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)	(I.R.S. Employer Identification Number)

101 Hartwell Avenue, Lexington, Massachusetts 02421
(Address of principal executive offices and zip code)

(781) 761-4646
(Registrant's telephone number, including area code)

N/A
(Former Name or Former Address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	TTOO	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On October 12, 2023, T2 Biosystems, Inc. (the "***Company***") issued a press release announcing preliminary financial results for its third quarter ended September 30, 2023. A copy of the Company's press release is furnished with this report as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 and Exhibit 99.1 of this Current Report on Form 8-K is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. Furthermore, such information, including Exhibit 99.1 attached hereto, shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly stated by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

On October 12, 2023, the Company issued a press release announcing the submission of a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) to expand the number of pathogens detected on the FDA-cleared T2Bacteria® Panel to include the detection of *Acinetobacter baumannii*.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 and Exhibit 99.2 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.

Item 8.01 Other Events

On October 12, 2023, the Company reported the following preliminary unaudited third quarter 2023 financial and operational results:

- Achieved preliminary third quarter 2023 total revenue of $1.5 million, comprised entirely of product revenue
- Achieved sepsis test panel revenue of $1.1 million
- Executed contracts for 5 T2Dx Instruments during the third quarter, including 2 in the U.S. and 3 internationally

- Completed installation for all seven initial T2Dx® Instruments sold under multi-year contract with a European distributor for T2Dx Instruments and sepsis test panels for Poland
- Converted $10.0 million, or approximately 20%, of term loan debt with CRG Servicing LLC in exchange for shares of T2 Biosystems equity
- Cash and cash equivalents totaled $24.3 million as of September 30, 2023, and the Company raised an additional $21.9 million in net proceeds through ATM sales during the third quarter
- Received FDA 510(k) clearance for the T2Biothreat™ Panel, a direct-from-blood diagnostic test
- Received FDA Breakthrough Device designation for Candida auris test, a direct-from-blood molecular diagnostic test
- Advanced the T2Resistance Panel toward FDA 510(k) submission, which we expect to occur during the first quarter of 2023
- Filed FDA 510(k) submission to expand the FDA-cleared T2Bacteria® Panel to include the detection of *Acinetobacter baumannii*
- The Company's milestone-based product development contract with BARDA ended on September 15, 2023, upon the completion of Option 3

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued October 12, 2023
99.2	Press Release issued October 12, 2023
104	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 our revenue results and cash balance, financial outlook, cost improvement measures, timing of completion of clinical trials, anticipated strategic priorities, status of product development pipeline, product demand, commitments or opportunities, and growth expectations or targets, as well as statements that include the words "expect," "intend," "plan", "believe", "project", "forecast", "estimate," "may," "should," "anticipate" and similar statements of a future or forward looking nature. These forward-looking statements are based on management's current expectations. The preliminary, estimated financial results for the third quarter contained in this Current Report on Form 8-K contain forward-looking statements and are subject to the completion of management's and the audit committee's final reviews and our other financial closing procedures and are therefore subject to change. You should not place undue reliance on such preliminary information and estimates because they may prove to be materially inaccurate. The preliminary information and estimates have not been compiled or examined by our independent auditors and they are subject to revision as we prepare our financial statements for the quarter ended September 30, 2023, including all disclosures required by U.S. generally accepted accounting principles, and as our auditors conduct their audit of these financial statements. While we believe that such preliminary information and estimates are based on reasonable assumptions, actual results may vary, and such variations may be material.

These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements,

including, but not limited to, (i) any inability to (a) realize anticipated benefits from commitments, contracts or products; (b) successfully execute strategic priorities; (c) bring products to market; (d) expand product usage or adoption; (e) obtain customer testimonials; (f) accurately predict growth assumptions; (g) realize anticipated revenues; (h) incur expected levels of operating expenses; or (i) increase the number of high-risk patients at customer facilities; (ii) failure of early data to predict eventual outcomes; (iii) failure to make or obtain anticipated FDA filings or clearances within expected time frames or at all; or (iv) the factors discussed under Item 1A. “Risk Factors” in the company’s Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Commission on March 31, 2023 and other filings the company makes with Commission from time to time. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this Current Report on Form 8-K. While the Company may elect to update such forward-looking statements at some point in the future, unless required by law, it disclaims any obligation to do so, even if subsequent events cause its views to change. Thus, no one should assume that the Company’s silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. These forward-looking statements should not be relied upon as representing the Company’s views as of any date subsequent to the date of this Current Report on Form 8-K.

