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 10, 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 2.02 Results of Operations and Financial Condition

On October 10, 2024, the Company held a conference call to discuss its new product development pipeline progress and financial results for its fiscal quarter ended September 30, 2024. A copy of the transcript of the conference call 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.

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 our growth opportunities as a result of the receipt of FDA 510(k) clearance for the T2Candida® Panel to include pediatric testing and development for the T2Resistance Panel, financial results and cash balance, financial outlook, instrument contracts, timing of completing clinical trials and filing of an FDA submission, product demand, commitments or opportunities, and growth expectations or targets 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 contained in this current report on Form 8-K 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 June 30, 2024, including all disclosures required by U.S. generally accepted accounting principles. While we believe that such information and estimates are based on reasonable assumptions, actual results may vary, and such variations may be material. You should not place undue reliance on such preliminary information and estimates because they may prove to be materially inaccurate. 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, 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 on Form 8-K. Any such forward-looking statements represent management's estimates as of the date of 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.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Transcript of conference call held on October 10, 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.

T2 BIOSYSTEMS, INC.

Date: October 16, 2024

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

Trip Taylor, IR

Thank you, operator. I would like to remind everyone that comments made by management today and answers to questions will include forward-looking statements. Those include statements related to T2 Biosystems' future financial and operating results and plans for developing and marketing new products.

Forward-looking statements are based on estimates and assumptions as of today and are subject to risks and uncertainties that may cause actual results to differ materially from those expressed or implied by these statements, including the risks and uncertainties described in T2 Biosystems' annual report on Form 10-K filed with the SEC on April 1, 2024, and other filings the company makes with the SEC from time to time. The company undertakes no obligation to publicly update or revise any forward-looking statements, except as required by law.

With that, I would like to turn the call over to Chairman and CEO, John Sperzel. John?

John Sperzel, CEO

Thank you for joining our investor call. The purpose of today's call is to discuss a number of recent developments that we believe can be transformative for T2 Biosystems. In advance of this call, we solicited questions from investors and we have incorporated our responses to those questions in today's script. While I will focus my comments on our core sepsis business, I will also address two additional business opportunities: bioterrorism and Lyme disease.

LET'S START WITH A BRIEF DESCRIPTION OF SEPSIS AND AN OVERVIEW OF OUR SEPSIS PORTFOLIO.

Sepsis is the body's overwhelming and often life-threatening response to infection that can lead to tissue damage, organ failure, and death. Sepsis is the leading cause of death in U.S. hospitals, claiming the lives of approximately 350,000 Americans annually. Sepsis

also represents the leading cost of U.S. hospitalization, costing our healthcare system an estimated $62 billion annually. Lastly, sepsis is the leading cause of 30-day hospital readmission in the U.S., with 19% of sepsis survivors re-hospitalized within 30 days and 40% within 90 days. To address the human and economic toll associated with sepsis, T2 Biosystems is commercializing the FDA-cleared T2Dx® Instrument and three sepsis test panels: the T2Bacteria® Panel, the T2Candida® Panel, and the T2Resistance® Panel.

The T2Bacteria Panel is the only FDA-cleared diagnostic test able to detect sepsis-causing bacterial species directly-from-blood, in just 3-5 hours. The T2Bacteria Panel simultaneously detects six bacterial species with 90% sensitivity and 98% specificity, including, *E. faecium*, *S. aureus*, *K. pneumoniae, A. baumannii, P. aeruginosa, and E. coli.* The six species detected by the T2Bacteria Panel account for nearly 75% of all bacterial bloodstream infections in the U.S.

The T2Candida Panel is the only FDA-cleared diagnostic test able to detect sepsis-causing *Candida* species directly-from-blood, in just 3-5 hours. The T2Candida Panel detects five *Candida* species with 91% sensitivity and 99% specificity, including, *C. albicans*, *C. tropicalis*, *C. parapsilosis*, *C. krusei*, and *C. glabrata*. According to the U.S. Centers for Disease Control and Prevention, or CDC, the five species detected by the T2Candida Panel account for up to 95% of all *Candida* bloodstream infections in the U.S.

