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):
March 20, 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 7.01. Regulation FD Disclosure.

On March 20, 2024, the Company issued a press release announcing certain business updates and held a conference call to discuss those updates. A copy of the press release and the transcript of the conference call are furnished with this report as Exhibits 99.1 and 99.2.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 and Exhibits 99.1 and 99.2 of this Current Report on Form 8-K are 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 Exhibits 99.1 and 99.2 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

On March 20, 2024, the Company provided an update on the following items:

- Announced plans to commercialize the T2Lyme Panel in the third quarter of 2024 as a laboratory developed test (LDT) without the need to be run on the T2Dx® Instrument providing throughput improvements and cost of goods advantages. The Company is currently in discussions with potential LDT partners and plans to provide early Lyme disease results to U.S. reference laboratories nationwide.
- Announced a new publication in *Journal of Clinical Microbiology* highlighting the clinical benefits and performance of the T2Resistance Panel, including demonstrating high accuracy, faster detection times, and the positive impact of faster test results on clinical interventions.
- Engaged Dr. Robin Robinson as a strategic advisor to aid in commercialization of the T2Biothreat Panel. Dr. Robinson is the former Director of the Biomedical Advanced Research and Development Authority (BARDA) and former Deputy Assistant Secretary for Preparedness and Response (ASPR).
- Received extension from the Nasdaq Hearings Panel to regain compliance with $35 million Market Value of Listed Securities requirement as set forth in Nasdaq Listing Rule 5550(b)(2) on or before May 20, 2024.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued March 20, 2024
99.2	Transcript of conference call held on March 20, 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 likelihood that the T2Lyme Panel will be launched in the third quarter of 2024, the ability of the Company to provide T2Lyme results to U.S. reference laboratories nationwide, the likelihood that the growing dataset for T2Resistance will be a catalyst for increased adoption in countries where the T2Resistance Panel is currently available for purchase, and the likelihood that increasing commercial support and U.S. Government engagement represents a material future growth catalyst as well as statements that include the words "expect," "may," "should," "anticipate," and similar statements of a future or forward-looking nature. 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, 2022, filed with the U.S. Securities and Exchange Commission, or SEC, on March 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.

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: March 20, 2024

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

T2 Biosystems Unveils T2Lyme Launch Plans and Provides Additional Business Updates

Anticipates commercial launch of the T2Lyme Panel in the third quarter of 2024

LEXINGTON, Mass., March 20, 2024 (GLOBE NEWSWIRE)— T2 Biosystems, Inc. (NASDAQ:TTOO) (the "Company"), a leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes, today announced plans for the T2Lyme Panel commercial launch and provided recent business updates.

Recent Highlights

- Announced plans to commercialize the T2Lyme Panel in the third quarter of 2024 as a laboratory developed test (LDT) without the need to be run on the T2Dx® Instrument providing throughput improvements and cost of goods advantages. The Company is currently in discussions with potential LDT partners and plans to provide early Lyme disease results to U.S. reference laboratories nationwide.
- Announced a new publication in *Journal of Clinical Microbiology* highlighting the clinical benefits and performance of the T2Resistance Panel, including demonstrating high accuracy, faster detection times, and the positive impact of faster test results on clinical interventions.
- Engaged Dr. Robin Robinson as a strategic advisor to aid in commercialization of the T2Biothreat Panel. Dr. Robinson is the former Director of the Biomedical Advanced Research and Development Authority (BARDA) and former Deputy Assistant Secretary for Preparedness and Response (ASPR).
- Received extension from the Nasdaq Hearings Panel to regain compliance with $35 million Market Value of Listed Securities requirement as set forth in Nasdaq Listing Rule 5550(b)(2) on or before May 20, 2024.

"Recently, we have made significant progress on our three corporate priorities that we believe positions us for a strong future. Specifically, the anticipated launch of the T2Lyme Panel in the third quarter, new data validating the clinical benefits of the T2Resistance Panel, and increasing commercial support and U.S. Government engagement on the T2Biothreat Panel each represent potential material growth catalysts," stated John Sperzel, Chairman and CEO of T2 Biosystems. "We continue to prioritize our Nasdaq listing and advance the review of strategic alternatives which are both intended to increase shareholder value."

Reiterated 2024 Financial Outlook

The Company continues to expect full year 2024 total sepsis and related product revenue of $10.0 million to $11.0 million, representing growth of 49% to 64%, compared to $6.7 million in 2023. The Company's 2024 revenue guidance consists entirely of sepsis and related product revenue and does not include potential sales of the T2Lyme Panel or the T2Biothreat Panel.

Webcast and Conference Call Information

The Company's management team will host a conference call today, March 20, 2024, beginning at 8:30 am ET. Investors interested in listening to the call may do so by dialing 888-506-0062 for domestic callers or 973-528-0011 for International callers and using conference ID 688651 approximately five minutes prior to the start time. A live and recorded webcast of the call will be available on the "Investors" section of the Company's website at www.t2biosystems.com.

