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): February 15, 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 February 15, 2024, the Company issued a press release announcing its financial results for its fiscal quarter and full year ended December 31, 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 99.1 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 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Transcript of conference call held on February 15, 2024
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: February 16, 2024

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 fourth quarter and full year 2023 results call. I will start by discussing our plan to comply with the Nasdaq listing requirements, including the proxy and press release we filed this afternoon. I will then review our 2023 progress and 2024 objectives across our three corporate priorities, before turning the call over to John Sprague, our Chief Financial Officer, who will review our financial results and provide our financial outlook for 2024. I will then provide closing remarks and opening the call for questions and answers.

As a reminder, on November 20, 2023, we received a letter from Nasdaq informing us that we had failed to comply with Market Value of Listed Securities, or MVLS, of at least $35 million for a period of 30 consecutive business days. Today, we participated in a meeting with the Nasdaq Listing Qualifications Hearing Panel, and we presented a detailed plan to regain compliance with the $35 million MVLS requirement. We expect a response from Nasdaq in the coming weeks. Our Nasdaq compliance plan includes the following steps:

Step one, which occurred today, and which was previously approved by stockholders, included the conversion of 82,422 shares of Series B Convertible Preferred Stock, held by our lender CRG Servicing LLC, or CRG, into 824,220 shares of T2 Biosystems common stock.

Step two, which also occurred today, included the filing of a preliminary proxy seeking approval at a special meeting of stockholders to be held on April 11, 2024, to allow CRG to convert up to $15 million, or nearly thirty-seven percent, of its term loan into T2 Biosystems common stock. We expect the issuance of common stock and the cancellation of this portion of the term loan to occur within 10 days of the meeting.

Additionally, while not part of our Nasdaq compliance plan, we have numerous business catalysts that we will discuss shortly, which we believe can create value and increase the market value of our listed securities.

We believe maintaining our Nasdaq listing is in the best interest of both the Company and our stockholders, as it maintains liquidity for stockholders, helps attract and retain key employees, broadens our access to capital, and better positions the company for potential mergers and acquisitions. Another benefit of our plan is that we are reducing the Company’s debt burden and thus lowering future interest payment expenses.

Now I will shift gears to discuss our 2023 progress and 2024 objectives across our three corporate priorities: accelerating our sales, enhancing our operations, and advancing our pipeline.

Starting with our first corporate priority — accelerating our sales.

As a reminder, 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 U.S. hospital readmission, causing 19% of sepsis survivors to be re-hospitalized within 30 days and 40% within 90 days. Rapid detection of sepsis-causing pathogens is critical, as mortality risk increases by up to 8% for each hour of delayed, targeted antimicrobial treatment. T2 Biosystems has the only FDA-cleared products able to detect sepsis-causing pathogens directly-from-blood, in 3-5 hours, without the need to wait days for a positive blood culture.

In 2023, the T2 Biosystems team achieved full year total revenue of $7.3 million, including product revenue of $6.7 million, and we achieved record T2Bacteria Panel sales in the U.S. market. We added 26 T2Dx Instruments to our growing installed base, which is now approaching 200 instruments globally, including 19 in international markets and 7 in the U.S. market.

In the fourth quarter of 2023, we achieved sepsis and related product revenue of $1.7 million, representing sequential growth of 13% compared to the third quarter, and sales accelerated each month of the quarter.

Looking forward to 2024, our objectives include continuing to expand our installed base of T2Dx Instruments, in the U.S. and International markets, and increasing test panel revenue. We plan to increase test panel revenue by selling more products to existing customers, by selling to new customers in our existing geographies, and by expanding our international distribution network into new countries.

During 2024, we expect to commercialize four new test panels, or tests, which run on the FDA-cleared T2Dx instrument, including the expanded T2Bacteria Panel, the T2Candida Panel with a pediatric indication, the T2Biothreat Panel, and the T2Lyme Panel. We believe each of these products represents an opportunity to increase test utilization among existing customers and attract new customers.