SIGNATURES

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

Date: October 12, 2023

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

T2 Biosystems Announces Preliminary Third Quarter 2023 Financial Results and Business Updates

Received FDA 510(k) clearance for the T2Biothreat Panel and significantly strengthened balance sheet

LEXINGTON, Mass., October 12, 2023 (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 preliminary unaudited financial results for the third quarter ended September 30, 2023 and business updates.

Recent Financial and Operational Highlights

- Achieved preliminary third quarter 2023 total revenue of $1.5 million, comprised entirely of product revenue, a decrease of 60% compared to the prior year period, primarily due to a $1.0 million reduction in BARDA revenue.
- Achieved sepsis test panel revenue of $1.1 million, a decrease of 31% compared to the prior year period, primarily due to ending the third quarter with a sepsis test backorder of $380,000.
- Executed contracts for 5 T2Dx Instruments during the third quarter, including 2 in the U.S. and 3 internationally.
- Completed installation for all seven initial T2Dx® Instruments sold under a multi-year contract with a European distributor for T2Dx Instruments and sepsis test panels for Poland.
- Strengthened balance sheet by converting $10.0 million, or approximately 20%, of term loan debt with CRG Servicing LLC in exchange for shares of T2 Biosystems equity.
- Cash and cash equivalents totaled $24.3 million as of September 30, 2023, and the Company raised an additional $21.9 million in net proceeds through ATM sales during the third quarter.

Recent Pipeline and Clinical Highlights

- Received FDA 510(k) clearance for the T2Biothreat™ Panel, a direct-from-blood diagnostic test; only FDA-cleared multi-target biothreat test developed/manufactured by a U.S. owned company.
- Received FDA Breakthrough Device designation for *Candida auris* test, a direct-from-blood molecular diagnostic test, marking the third T2 Biosystems' product to receive this designation.
- Advanced the T2Resistance Panel toward FDA 510(k) submission, which we expect to occur during the first quarter of 2024.
- Filed FDA 510(k) submission to expand the FDA-cleared T2Bacteria® Panel to include the detection of *Acinetobacter baumannii*.
- The Company's milestone-based product development contract with BARDA ended on September 15, 2023, upon the completion of Option 3.

"Our third quarter results were highlighted by the receipt of FDA 510(k) clearance for the T2Biothreat Panel and 510(k) submission to add *Acinetobacter baumannii* detection to the FDA-cleared T2Bacteria Panel, which are both intended to create growth opportunities by expanding the test menu on our FDA-cleared T2Dx Instrument," stated John Sperzel, Chairman and CEO of T2 Biosystems. "Operationally, we have taken aggressive measures to address the sepsis test backorder, we have significantly improved our balance sheet by raising capital and by reducing our debt, and we have taken steps to maintain our Nasdaq listing, all of which will allow the Company to further advance our corporate priorities."

Preliminary Third Quarter 2023 Financial Results

Total revenue for the third quarter of 2023 was $1.5 million, comprised entirely of product sales, a 60% decrease compared to $3.7 million in the prior year period, driven by 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.

Cash and cash equivalents totaled $24.3 million as of September 30, 2023. The Company raised $21.9 million in net proceeds through ATM sales in the third quarter of 2023 and on July 6, 2023, converted $10 million, or approximately 20%, of its term loan into equity.

The Company's third quarter 2023 financial results are preliminary and are subject to the completion of the review of the Company's third quarter 2023 financial statements. Complete third quarter 2023 financial results will be announced in November.

Updated 2023 Financial Outlook

The Company expects fourth quarter 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, the Company now expects full year total sepsis and related product revenue of $7.5 million, representing a decline of 10% compared to 2022.