The T2Resistance Panel is a CE-marked diagnostic test able to detect antibiotic resistance genes directly-from-blood, in just 3-5 hours. The T2Resistance Panel simultaneously detects thirteen antibiotic resistance genes from both Gram-positive and Gram-negative bacterial pathogens. The T2Resistance Panel is currently marketed and sold in Europe under a CE-mark and has received FDA Breakthrough Device designation which will provide for a prioritized 510(k) review process. We expect to submit the T2Resistance Panel to the FDA during the fourth quarter of 2024.

Our competitors claim that their products can detect sepsis-causing pathogens or antimicrobial resistance in 1.5 to 3 hours; however, and this is important, that is after they wait 1-5 days for a positive blood culture. A September 20, 2024, article which appeared in The Lancet, a world-leading medical journal, titled "Changing the Culture of Blood Culture" described the weaknesses of blood culture, including poor sensitivity (i.e., missed infections), slow time to result (i.e., typically 2-3 days); vulnerability to contamination; reduced effectiveness in patients who have received antibiotics; and a labor-intensive process requiring skilled technicians.

Accordingly, our ability to detect sepsis-causing pathogens and antibiotic resistance genes direct-from-blood, without first requiring a positive blood culture, is a significant competitive advantage. We have a broad intellectual property portfolio that protects our proprietary direct-from-blood detection method. In fact, last week, we announced that we had successfully defended against an opposition filed against a key patent in our direct-from-blood detection method in the European Union. The opposition was filed by two of the world's largest diagnostics companies, one of which was bioMerieux, a leader in blood culture-based diagnostics. On September 19, 2024, the European Patent Office ruled that T2 Biosystems' intellectual property position on direct-from-blood pathogen detection was maintained and we think this is very important in protecting our competitive advantage in this space.

LET'S MOVE TO THE EXCLUSIVE U.S. AGREEMENT WITH CARDINAL HEALTH.

On our last earnings call, I mentioned that we had been exploring a range of strategic alternatives to accelerate the growth of our business, and that we were in negotiations with a multibillion-dollar healthcare company regarding a potential U.S. commercial partnership. On October 7, 2024, we announced that we had entered into a multi-year exclusive U.S. agreement with Cardinal Health. Under the agreement, Cardinal Health has exclusive rights to sell the T2Dx Instrument, the T2Bacteria Panel, and the T2Candida Panel in the United States.

Who is Cardinal Health?

Cardinal Health is a distributor of pharmaceuticals, a global manufacturer and distributor of medical and laboratory products, and a provider of performance and data solutions for healthcare facilities. Cardinal Health trades on the New York Stock Exchange under the symbol CAH, has annual revenue of more than $200 billion, has operations in more than 30 countries, and has approximately 48,000 employees.

How does an exclusive U.S. agreement with Cardinal Health help T2 Biosystems?

We believe our agreement with Cardinal Health will be transformative, with the objectives of accelerated revenue growth and a faster path to profitability by expanding our access to the more than 6,000 U.S. hospitals. We expect the exclusive nature of the agreement to align interests and motivate Cardinal's commercial team.

Cardinal Health is one of the largest healthcare companies in the U.S. that sells to 90% of U.S. hospitals through its extensive commercial organization and holds contracts with a large number of GPOs. We expect this collaboration to greatly expand our access to the U.S. hospital market as Cardinal Health has significant commercial and distribution infrastructure, including capital equipment specialists who will sell the T2Dx Instrument.

What are the terms of the exclusive U.S. agreement with Cardinal Health?

