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 7, 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)**	**(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 October 7, 2024, the Company issued a press release announcing its financial results for its fiscal quarter ended September 30, 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 October 7, 2024, the Company reported the following preliminary unaudited third quarter 2024 financial and operational results:

- Achieved third quarter total revenue of $2.0 million, representing an increase of 35% compared to the prior year period, driven by increased sepsis test revenue and instrument revenue.
- Achieved sepsis test panel revenue of $1.6 million, representing an increase of 42% compared to the prior year period, driven by increased T2Bacteria® Panel revenue in the U.S.
- Executed contracts for 11 T2Dx® Instruments during the third quarter, including 1 in the U.S. and 10 internationally.
- Expanded international distribution network by entering into an exclusive distribution agreement covering Malaysia and Indonesia.
- Received clearance from the U.S. Food and Drug Administration (FDA) to market the T2Candida® Panel for pediatric patients.
- Advanced the T2Resistance® Panel toward U.S. FDA 510(k) submission which is expected to occur during the fourth quarter of 2024.
- Defended successfully against an opposition of a key patent for the Company's innovative direct-from-blood pathogen detection method filed with the European Patent Office by bioMerieux.

Cardinal Distribution Agreement

On October 1, 2024, the Company entered into a Distribution Agreement, or the Distribution Agreement, with Cardinal Health 200, LLC, or Cardinal, appointing Cardinal as the exclusive distributor for certain company products in the United States and it territories. Under the Distribution Agreement, Cardinal will have exclusive rights to sell the Company's FDA-cleared direct-from-blood diagnostics for the rapid detection of sepsis-causing pathogens, including the T2Dx Instrument, the T2Bacteria Panel, and the T2Candida Panel. The Distribution Agreement has an initial term of three years and is subject to automatic renewal unless terminated earlier by the parties.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued October 7, 2024
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 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 as of and for the quarter ended September 30, 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 June 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: October 7, 2024

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

T2 Biosystems Announces Preliminary Third Quarter 2024 Financial Results

Achieved 35% increase in total revenue compared to prior year period

LEXINGTON, Mass., October 7, 2024 (GLOBE NEWSWIRE)—T2 Biosystems, Inc. (NASDAQ: TTOO), a leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes, today announced preliminary unaudited financial and operational results for the third quarter 2024.

Recent Financial and Operational Highlights (unaudited)

- Achieved third quarter total revenue of $2.0 million, representing an increase of 35% compared to the prior year period, driven by increased sepsis test revenue and instrument revenue.
- Achieved sepsis test panel revenue of $1.6 million, representing an increase of 42% compared to the prior year period, driven by increased T2Bacteria® Panel revenue in the U.S.
- Executed contracts for 11 T2Dx® Instruments during the third quarter, including 1 in the U.S. and 10 internationally.
- Expanded international distribution network by entering into an exclusive distribution agreement covering Malaysia and Indonesia.

Recent Pipeline and Clinical Highlights

- Received clearance from the U.S. Food and Drug Administration (FDA) to market the T2Candida® Panel for pediatric patients.
- Advanced the T2Resistance® Panel toward U.S. FDA 510(k) submission which is expected to occur during the fourth quarter of 2024.
- Defended successfully against an opposition of a key patent for the Company's innovative direct-from-blood pathogen detection method filed with the European Patent Office by bioMerieux.
- The article "Changing the Culture of Blood Culture" recently published in *The Lancet*, a world-leading medical journal, highlighted the weaknesses of blood culture, and the ideal characteristics of culture-independent diagnostics consistent with the features and benefits provided by the T2Bacteria Panel, the T2Candida Panel, and the T2Resistance Panel.

"During the third quarter, our team delivered total revenue growth of 35% compared to the prior year period, which included more than a 200% increase in sales of the T2Bacteria Panel in the U.S., and more than a 75% increase in sales of the T2Dx Instrument in international markets," stated John Sperzel, Chairman and CEO of T2 Biosystems. "In addition, we successfully defended a key European patent that protects our direct-from-blood detection methods, we received FDA-clearance to market and sell the T2Candida Panel for pediatrics, and we advanced the T2Resistance Panel toward FDA submission which we expect to occur during the fourth quarter of 2024."

2024 Financial Outlook

The Company now expects fourth quarter 2024 total sepsis product revenue of $2.5 million to $3.5 million, representing growth of 49% to 109%, compared to the fourth quarter of 2023. The Company's 2024 revenue guidance consists entirely of sepsis product revenue and does not include potential sales of the T2Biothreat Panel or the T2Lyme Panel.

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 about global commercial expansion and international strategy, and the potential for strong growth in the region, 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) continue to operate as a going concern and raise additional debt or equity financing necessary to fund working capital, make capital expenditures and service our debt, (b) realize anticipated benefits from commitments, contracts or products; (c) successfully execute strategic priorities; (d) bring products to market; (e) expand product usage or adoption; (f) obtain customer testimonials; (g) accurately predict growth assumptions; (h) realize anticipated revenues; (i) incur expected levels of operating expenses; or (j) 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