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 12, 2023

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 12, 2023, the Company issued a press release announcing its financial results for its fiscal quarter ended September 30, 2023, and held a conference call to discuss those results. 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. 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 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Transcript of conference call held on October 12, 2023
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 17, 2023

T2 BIOSYSTEMS, INC.

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 March 31, 2023, 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 all for joining our third quarter 2023 results and business update call. Today, I will start by discussing our market opportunity and performance during the third quarter – including both the progress we have made across our three corporate priorities and updated financial outlook for the remainder of 2023. I will then address the press release that we issued earlier today, before providing closing remarks and opening the call for questions and answers.

Our mission at T2 Biosystems is to fundamentally change the way medicine is practiced through transformative culture-independent diagnostics that improve the lives of patients around the world. We are applying our patented technology in three areas: sepsis, bioterrorism, and Lyme disease. These three markets also share a common need that we will discuss during today's call – that is the need for rapid detection and targeted treatment. Importantly, we believe these markets, collectively, represent a multi-billion dollar opportunity.

Sepsis continues to exact an enormous human and economic toll. Sepsis is the number one cause of death in U.S. hospitals, claiming the lives of 270,000 Americans annually, plus another 80,000 who die in hospice each year. Sepsis is the number one cost of U.S. hospitalization, costing our healthcare system an estimated $62 billion annually. Finally, sepsis is the number one cause of 30-day re-hospitalization in the U.S., causing 19% of sepsis survivors to be re-hospitalized within 30 days, and 40% within 90 days.

T2 Biosystems' products, including the T2Dx Instrument, the T2Bacteria Panel, and the T2Candida Panel, are the only FDA-cleared products able to detect sepsis-causing pathogens directly-from-blood, in just 3-5 hours, without the need to wait days for a positive blood culture. The need for rapid pathogen detection and targeted antimicrobial treatment is critical for patients at risk of sepsis, as data shows that mortality risk increases by up to 8% for each hour of delayed, targeted antimicrobial therapy.

A meta-analysis was completed analyzing 14 controlled studies comparing our sepsis products to blood culture-based products. The results, published in a peer-reviewed medical journal, showed T2 Biosystems' products identified sepsis-causing pathogens 77 hours faster than blood culture-based products, allowed patients to receive targeted antimicrobial therapy 42 hours faster than blood culture-based products, allowed de-escalation of empiric antimicrobial therapy 7 hours faster than blood culture-based products, and allowed patients to leave the ICU or hospital 5 days faster than blood culture-based products.

We believe the comparative advantages offered by our products, over blood culture-based products, are the key to improving patient outcomes, reducing cost, and addressing the global threat of antimicrobial resistance.

The T2 Biosystems team achieved a number of important milestones during the third quarter of 2023, which we believe have better positioned the company for near and long-term success. We received FDA 510(k) clearance for the T2Biothreat Panel; we received FDA Breakthrough Device designation for the *Candida auris* test; we filed the FDA 510(k) submission for the expanded T2Bacteria Panel; we converted 20% of our debt to equity; we raised additional capital; and we regained compliance with Nasdaq market value of listed securities requirement.

Our preliminary financial results for the third quarter of 2023 include total revenue of $1.5 million, which was comprised entirely of non-COVID product revenue, compared to $3.7 million in the prior year period. The decline was primarily due to a $1.0 million reduction in BARDA revenue, a $0.4 million sepsis test backorder, a $0.3 million reduction in international T2Dx Instrument sales, and a $0.3 million reduction in COVID-19 test sales. The sepsis test backorder directly impacted T2Dx Instrument and sepsis test demand during the third quarter and led to performance below our expectations. I'll discuss the actions we took, and progress made to address the backorder during our operations update; however, I am pleased to report that as of today we have already resolved the majority of the backorder that existed as of September 30th.

We expect fourth quarter 2023 sepsis and related product revenue of $2.4 million, representing a sequential quarterly increase of 60%, compared to the third quarter of 2023. As a result of the sepsis test backorder, we expect total 2023 sepsis and related product revenue of $7.5 million, representing a decline of 10% compared to 2022. As we have previously disclosed, there will be no revenue from BARDA in the fourth quarter of 2023.