The terms of the agreement with Cardinal Health are confidential but I able to provide some color on the agreement. The economics and logistics are similar to the terms we have with our international distributors. For example, T2 Biosystems will sell our FDA-cleared products to Cardinal Health — including the T2Dx Instrument, the T2Bacteria Panel, and the T2Candida Panel – and Cardinal Health will sell the products to U.S. hospitals.

What can this exclusive agreement do for Cardinal Health?

The agreement gives Cardinal Health exclusive rights to the only FDA-cleared direct-from-blood pathogen detection products. In addition to the economic benefits, having access to T2 Biosystems' sepsis products strengthens Cardinal Health's product offering to microbiology laboratories.

LET'S MOVE TO THE COLLABORATION WITH PRXCISION, INC.

We believe that Artificial Intelligence, or AI, will have an important and increasing role in healthcare delivery, and specifically in the management of patients at risk of sepsis. AI can be used to diagnose diseases, develop personalized treatment plans, and assist clinicians with decision-making. We have been searching for an AI-powered decision support platform to combine with our rapid direct-from-blood pathogen detection products.

On October 8, 2024, we announced a co-marketing collaboration with Prxcision, Inc. with the goal of pioneering a new frontier in antibiotic stewardship to combat the growing threat of antimicrobial resistance.

Antibiotic resistance is one of the greatest threats facing modern medicine, with millions of lives at risk. Over 1.27 million deaths are reported annually due to antimicrobial resistance, or AMR, which threatens to render essential antibiotics useless. The stakes are high, and time is critical—each hour of delayed targeted treatment can increase the risk of death by up to 8% for sepsis patients.

Who is Prxcision?

Prxcision, Inc. is a NY-based private company that is leveraging two decades of expertise in antibiotic development to create a real-time, AI-powered decision support platform. The product, pRxcision, is integrated with electronic health records (like EPIC and Cerner), and provides clinicians with ranked, evidence-based antibiotic regimens tailored to each patient's needs. This approach can potentially stop antibiotic misuse, break the cycle of antibiotic resistance, reduce healthcare costs, and ultimately save lives. I encourage you to watch a presentation and demo of the pRxcision platform at www.prxcision.com/demo

How does the pRxcision Platform Work?

The pRxcision platform is designed to leverage data from diagnostics, such as our T2Dx, to provide another level of precision—using advanced pharmacokinetic models, pathogen profiles, and real-time patient data to enable clinicians to prescribe the right drug, dose, and duration as the patient's condition evolves. The platform adapts continuously to changing clinical information, providing ranked, evidence-based treatment regimens that help clinicians optimize care and improve outcomes.

How does a collaboration with Prxcision, Inc. help T2 Biosystems?

By combining our direct-from-blood diagnostics with the AI-driven pRxcision platform, we believe we can empower clinicians with the information to stop infections in their tracks, faster than ever before. Beyond improving patient care, this collaboration is intended to drive product adoption and create exciting opportunities for growth in a rapidly evolving market. With speed and accuracy at its core, we believe the combined solution can provide hospitals with a powerful tool to improve outcomes and reduce costs. By offering real-time insights and targeted treatment information, T2 Biosystems and Prxcision, Inc. aim to reduce the burden of AMR, helping healthcare systems across the U.S. take a proactive stance against one of the top global public health threats.

LET'S MOVE TO THE FDA 510(k) CLEARANCE FOR T2CANDIDA PEDIATRICS.

On September 16, 2024, we announced that we had received clearance from the U.S. Food and Drug Administration to market the FDA-cleared T2Candida Panel for the detection of sepsis causing fungal pathogens in pediatric patients. This FDA clearance marks another important milestone in our commitment to expand the clinical utility of our sepsis test panels and allows our commercial team to immediately begin marketing and selling our test to over 200 U.S. children's hospitals, a significant expansion of our total addressable market.

Studies show that the T2Candida Panel detects *Candida* species significantly faster, and with greater sensitivity, when compared to blood culture-based diagnostics, and we believe the new pediatric testing claim will allow clinicians to improve outcomes and reduce cost by achieving faster targeted antifungal treatment for their pediatric patients.