The expanded T2Bacteria Panel, to include the detection of *Acinetobacter baumannii*, was developed using direct feedback from customers on which bacteria species are most important to identify. We expect this latest FDA clearance to drive increased adoption of our platform, as the expanded test panel now covers nearly 75% of all sepsis-causing bacterial pathogens commonly found in blood stream infections. Rapid detection of these pathogens is essential to getting infected patients on the appropriate antimicrobial therapy and improving clinical outcomes.

We are expecting a positive outcome on our FDA submission to expand the use of the T2Candida Panel to include pediatric testing. We believe an expanded claim for our FDA-cleared T2Candida Panel to include pediatric testing will drive increased adoption of our platform as it opens a new pediatric market segment and will allow clinicians to improve outcomes and reduce cost by achieving faster targeted antifungal treatment for their pediatric patients.

Following the FDA clearance of the T2Biothreat Panel in September 2023, which we developed in collaboration with the U.S. Government, or BARDA, we shifted our focus to commercialization. Given the ongoing wars in Europe and the Middle East, we believe the global population is at an increased risk of exposure to bioterrorism. The T2Biothreat Panel provides unique biothreat targets and we believe it offers unparalleled sensitivity and specificity, creating multiple opportunities for sales, including to the U.S. Laboratory Response Network, the U.S. Strategic National Stockpile, state or public health labs, other government agencies, and international government allies.

Given our advances with the T2Lyme Panel, we intend to commercialize a laboratory developed test version of the T2Lyme panel in 2024. Accordingly, we are exploring potential partners to capitalize on what we believe is a significant opportunity.

Internationally, we sell our products through a network of distributors. During 2024, we expect continued expansion of our international distributor network. Today, we announced that we have expanded distribution into the Netherlands, Belgium, and Vietnam, and we have re-entered the market in Switzerland through one of our existing distributors.

As part of our commercial growth strategy, we have prioritized expanding our clinical evidence. We recently announced our collaboration with the NIH-funded Antibacterial Resistance Leadership Group, or ARLG, to evaluate T2 Biosystems' direct-from-blood diagnostic technology for the detection of ventilator associated pneumonia. Specifically, the FDA-cleared T2Bacteria Panel, and the T2Resistance Panel, will be evaluated for the ability to detect infections in the blood currently missed by conventional methods in a prospective, observational, diagnostic, feasibility study. The study will aid in exploring whether combined diagnostic testing can provide more targeted antimicrobial therapy, strengthen stewardship, and improve outcomes, and we look forward to providing an update once available.

At IDWeek 2023 in October, our team presented new clinical data with encouraging early detection data for the T2Resistance Panel. The poster included data showing rapid detection of antibiotic resistance genes direct from whole blood samples by T2 Magnetic Resonance (T2MR). Oral and poster presentations demonstrating speed, accuracy, and clinical benefits of the T2Dx Instrument and T2 Biosystems' sepsis panels were also presented by customers. Real world performance and use case of our products were highlighted as part of sepsis patient management. We continue to appreciate our customer support aiding in increasing awareness of both the clinical and economic benefits of our technology.

Moving to our second corporate priority — enhancing our operations.

Throughout 2023 we made significant progress enhancing our operations. This included strengthening our operations leadership, mitigating raw material issues, improving manufacturing processes, and addressing the sepsis test panel backorder. I am pleased to announce that we cleared all backorders for the T2Bacteria Panel and the T2Candida Panel in December 2023, and we cleared all backorders for the T2Resistance Panel in January 2024.

During 2023, we made material headcount and operating expense reductions. We strengthened our balance sheet by reducing our debt by $10 million, or approximately 20%, extended the interest-only period and maturity date of our term loan to December 31, 2025, and permanently reduced the minimum cash covenant from $5 million to $500,000.

