing.

Item 8.01 Other Events

Preliminary Results

On January 7, 2025, the Company reported the following preliminary unaudited fourth quarter and full year 2024 financial and operational results:

- Achieved record product revenues of $2.3 million for the fourth quarter of 2024 and $8.3 million for the full-year 2024, representing increases of 37% and 23% respectively, compared to the prior year period, driven by record sepsis test sales.
- Executed contracts for 27 T2Dx® Instruments in 2024, including 23 T2Dx Instruments for outside the U.S. and 4 T2Dx Instruments for the U.S.
- Entered into a multi-year exclusive U.S. agreement with Cardinal Health (NYSE: CAH), granting Cardinal exclusive rights to sell the T2Dx Instrument, the T2Bacteria Panel, and the T2Candida® Panel, the only FDA-cleared products able to detect sepsis-causing pathogens directly-from-blood.
- Announced co-marketing collaboration with Prxcision, to market the Company's rapid direct-from-blood diagnostics with Prxcision's real-time AI-powered decision support platform to combat the escalating crisis of antibiotic resistance.
- Expanded international distribution network to include the Netherlands, Belgium, Qatar, Vietnam, Malaysia, and Indonesia, and re-entered Switzerland.
- Extended multi-year capital equipment supplier agreement with Vizient, Inc., the largest member-driven health care performance improvement company in the US, through March 31, 2026.

- Converted $30 million of the Company's term loan with entities affiliated with CRG Servicing, LLC ("CRG") into T2 Biosystems' common stock, reducing the Company's debt and quarterly interest payments by approximately 80% over the past year.
- Cash and cash equivalents were $1.7 million as of December 31, 2024.
- Received FDA 510(k) clearance to expand the pathogen detection capabilities of the FDA-cleared T2Bacteria® Panel to add detection of Acinetobacter baumannii.
- Received FDA 510(k) clearance to expand the use of the FDA-cleared T2Candida® Panel to include pediatric testing.
- Advanced the T2Resistance Panel toward U.S. FDA 510(k) submission, expected to occur during the first quarter of 2025.
- Successfully defended against an opposition filed against a key patent for its direct-from-whole blood detection method in the European Union
- 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*.
- Announced plans to license the Company's proprietary technology to expand its leadership in direct-from-whole-blood detection of sepsis-causing bacterial and fungal pathogens.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued January 7, 2025
104.1	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 Company's revenue results, financial outlook, product demand, commitments or opportunities, and growth expectations or targets, 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 fourth quarter and full year 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 financial information and estimates included herein have not been reviewed or examined by our independent auditors and they are subject to revision as we prepare our financial statements as of and for the quarter and full year ended December 31, 2024, including all disclosures required by U.S. generally accepted accounting principles. 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 heading "Risk Factors" in the company's Annual Report on Form 10-K for the year ended December 31, 2023 and Quarterly Report on Form 10-Q for the period ended September 30, 2024, 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: January 7, 2025

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

T2 Biosystems Announces Preliminary Fourth Quarter and Full Year 2024 Financial Results

Achieved record fourth quarter and full-year 2024 sepsis product revenues

LEXINGTON, Mass., January 7, 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 preliminary unaudited financial and operational results for the fourth quarter and full year ended December 31, 2024.

Full Year 2024 and Recent Commercial Highlights (unaudited)

- Achieved record product revenues of $2.3 million for the fourth quarter of 2024 and $8.3 million for the full-year 2024, representing increases of 37% and 23% respectively, compared to the prior year period, driven by record sepsis test sales.
- Executed contracts for 27 T2Dx® Instruments in 2024, including 23 T2Dx Instruments for outside the U.S. and 4 T2Dx Instruments for the U.S.
- Entered into a multi-year exclusive U.S. agreement with Cardinal Health (NYSE: CAH), granting Cardinal exclusive rights to sell the T2Dx Instrument, the T2Bacteria Panel, and the T2Candida® Panel, the only FDA-cleared products able to detect sepsis-causing pathogens directly-from-blood.
- Announced co-marketing collaboration with Prxcision, to market the Company's rapid direct-from-blood diagnostics with Prxcision's real-time AI-powered decision support platform to combat the escalating crisis of antibiotic resistance.
- Expanded international distribution network to include the Netherlands, Belgium, Qatar, Vietnam, Malaysia, and Indonesia, and re-entered Switzerland.
- Extended multi-year capital equipment supplier agreement with Vizient, Inc., the largest member-driven health care performance improvement company in the US, through March 31, 2026.
- Converted $30 million of the Company's term loan with entities affiliated with CRG Servicing, LLC ("CRG") into T2 Biosystems' common stock, reducing the Company's debt and quarterly interest payments by approximately 80% over the past year.
- Cash and cash equivalents were $1.7 million as of December 31, 2024.

Full Year 2024 and Recent Pipeline and Clinical Highlights

- Received FDA 510(k) clearance to expand the pathogen detection capabilities of the FDA-cleared T2Bacteria® Panel to add detection of *Acinetobacter baumannii*.
- Received FDA 510(k) clearance to expand the use of the FDA-cleared T2Candida® Panel to include pediatric testing.
- Advanced the T2Resistance Panel toward U.S. FDA 510(k) submission, expected to occur during the first quarter of 2025.
- Successfully defended against an opposition filed against a key patent for its direct-from-whole blood detection method in the European Union
- 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*.

"We made considerable progress across the business during 2024, increasing our global installed base of T2Dx Instruments, and generating record sales for our sepsis test panels, including record U.S. sales of the T2Bacteria Panel and record international sales of the T2Resistance Panel. We entered into an exclusive U.S. commercial distribution agreement with Cardinal Health during the fourth quarter which we expect to be a

commercial growth driver, and we are training Cardinal's sales team the week of January 6, 2025," stated John Sperzel, Chairman and CEO of T2 Biosystems. "We are excited by the progress on our product pipeline in 2024, which included FDA 510(k) clearances for the expanded T2Bacteria Panel to include the detection of *Acinetobacter baumannii*, and the expanded claim for the T2Candida Panel to include pediatric testing. Additionally, we have three pipeline products that have received FDA Breakthrough Device designation, including the U.S. T2Resistance Panel, the T2Lyme Panel, and the *Candida auris* test. We believe we are well-positioned heading into 2025, and we expect to accelerate our product sales, enhance our operations, and continue to advance our new product pipeline."

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, the likelihood that the exclusive U.S. commercial distribution agreement with Cardinal Health will be a commercial growth driver, and our ability to accelerate product sales, enhance our operations, and continue to advance our new product pipeline, as well as statements that include the words "expect," "may," "should," "anticipate," and similar statements of a future or forward-looking nature. The preliminary, estimated financial results for the fourth quarter and fiscal year ended 2024 contained in this press release 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. The preliminary financial information and estimates included herein have not been examined or reviewed by our independent auditors and they are subject to revision as we prepare our financial statements as of and for the quarter and fiscal year ended December 31, 2024, including all disclosures required by U.S. generally accepted accounting principles. You should not place undue reliance on such preliminary information and estimates because they may prove to be materially inaccurate. 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 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:
Philip Trip Taylor, Gilmartin Group
ir@T2Biosystems.com
415-937-5406