According to the *Journal of Fungi*, a peer-reviewed scientific journal that provides an advanced forum for studies related to pathogenic fungi, *Candida* species are a major contributor to morbidity and mortality in hospitalized children. Moreover, children with

invasive candidiasis present a significant burden to the U.S. healthcare system, with a mean increased hospital length of stay of 21 days and approximately $92,000 in excess hospital costs.

A *Journal of Clinical Microbiology* (2022) study conducted at the Bambino Gesù hospital in Rome, Italy found that pediatric patients suspected of fungal bloodstream infections that were tested with the T2Candida Panel received species identification results 121.8 hours faster compared to blood culture.

LET'S MOVE TO THE PLAN TO COMMERCIALIZE THE T2LYME PANEL

Consistent with the September 9, 2024, update on our new product development pipeline, we maintain our plan to launch the T2Lyme Panel as a Laboratory Developed Test (LDT), and we anticipate launching our T2Lyme Panel by the start of the 2025 tick season. Rather than pursue a partnership for the LDT launch, the Company has decided to build or buy its own laboratory.

The Company believes this strategy will be in the best long-term interest of its stockholders as it is expected to result in higher profit margins, give the Company complete control of its Lyme business, and also provide the potential to use the Lyme laboratory for other tests developed by the Company.

According to the CDC, Lyme disease is the leading vector-borne disease in the U.S., with an estimated 3.4 million tests performed each year at a cost of nearly $500 million. The current diagnostic process is a two-tiered antibody test algorithm that relies on the presence of antibodies, and which is only accurate four to eight weeks after infection. During those weeks, the bacteria may spread throughout the body and become much harder to eradicate and treat effectively, and may lead to chronic, debilitating disease.

LET'S MOVE TO THE PLAN TO COMMERCIALIZE THE U.S. T2RESISTANCE PANEL

The Company plans to submit a 510(k) premarket notification to the FDA during the fourth quarter of 2024 and expects to receive a prioritized FDA review given the T2Resistance Panel previously received FDA Breakthrough Device designation.

According to the CDC, antimicrobial resistance is an urgent global public health threat. To address the threat caused by AMR, the Company has developed the T2Resistance Panel, a direct-from-blood molecular diagnostic test that runs on the FDA-cleared T2Dx® Instrument and simultaneously detects 13 antibiotic resistance genes, in just 3-5 hours, without the need to wait days for a positive blood culture.

In March 2024, the results of a new study were published in *Journal of Clinical Microbiology* highlighting the benefits of the T2Resistance Panel compared to blood culture and standard microbiology methods, including high accuracy (i.e., 94.7% sensitivity, 97.4% specificity), rapid turnaround time (i.e., results available is 4.4 hours vs. 58.3 hours), and clinical impact (i.e., clinical interventions in 41% of patients in the study, or 24 of 59 patients).

LET'S MOVE TO THE PLAN TO COMMERCIALIZE THE T2BIOTHREAT PANEL

The T2Biothreat Panel is an FDA-cleared direct-from-blood molecular diagnostic test that runs on the T2Dx Instrument and simultaneously detects six biothreat pathogens, including the organisms that cause anthrax, tularemia, glanders, melioidosis, plague, and typhus.

These six pathogens have been identified as threats by the CDC and, if not treated promptly, can have mortality rates of 40-90%. Our clinical evaluation of the T2Biothreat Panel demonstrated positive percent agreement, or sensitivity, of 100% for all targets except *Francisella tularensis*, which was 94.3%, and negative percent agreement, or specificity, of 100% for all six targets.

The National Biodefense Strategy and Implementation Plan includes an objective to "enhance preparedness to save lives through development, testing, evaluation, manufacturing, regulatory approval, distribution, and administration of countermeasures." The T2Biothreat Panel was designed for this purpose, in collaboration with the U.S. Government, or BARDA, and we expect it to play a role in our nation's effort to counter biological threats.