Nasdaq Listing Status

The Company regained compliance with Nasdaq market value of listed securities of $35 million on July 6, 2023 and today effected a 1 for 100 reverse stock split intended to regain compliance with Nasdaq minimum bid price rule.

Webcast and Conference Call Information

The Company's management team will host a conference call today, October 12, 2023, beginning at 4:30 pm 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 505931 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, the T2Biothreat™ Panel, and the T2SARS-CoV-2™ Panel and are powered by the proprietary T2 Magnetic Resonance (T2MR®) technology. T2 Biosystems has an active pipeline of future products, including the expanded T2Bacteria Panel to add *Acinetobacter baumannii*, the *Candida auris* test, and the T2Lyme™ Panel, as well as next-generation products for the detection of bacterial and fungal pathogens and associated antimicrobial resistance markers. 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 our growth opportunities as a result of the receipt of FDA 510(k) clearance for the T2Biothreat Panel and 510(k) submission to add *Acinetobacter baumannii* detection to the FDA-cleared T2Bacteria Panel, maintenance of our Nasdaq listing, our market opportunity, revenue 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. 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; (iv) failure to regain and maintain compliance with Nasdaq listing requirements and receipt of shareholder approval at our upcoming annual meeting of a reverse stock split; or (v) 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
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415-937-5406

Exhibit 99.2

T2 Biosystems Announces FDA 510(k) Submission to Expand the Pathogen Detection on its FDA-Cleared T2Bacteria Panel to Include Detection of Acinetobacter baumannii

LEXINGTON, Mass., October 12, 2023 (GLOBE NEWSWIRE)—T2 Biosystems, Inc. (NASDAQ:TTOO), a leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes, today announced that it has submitted a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) to expand the number of pathogens detected on the FDA-cleared T2Bacteria® Panel to include the detection of *Acinetobacter baumannii (A. baumannii)*.

A. baumannii is a cause of bloodstream infections especially in critically ill patients, which can range from a benign transient bacteremia to septic shock. 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%. *A. baumannii* infections typically occur in people in healthcare settings and pose risk to those who are on ventilators, have devices such as catheters, have open wounds from surgery, are in intensive care units, or have prolonged hospital stays.

“We are excited about the potential to expand the number of pathogens detected by our FDA-cleared T2Bacteria Panel to include the detection of *A. baumannii*,” stated John Sperzel, Chairman and CEO of T2 Biosystems. “We believe the addition of *A. baumannii* will lead to increased adoption as it increases the detection capabilities of our FDA-cleared T2Bacteria Panel to approximately 75% of all sepsis-causing bacterial pathogens commonly found in blood stream infections.”

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. There are few antimicrobial options for carbapenem resistant *A. baumannii*, which can increase mortality rates to 70%. *Acinetobacter* resistance to many antibiotics, including carbapenems, highlights the importance of rapid detection and targeted antimicrobial treatment.

The T2Bacteria Panel is the first and only FDA-cleared product able to detect sepsis-causing pathogens directly in whole blood, in 3 to 5 hours, without the need to wait days for a positive blood culture. The FDA-cleared T2Bacteria Panel currently detects E. faecium, S. aureus, K. pneumoniae, P. aeruginosa, and E. coli, and the CE marked version detects the aforementioned pathogens plus *A. baumannii.* Rapid detection of these pathogens is essential to getting infected patients on the appropriate antimicrobial therapy and improving clinical outcomes.

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, the T2Biothreat™ Panel, and the T2SARS-CoV-2™ Panel and are powered by the proprietary T2 Magnetic Resonance (T2MR®) technology. T2 Biosystems has an active pipeline of future products, including the expanded T2Bacteria Panel to add *Acinetobacter baumannii*, the *Candida auris* test, and the T2Lyme™ Panel, as well as next-generation products for the detection of bacterial and fungal pathogens and associated antimicrobial resistance markers. 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 our ability to expand the number of pathogens detected by our FDA-cleared T2Bacteria Panel to include the detection of *A. baumannii*, including our ability to increase the detection capabilities of our FDA-cleared T2Bacteria Panel to approximately 75% of all sepsis-causing bacterial pathogens commonly found in blood stream infections, 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.

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