We are very pleased with the recent progress in strengthening our balance sheet. As of September 30, 2023, cash and cash equivalents totaled $24.3 million, including proceeds raised through our ATM facility during the quarter. We reduced our debt and quarterly interest payments by converting $10 million, or approximately 20%, of the CRG term loan to equity. We also implemented operating expense reductions at the end of the second quarter, and headcount reductions throughout the first half of the year which we have held at under 100 full-time employees.

As we advance our mission, we remain focused on three corporate priorities, 1) accelerating our sales, 2) enhancing our operations, and 3) advancing our pipeline. We will discuss each of these priorities in more detail.

Starting with our first priority – accelerating our sales. Commercially, we are focused on expanding the installed base of T2Dx Instruments and increasing sepsis test utilization in existing and new hospital accounts. In the third quarter, we executed contracts for 5 T2Dx Instruments, including 2 in the U.S. and 3 outside the U.S. We achieved total revenue of $1.5 million, comprised entirely of sepsis and related product revenue. Sepsis test panel revenue was $1.1 million, and we ended the quarter with a $380,000 backorder, demonstrating continued demand for our products.

Our commercial team is targeting new hospital accounts, while working with existing accounts to increase their sepsis testing volumes. We have integrated the sales, medical affairs, and service teams to educate and align key stakeholders on broader sepsis testing protocols. Annualized U.S. sepsis test utilization during the third quarter was $108,000 per instrument, which was impacted by the sepsis test backorder. We believe our integrated commercial approach and clearing a substantial portion of the backorder can drive deeper penetration within each account over the near-term. In a number of hospital accounts, annualized utilization is well above the $200,000 goal we expect to achieve over time across our U.S. installed base.

As a testament to our commercial team’s strong efforts in increasing education and identifying use cases, our customers have continuously demonstrated their support by presenting case studies highlighting the benefits of our products at industry conferences. During the September Sepsis Alliance Summit, Butler Hospital presented on the critical need our products fill in accelerating pathogen identification time, enabling a rapid diagnosis with independent species identification. As we discussed on the previous call,

Butler Hospital has developed a protocol to trigger the use of the T2Bacteria Panel and have shown that the T2Bacteria Panel allowed for targeted therapy as much as 37 hours faster than blood culture-based methods. At the upcoming IDWeek conference in Boston on October 13, hospital experiences with T2Candida and T2Bacteria will be presented by infectious disease pharmacists from the University of Louisville Health System and Robert Wood Johnson University Hospital. Creating additional reference accounts like these hospital users is an important part of our commercial strategy. We are grateful for our strong customer support as they spread more awareness around our instrument's clinical and economic benefits.

We continue to add to our clinical data library and this past quarter have been conducting studies to advance the capability to test in new ways. As a reminder, we announced a clinical collaboration with Vanderbilt University Medical Center during the second quarter to implement and evaluate our FDA-cleared T2Dx Instrument and T2Bacteria Panel in a clinical setting. Included in the clinical collaboration is a prospective study that will assess the capability of the T2Bacteria Panel to improve clinical interventions and antibiotic usage for patients with a bloodstream infection. The T2Dx Instrument has been installed at Vanderbilt, the IRB has been approved, and patient enrollment is expected to begin next month. We look forward to discussing future updates on this collaboration and clinical evidence, once available.

Bolstering our efforts is the increasing awareness of sepsis as a public health emergency. In September, we promoted Sepsis Awareness Month. September is recognized as a month to reflect upon the fact that sepsis takes a life every 90 seconds in the United States. Thomas Heymann, CEO of Sepsis Alliance, stated, "Sepsis is a public health crisis that no one is talking about." We appreciate the work Sepsis Alliance is doing to raise awareness and educate people regarding sepsis. We commend Massachusetts Governor, Maura Healey, for recognizing the patient impact of sepsis and for issuing a proclamation to recognize September as Sepsis Awareness Month in Massachusetts. We also applaud the U.S. Centers for Disease Control and Prevention, or CDC, for taking action to streamline U.S. hospital sepsis program guidelines through their Hospital Sepsis

Program Core Elements. The program is designed to help hospitals to implement, monitor and optimize sepsis programs through seven elements: Hospital Leadership Commitment, Accountability, Multi-Professional Expertise, Action, Tracking, Reporting, and Education. By establishing these core elements, they aim to improve upon old, disjointed processes that have failed patients and created a massive burden for our healthcare system.