There are two references to the T2Biothreat Panel in the Assistant Secretary for Preparedness and Response, or ASPR's FY2025 budget justification document, which covers the period of October 1, 2024 through September 30, 2025. The first is in Building a Robust and Formidable Medical Countermeasure Development Pipeline and includes the statement: "In partnership with industry, BARDA has built a robust pipeline of medical countermeasures, or MCMs, in advanced development…" and lists the T2Biothreat Panel for multi-target biothreat testing. The second is in Biodosimetry and Diagnostics and includes the statement: "Also in FY 2023, the first BARDA supported Biothreat test panel (a test which targets multiple biothreat agents simultaneously) was cleared by the FDA from T2 Biosystems. These efforts are part of BARDA's successes in preparation for potential future biothreat outbreaks."

The T2Biothreat Panel detects unique biothreat pathogens and we believe it provides unparalleled sensitivity and specificity, creating multiple potential sales opportunities which we are pursuing, including to CDC's U.S. Laboratory Response Network, ASPR's U.S. Strategic National Stockpile, U.S. state and public health laboratories, other U.S. government agencies, and international government allies.

Finally, we are very pleased to inform you that our U.S. Government lobbying efforts have resulted in the following language being included in the 2025 Senate Appropriations Bill, "Rapid Detection of Bioterrorism Agents.—The Committee is concerned that the Nation is not prepared to rapidly detect biological agents, such as anthrax, tularemia, melioidosis, glanders, and plague, even though BARDA has successfully supported development of diagnostic technologies that detect such biothreats, in some cases simultaneously. The Committee strongly urges ASPR to prioritize partnerships with domestic manufacturers capable of producing rapid diagnostics that can detect such threats and develop a diagnostic testing preparedness plan for use during public health emergencies, disasters, and other serious public health threats."

LET'S MOVE TO OUR THIRD QUARTER 2024 PRELIMINARY UNAUDITED RESULTS

- We 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.
- We achieved sepsis test panel revenue of $1.6 million, representing an increase of 42% compared to the prior year period, driven by greater than a 200% increase in T2Bacteria Panel revenue in the U.S.
- We executed contracts for 11 T2Dx Instruments during the third quarter, including 1 in the U.S. and 10 internationally.
- We expanded our international distribution network by entering into an exclusive distribution agreement covering Malaysia and Indonesia.
- We received FDA clearance to market the T2Candida Panel for pediatric patients.
- We advanced the T2Resistance Panel toward U.S. FDA 510(k) submission which is expected to occur during the fourth quarter of 2024.
- We 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.
- We highlighted the article "Changing the Culture of Blood Culture" recently published in *The Lancet*, a world-leading medical journal, which highlighted the weaknesses of blood culture, and the ideal characteristics of culture-independent diagnostics that are consistent with the features and benefits provided by the T2Dx Instrument, the T2Bacteria Panel, the T2Candida Panel, and the T2Resistance Panel.

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. . This represents full year 2024 revenue of $8.5 to 9.5 million and growth of 18% to 32%. 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.

FINALLY, OUR CLOSING REMARKS

We are extremely pleased with the developments, including the exclusive U.S. agreement with Cardinal Health and the collaboration with Prxcision. We believe these have the potential to transform our business and positively impact patient care.

Operationally, we continue to grow our core sepsis revenue, evidenced by the 35% growth achieved in the third quarter of 2024, compared to the prior year period. We are also pleased by the progress in our pipeline, including the recent T2Candida Panel FDA-clearance for pediatric patients and the advancements toward a fourth quarter 2024 FDA submission for the T2Resistance Panel.

We continue to evaluate all strategic alternatives and regularly have discussions on this topic with potential partners. We look forward to speaking in early November, when we plan to issue our audited third quarter 2024 financial and operational results and hold our earnings call.

Operator, we can now open the call for additional questions from analysts.