Looking forward to 2024, as I mentioned earlier, we will further strengthen our balance, following stockholder approval, through the conversion of $15 million, or nearly 37 percent, of our term loan with CRG into T2 Biosystems equity. In addition, we expect to reduce inventory levels to positively impact our balance sheet, reduce scrap to increase efficiency and improve product gross margins, continue to improve on-time delivery of our T2Dx Instruments and sepsis test panels, and complete the Oracle ERP system cutover.

Moving to our third corporate priority — advancing our pipeline.

As a reminder, we are applying our proprietary direct-from-blood technology to three areas — sepsis, bioterrorism, and Lyme disease — which all share a critical need for rapid pathogen detection and targeted antimicrobial treatment. We have made significant advancements across our new product pipeline, which is focused on expanding the test menu on the FDA-cleared T2Dx Instrument. During 2023, we filed three FDA submissions and we have already received two FDA 510(k) clearances.

First, we submitted a 510(k) premarket notification to the FDA for the T2Biothreat Panel, and we announced receipt of FDA 510(k) clearance in September 2023. As a reminder, 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, including the organisms that cause anthrax, tularemia, glanders, melioidosis, plague, and typhus. These 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, for all six targets of 100%.

Second, we submitted a 510(k) premarket notification to the FDA for the expanded T2Bacteria Panel, to include detection of *Acinetobacter baumannii*, and we announced receipt of FDA 510(k) clearance earlier this week. As a reminder, the T2Bacteria Panel is the only FDA-cleared diagnostic test able to detect sepsis-causing bacterial pathogens directly from blood, in just 3-5 hours, without the need to wait days for a positive blood culture. The expanded T2Bacteria Panel now covers approximately 75% of all sepsis causing bacterial pathogens commonly found in blood stream infections, including *E. faecium, S. aureus, K. pneumonia, A. baumannii, P. aeruginosa, and E. coli*.

In a large study of nosocomial bloodstream infections, *A. baumannii* was the tenth most common pathogen and has a crude ICU mortality rate of 34.0% to 43.4%. Due to the emergence of pan-antibiotic resistant *A. baumannii*, the World Health Organization has identified *A. baumannii* as the most critically important bacteria that requires improved prevention and therapeutic approaches. *Acinetobacter* resistance to many antibiotics, including carbapenems, highlights the importance of rapid detection and targeted antimicrobial treatment.

Third, in December 2023, we submitted a 510(k) premarket notification to the FDA to expand the use of the FDA-cleared T2Candida Panel to include pediatric testing. As a reminder, the T2Candida Panel is 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. According to the U.S. Centers for Disease Control and Prevention, or CDC, up to 95% of all invasive *Candida* infections in the U.S. are caused by the five *Candida* species detected by the T2Candida Panel, including *C. albicans*, *C. tropicalis*, *C. parapsilosis*, *C. krusei*, and *C. glabrata*.

Candida species are a major contributor to morbidity and mortality in hospitalized children and present as a significant burden to the U.S. healthcare system with a mean increased hospital length of stay of 21 days, and an estimated $92,000 in excess hospital costs for children with invasive candidiasis. A 2022 *Journal of Clinical Microbiology* 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.

Looking forward to 2024, we expect continued advances in our pipeline. Following my comments on pediatric testing, and as part of our commitment to expand the clinical utility of our sepsis test panels, we expect to receive FDA 510(k) clearance to expand the use of the T2Candida Panel to include pediatric testing. We also plan to submit a 510(k) premarket notification to the FDA to expand the use of the FDA-cleared T2Bacteria Panel to include pediatric testing.

In addition, we have three new tests in our pipeline – including the U.S. T2Resistance Panel, the T2Lyme Panel, and the *Candida auris* test. Each of these new test panels, or tests, is designed to run on our FDA-cleared T2Dx Instrument, and each previously received FDA Breakthrough Device designation, which will provide for a prioritized FDA review upon submission.