It is extremely encouraging to have these additional stakeholders prioritizing awareness and calling for action to combat the public health threat of sepsis. Our message is being amplified by these external voices and we expect this to stimulate additional conversations with potential customers and advance current dialogues. It is clear that significant change is required for how we manage patients suspected of sepsis. We are confident the growing public recognition can be a catalyst for positive change and that adoption of our sepsis products in U.S. hospitals will advance the standard of care.

Following the FDA approval of the T2Biothreat Panel, we immediately shifted our focus with this product toward commercialization. We believe there are multiple opportunities to sell the T2Biothreat Panel, including to the U.S. Laboratory Response Network, state or public health labs, the U.S. Strategic National Stockpile, other government agencies (e.g., CDC, NIH, DoD), and international governments that are U.S. allies.

Given the ongoing wars in Europe and the Middle East, we believe the global population is at an increased risk of exposure to bioterrorism. We are proud to have developed a test to protect Americans from the consequences of deliberate or naturally occurring outbreaks of certain biothreat pathogens.

Moving to our second priority – enhancing our operations. On our last call, we discussed numerous steps we have taken to enhance our operations, including our cost structure, balance sheet, supply chain, and manufacturing.

Since our last call and the close of the third quarter, we have made significant progress addressing our manufacturing processes aimed at resolving the sepsis test panel backorder. At the end of the third quarter, the sepsis test panel backorder was $380,000. I am pleased to report that we cleared the majority of the backorder in early October, we expect to clear the remainder of it this quarter, and we expect to finish 2023 with zero backorder.

The backorder was caused by a number of factors, including raw materials, personnel changes, processes, and equipment. We attribute the recent manufacturing improvements to the key measures we have previously implemented, including hiring a new Vice President of Operations, advanced procurement of raw materials, process improvements, and investments in equipment. The demand for our sepsis test panels within the U.S. and international markets remains strong.

Moving to our third priority – advancing our pipeline. Our new product development priorities have targeted three areas: sepsis, bioterrorism, and Lyme disease. These represent areas of significant unmet medical need in which rapid detection can lead to faster targeted antimicrobial treatment and improved patient outcomes.

We have been advancing five new products intended to expand the test menu on our FDA-cleared T2Dx Instrument and drive increased adoption, including: the T2Biothreat Panel, the addition of *Acinetobacter baumannii* to our FDA-cleared T2Bacteria Panel, the T2Resistance Panel, the T2Lyme™ Panel, and a *Candida auris* test. Each new test panel, or test, represents a differentiated solution to rapidly identify harmful pathogens and potentially allow clinicians to achieve faster, targeted antimicrobial therapy.

The T2Biothreat Panel is a direct-from-blood molecular diagnostic test that runs on the FDA-cleared T2Dx Instrument and simultaneously detects six biothreat pathogens, in 4 hours, including the organisms that cause anthrax, tularemia, glanders, melioidosis, plague, and typhus. If not treated promptly, infections with the pathogens included on the T2Biothreat Panel can result in mortality rates of 40-90%, according to *Medical Aspects of Biological Warfare* and The Center for Food Security and Public Health.

The T2Biothreat Panel clinical evaluation assessed the sensitivity and specificity to detect targets in blood samples containing a range of bacterial concentrations. The positive percent agreement, or sensitivity, for all targets at 1-3 times the limit of detection was 100% for all targets except *Francisella tularensis*, which was 94.3%. The negative percent agreement, or specificity, for all six targets in healthy or febrile blood containing no bacteria was 100%. We believe this represents unparalleled performance.

As expected, we received FDA 510(k) clearance for the T2Biothreat Panel during the third quarter of 2023, which allows us to market and sell the test in the U.S. The FDA 510(k) clearance marks a major milestone in our collaboration with the U.S. Government, specifically BARDA, and our commitment to protect Americans from the consequences of deliberate or naturally occurring outbreaks of these biothreat pathogens.

It is important to note that the T2Biothreat Panel is the first and only FDA-cleared product able to simultaneously detect these six high-priority biothreat pathogens, and the only FDA-cleared multi-target biothreat product developed and manufactured by a U.S. owned company. We believe these facts will be important in discussions regarding purchases of the T2Biothreat Panel, which we intend to sell to commercial markets and governments.