About T2 Biosystems

T2 Biosystems, a leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes, is dedicated to improving patient care and reducing the cost of care by helping clinicians effectively treat patients faster than ever before. T2 Biosystems' products include the T2Dx® Instrument, the T2Bacteria® Panel, the T2Candida® Panel, the T2Resistance® Panel, and the T2Biothreat™ Panel, and are powered by the proprietary T2 Magnetic Resonance (T2MR®) technology. T2 Biosystems has an active pipeline of future products, including the U.S. T2Resistance Panel, the Candida auris test, and the T2Lyme™ Panel. For more information, please visit www.t2biosystems.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding the likelihood that the T2Lyme Panel will be launched in the third quarter of 2024, the ability of the Company to provide T2Lyme results to U.S. reference laboratories nationwide, the likelihood that the growing dataset for T2Resistance will be a catalyst for increased adoption in countries where the T2Resistance Panel is currently available for purchase, and the likelihood that increasing commercial support and U.S. Government engagement represents a material future growth catalyst, 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) 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, 2022, filed with the U.S. Securities and Exchange Commission, or SEC, on March 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 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

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 for joining our investor call. The purpose of today's call is to unveil our launch plan for the T2Lyme Panel and to update our stockholders on our progress across the business, including the T2Biothreat Panel, the T2Resistance Panel, ongoing commercial and strategic discussions, and Nasdaq compliance. After my prepared remarks, we will open the call for questions and answers.

Starting with the T2Lyme Panel and our 2024 Launch Plan.

The T2Lyme Panel is a direct-from-blood molecular diagnostic test designed for the early detection of *Borrelia burgdorferi*, the bacterium that causes Lyme disease in the U.S.

Lyme disease is the leading vector-borne disease in America, with an estimated 3.4 million tests performed each year. The current diagnostic process is a two-tiered antibody test algorithm that relies on the presence of antibodies and can only be used accurately four to eight weeks after infection. If left untreated, the bacteria may spread throughout the body and become much harder to eradicate and treat effectively. Although early symptoms of Lyme disease are similar to the flu, *Borellia burgdorferi* infections can lead to chronic debilitating disease.

To address this critical unmet need, we have developed a highly sensitive diagnostic test for the detection of early Lyme disease, with an analytical sensitivity that is in line with our FDA-cleared sepsis tests. We believe our test will detect Lyme disease within the first 30 days after infection, compared to antibody tests that can take 30-60 days after infection. We are finalizing internal validation and verification, and we expect to be in position for a product launch during the third quarter of 2024.

We plan to launch our T2Lyme Panel as a Laboratory Developed Test, or LDT, and we believe there are numerous potential advantages of launching the T2Lyme Panel in this format, including: 1) faster time to market, 2) higher test throughput, and 3) stronger product contribution margins.

Importantly, in a LDT format, we can run the test without the T2Dx Instrument, which can provide the potential to process hundreds of Lyme tests per day. This is because the individual components of our underlying technology can be leveraged to process a higher volume of samples. Given the LDT format does not require the T2Dx Instrument, or the costs associated with a cartridge, we expect to realize strong product contributions margins. Our market research confirms that reference laboratories often charge greater than $250 for the two-tiered Lyme test, and greater than $250 for PCR Lyme tests.

Our objective is to provide early Lyme disease results to major U.S. reference laboratories. We believe we can utilize their retail networks to collect patient samples, which would allow us to provide testing to Lyme patients across the country. These samples would then be sent to our LDT partner to perform the T2Lyme Panel in their lab. It is important to note that T2Lyme Panel sales are not in our current 2024 revenue guidance, so any potential sales during 2024 represent upside to that guidance.

Moving to the T2Biothreat Panel and our Commercial Progress.

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 MCM 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.

To advance our commercial opportunities for the T2Biothreat Panel, we have entered into an agreement with Dr. Robin Robinson to serve as a strategic advisor. Dr. Robinson has significant experience and expertise leading U.S. Government entities in the areas of medical countermeasures and biodefense, including serving as director of the Biomedical Advanced Research and Development Authority, or BARDA, and the Deputy Assistant Secretary in the Office of the Assistant Secretary for Preparedness and Response, or ASPR, within the U.S. Department of Health and Human Services. We believe Dr. Robinson's vast network across multiple U.S. Government agencies – including CDC, ASPR, BARDA, DoD, and NIH – coupled with his expertise in medical countermeasures and biodefense, will be invaluable as we pursue government contracts to procure the T2Biothreat Panel and protect our nation from the consequences of deliberate of accidental exposure to biothreats.

It is important to note that T2Biothreat Panel sales are not in our current 2024 revenue guidance, so potential sales during 2024 represent upside to that guidance.

Moving to the T2Resistance Panel and our Newly Published Clinical Results.

The T2Resistance Panel is 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. We believe the T2Resistance Panel will be a catalyst to drive broader adoption of our sepsis products.

On Monday, we issued a press release to announce the results of a new study that was published in the *Journal of Clinical Microbiology*, highlighting the performance and clinical benefits of the T2Resistance Panel.