The T2Resistance Panel is a direct-from-blood molecular diagnostic test designed to 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. We believe the T2Resistance Panel will be a very important addition to our expanding test menu, as we expect it to be the first direct-from-blood, or culture independent, antimicrobial resistance test, and that can drive increased adoption of our platform. We have completed all external testing in the T2Resistance Panel U.S. clinical trial, we are now focused on internal stability and shelf-life testing, and we expect to submit a 510(k) premarket notification to the FDA in the third quarter of 2024.

The T2Lyme Panel is a direct-from-blood molecular diagnostic test designed to detect *Borrelia burgdorferi*, the bacteria that is the major cause of Lyme disease in the U.S. There is a critical need for new Lyme disease diagnostics. With an estimated 476,000 cases annually, Lyme disease is by far the leading vector-borne disease in America. The current diagnostic process, a two-tiered antibody test algorithm originally developed in 1994 for disease surveillance and not as a stand-alone diagnostic test, relies on the presence of antibodies and can only be used accurately four to six weeks after infection. Early diagnosis of Lyme disease is critical. If left untreated, the debilitating disease can spread throughout the body and become harder to eradicate.

As we announced earlier this month, we have been selected as a Phase 2 winner in the LymeX Diagnostics Prize and will receive $265,000 to help accelerate the development of our T2Lyme Panel for the early detection of Lyme disease. We appreciate the support from the Lyme Innovation Accelerator, or LymeX, from the U.S. Department of Health and Human Services and the Steven & Alexandra Cohen Foundation.

As I mentioned earlier, we are advancing the T2Lyme Panel toward commercialization and plan the initial U.S. launch as a Laboratory Developed Test, or LDT. We are in discussion with potential laboratory partners, and we are also exploring the potential to obtain non-dilutive, grant-based funding to advance the T2Lyme Panel.

The *Candida auris* test is a direct-from-blood molecular diagnostic test designed to detect *Candida auris* species, in just 3-5 hours, without the need to wait days for a positive blood culture. We believe the addition of a *Candida auris* test will strengthen our value proposition and lead to increased adoption of our platform.

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. The CDC estimates the costs associated with U.S. fungal diseases 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.

With that, I will now turn the call over to John Sprague to provide a detailed update of our fourth quarter financial results and our financial outlook for 2024.

John Sprague

Thank you, John.

Fourth quarter 2023 revenues were $1.7 million, all from product sales, a 69% decrease compared to the prior year period, driven by lower international T2Dx Instrument sales and lower sepsis test sales due to production backorders. We resolved the production backorders in January 2024.

Cash and cash equivalents were $15.7 million as of December 31, 2023. In the fourth quarter of 2023 we raised $0.8 million in net proceeds from ATM sales.

In October 2023, CRG extended the Term Loan Agreement interest-only period and maturity date to December 2025 and reduced the minimum cash covenant from $5,000,000 to $500,000.

We expect total sepsis and related product revenues to grow between 49% and 64% to $10.0 million to $11.0 million in 2024 over 2023 and this target excludes any potential sales from our T2Biothreat or T2Lyme Panel panels.

Thank you and back to John Sperzel for the closing remarks.

John Sperzel

We made considerable progress across the business during 2023, increasing our global installed base of T2Dx Instruments, generating record sales of our T2Bacteria Panel, strengthening our supply chain and manufacturing operations, advancing multiple new product development initiatives, and strengthening our balance sheet.

We are very excited by the progress on our new product pipeline, which includes the recent FDA 510(k) clearances for the expanded T2Bacteria Panel, to include the detection of *Acinetobacter baumannii*, the T2Biothreat Panel, and the pending FDA clearance to expand the T2Candida Panel to include pediatric testing. Additionally, three products in our pipeline 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 2024, and we remain focused on accelerating our sales, enhancing our operations, and advancing our pipeline.

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