2. The expanded T2Bacteria Panel to include detection of *Acinetobacter baumannii* is a direct-from-blood molecular diagnostic test designed to run on the FDA-cleared T2Dx Instrument and provide results in just 3-5 hours, without the need to wait days for a positive blood culture. Adding *Acinetobacter baumannii* detection to our FDA-cleared T2Bacteria Panel will expand our detection capabilities to approximately 75% of all sepsis-causing bacterial pathogens commonly found in blood culture.

Acinetobacter baumannii can cause bloodstream infections, especially in critically ill patients, which can range from benign transient bacteremia to septic shock, and has been reported to have a crude ICU mortality rate of 34% to 43%. *Acinetobacter* infections rarely occur outside of health care settings in the United States and can disproportionately impact those with weakened immune systems, chronic lung disease, or diabetes. *Acinetobacter baumannii* can be resistant to many antibiotics, including carbapenems, which highlights the importance of rapid detection and targeted antimicrobial treatment.

Today, we issued a press release to announce that we have filed an FDA submission for 510(k) clearance to add *Acinetobacter baumannii* to the T2Bacteria Panel, as scheduled. As a reminder, the CE marked version of the T2Bacteria Panel, which we sell in certain international markets, already includes the detection of *Acinetobacter baumannii*.

3. The T2Resistance Panel is a direct-from-blood molecular diagnostic test run on the FDA-cleared T2Dx Instrument and simultaneously detect 13 antibiotic resistance genes known to cause antibiotic resistant infections, in just 3-5 hours, without the need to wait days for a positive blood culture.

The T2Resistance Panel, which is marketed and sold in Europe under CE mark, detects resistance genes that may confer resistance to common antimicrobials such as carbapenems, methicillin, and vancomycin. We have advanced the U.S. clinical trial, including completing patient enrollment, and we plan to file an FDA submission for 510(k) clearance after completing additional internal testing, including stability testing, which we expect to occur in the first quarter of 2024.

As a reminder, the T2Resistance Panel was granted Breakthrough Device Designation by the FDA, which provides for a prioritized review process upon FDA submission.

4. The T2Lyme™ Panel is a direct-from-blood molecular diagnostic test designed to run on the FDA-cleared T2Dx Instrument and detect Borrelia burgdorferi, the bacteria that is the major cause of Lyme disease in the U.S.

The T2Lyme Panel is intended to test individuals with signs and symptoms of Lyme disease, and aid in the diagnosis of early Lyme disease, and we believe it will provide a significant advantage over the currently recommended serological testing that requires the presence of antibodies, which can take the body two to six weeks to create, post infection.

In 2022, our T2Lyme Panel was named a winner in the Lyme Innovation accelerator, or LymeX, a partnership between the U.S. Department of Health and Human Services and the Steven & Alexandra Cohen Foundation, the largest public-private partnership for Lyme disease that plans to award up to a total of $9 million to future award winners. We have recently received additional interim funding from LymeX and submitted a Phase 2 progress report, which will be evaluated for moving to Phase 3 of the accelerator. We also received FDA Breakthrough Device designation for the T2Lyme Panel, which allows for a prioritized review process upon submission to the FDA.

We have completed the early assay development for the T2Lyme Panel and we established a preliminary level of detection, or LoD, of 2 CFU/mL. We are in discussions regarding the potential to initiate commercialization of the T2Lyme Panel as a Laboratory Developed Test and subsequently plan to commence a U.S. clinical trial to support submission for FDA 510(k) clearance.

5. The *Candida auris* test is a direct-from-blood molecular diagnostic test designed to run on the FDA-cleared T2Dx Instrument and detect *Candida auris* species in just 3-5 hours, without the need to wait days for a positive blood culture.

Candida auris is a multidrug-resistant fungal pathogen that has a mortality rate of up to 60% and is recognized as a serious global health threat by the CDC and the World Health Organization. *Candida auris* is difficult to identify with standard laboratory methods, which can lead to inappropriate treatment. The CDC estimates the costs associated with U.S. fungal diseases, in general, are as high as $48 billion annually, and has called on public health professionals to help lower the burden of fungal disease by continuing to raise awareness of the life-saving benefits of early detection and proper treatment.