The prospective study included 59 patients at two sites, and intended to determine the clinical sensitivity, time to detection, and clinical impact of the T2Resistance Panel compared to blood culture and conventional microbiology methods. Highlights included:

High Accuracy: The T2Resistance Panel demonstrated clinical sensitivity of 94.7% and specificity of 97.4% (adjudicated). This is consistent with the clinical performance of our two FDA-cleared sepsis panels: the T2Bacteria Panel and the T2Candida Panel.

Rapid Turnaround Time: The T2Resistance Panel results were available on average in 4.4 hours compared to 58.3 hours with blood culture-based methods. The T2Resistance Panel provided a 92% improvement in time to result compared to blood culture-based diagnostics.

Clinical Impact: There were 49 clinical interventions in 24 of the 59 patients, resulting in 17 antibiotic escalations and 32 discontinuations of unnecessary antibiotics. The use of the T2Resistance Panel led to a change in antibiotic therapy for 41% of the patients in this study, as those patients were on the wrong or unnecessary antibiotics. We believe this performance data demonstrates the enormous potential of this unique and highly differentiated product, to reduce cost, improve patient outcomes, and reduce the threat of antibiotic resistance.

These results demonstrate the strongest clinical impact of the T2Resistance Panel to date in a real-world hospital setting. We expect this to be a catalyst for greater adoption of the T2Resistance Panel in countries where we currently market under CE mark. We also believe the international experience with direct-from-blood detection of resistance genes is an important precursor to our launch in the U.S. market. As a reminder, we plan to submit a 510(k) premarket notification to the U.S. Food and Drug Administration, or FDA, during the third quarter of 2024, and we have previously received Breakthrough Device designation from the FDA, which provides for a prioritized FDA review upon submission.

Moving to our Ongoing Commercial and Strategic Discussions.

As previously discussed, we engaged an advisory firm in 2023 to explore all potential strategic alternatives to maximize value, including an acquisition, merger, reverse merger, other business combination, sale of assets, licensing, and other strategic transactions. Over the past 12 months, we have engaged with a number of potential partners and continue to explore potential commercial and/or strategic partnerships.

Moving to our Nasdaq Compliance Plan.

On March 12, 2024, we announced that the Nasdaq Hearings Panel has granted our request for continued listing on the Nasdaq Stock Market, subject to the Company demonstrating compliance with Nasdaq's market value of listed securities ("Market Value") requirement, as set forth in Nasdaq Listing Rule 5550(b)(2) (the "Rule") on or before May 20, 2024.

We continue to prioritize maintaining our Nasdaq listing and consider it to be in the best interest of both the Company and its stockholders, as we believe listing on the Nasdaq Stock Market 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.

The Rule requires that the Company maintain a closing Market Value of at least $35.0 million for a minimum of ten consecutive business days. During the extension period, we will continue to actively monitor our Market Value and take appropriate action, if necessary and as advised by our Board of Directors, to remedy the deficiency.

These actions may include the potential conversion of $15.0 million dollars of outstanding indebtedness held by our, CRG, to equity in the company. Additionally, while not part of our Nasdaq compliance plan, we have numerous potential business catalysts that we believe can create value and increase the market value of our listed securities. There can be no assurance, however, that the company will be able to timely comply with the terms of the Nasdaq Hearings Panel's decision.

In its written decision, the Nasdaq Hearings Panel stated, “The Company has outlined what appears to be a reasonable plan to regain compliance with the Exchange’s listing requirements. It has also described its range of products that appear well poised to gain notable sales in the medical testing space, based on its descriptions of the products’ efficacy. In light of the developments in the Company’s products, the fact that the Company has already executed the conversion agreement with CRG, and the short time period requested to cure its listing deficiency, the Panel believes an exception is appropriate.”

We have given notice of a Special Meeting of stockholders to be held on April 11, 2024 for the following purposes: 1) to vote on the approval of the CRG debt to equity conversion; and 2) to transact such other business as may properly come before the Special Meeting or at any and all adjournments or postponements thereof.

Your vote is important. Whether or not you are able to participate in the Special Meeting online, it is important that your shares be represented. To ensure that your vote is recorded promptly, please vote as soon as possible by submitting your proxy by telephone, via the Internet at the address listed on the proxy card, or by signing, dating, and returning the proxy card, which requires no postage if mailed in the United States.

Summary Remarks

To summarize, we believe the T2Lyme Panel offers potential to significantly increase our revenue and we plan to launch our test for the detection of early Lyme disease as a Laboratory Developed Test, or LDT, in the third quarter of 2024. We continue to advance our discussions with the U.S. Government regarding the use of our T2Biothreat Panel, to protect Americans from the threat of bioterrorism, and we have engaged Dr. Robin Robinson, to accelerate our efforts. We are thrilled with the new data on our T2Resistance Panel, which showed excellent clinical performance, significantly faster time to detection, and the potential to significantly improve antibiotic stewardship. We continue to explore strategic options, and we are in ongoing discussions with a number of firms regarding strategic and/or commercial partnerships. Finally, we received an extension to comply with the Nasdaq Market Value requirement and we are optimistic that the plan will result in the attainment of the listing requirements.

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