As a reminder, we currently market and sell the T2Candida Panel, the only FDA-cleared diagnostic test able to detect sepsis-causing *Candida* pathogens directly from blood, in just 3-5 hours, without the need to wait days for a positive blood culture. The T2Candida Panel runs on the FDA-cleared T2Dx Instrument and simultaneously detects five *Candida* species, including *Candida albicans*, *Candida tropicalis*, *Candida parapsilosis*, *Candida krusei*, and *Candida glabrata*, which causes over 90% of Candida blood infections. Rapid detection of these pathogens, as well as *Candida auris*, is essential to getting infected patients on targeted antifungal therapy and improving patient outcomes.

During the third quarter of 2023, we received FDA Breakthrough Device designation for the *Candida auris* test, which provides greater and more frequent access to the FDA and may accelerate our path to FDA clearance.

Regarding our longer-term product development initiatives, while we met all milestones set forth in the BARDA contract related to the next-generation instrument and comprehensive sepsis panel, or AMR panel, BARDA informed us that our milestone-based product development contract ended on September 15, 2023, upon the expiration of Option 3. Following the recent FDA 510(k) clearance for the T2Biothreat Panel, and the recently-completed patient enrollment for the T2Resistance Panel, BARDA has decided not to fund additional product development under this contract. We may apply for additional BARDA funding under new contract solicitations.

Earlier today, we issued a press release announcing a reverse split of our stock at a 1 to 100 ratio, effective today October 12, 2023, and to begin trading on a split-adjusted basis when the market opens tomorrow October 13, 2023. Proportional adjustments will be made to the number of shares of common stock reserved for issuance under the Company’s equity incentive plans and the number of shares of common stock subject to outstanding warrants, convertible preferred and Series A stock held by CRG Servicing LLC, and equity awards, as well as the applicable share price. The reverse stock split will not affect the number of authorized shares of the Company’s common stock or the par value of the common stock.

As a reminder, Nasdaq Capital Market listing rules require the Company to maintain a market value of listed securities of at least $35 million and a minimum bid price of $1.00. On July 6, 2023, we participated in an appeal hearing with the Nasdaq that led to a formal response approving our appeal and granting an extension to regain compliance until November 20, 2023. As previously reported, we regained compliance with the market value of listed securities requirement on August 7, 2023. While we have seen an increase in our stock price since the July 6th Nasdaq hearing, our stock price has not increased enough to achieve the minimum bid price organically. Therefore, our Board of Directors has decided to affect the reverse stock split to bring the Company into compliance with the minimum bid price and maintain our Nasdaq listing.

We believe it is in the best interest of the Company and our stockholders to maintain our Nasdaq listing for several reasons: 1) to maintain liquidity for the stock, 2) to broaden opportunities for future access to capital, 3) to attract and compensate employees, and 4) to pursue potential mergers and acquisitions.

I also want to clarify how this impacts the actions we have taken to reduce our debt and quarterly interest payments. In July, we announced the conversion of $10 million, or approximately 20%, of our term loan with CRG Servicing LLC, or CRG, into 48,345,798 shares of common stock, which CRG sold during September 2023. Additionally, CRG is entitled to convert its 93,297,259 shares of Series B Convertible Preferred Stock into shares of common stock. As a result of the reverse stock split announced today, the Series B Convertible Preferred stock would convert to 932,973 shares.

In summary, we achieved important milestones across our three corporate priorities during the third quarter of 2023. Commercially, we continue to increase our global T2Dx Instrument installed base, maintain strong demand for our sepsis test panels, raise awareness of the value of our products directly and through Key Opinion Leaders and Clinical Evaluations at prestigious hospitals like Vanderbilt University Medical Center. Operationally, we strengthened our balance sheet and we made significant progress in in our supply chain and manufacturing operations to address the sepsis test backorder. Scientifically, we received FDA 510(k) clearance for the T2Biothreat Panel, received FDA Breakthrough Device designation for the Candida auris test, filed the FDA 510(k) submission to add detection of *Acinetobacter baumannii* to the T2Bacteria Panel, and advanced the T2Resistance Panel toward FDA 510(k) submission.

I’d like to turn the call back over to the operator to open the line for questions. Operator?