

**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):  
July 12, 2023**

**T2 BIOSYSTEMS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36571**  
(Commission  
File Number)

**20-4827488**  
(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:

<u>Title of each class</u>	<u>Trading symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common stock, par value \$0.001 per share	TTOO	The Nasdaq Stock Market LLC (Nasdaq Global 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 July 12, 2023, the Company issued a press release announcing its financial results for its fiscal quarter ended June 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 8.01 Other Events**

### *Preliminary Results*

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

- Achieved second quarter total revenue of \$2.0 million, comprised entirely of product revenue.
- Achieved sepsis test panel revenue of \$1.3 million, representing an increase of 7% compared to the prior year period, despite ending the second quarter with a \$0.4 million backorder.
- Executed contracts for 11 T2Dx<sup>®</sup> Instruments during the second quarter, including 4 in the U.S. and 7 internationally.
- Secured multi-year contract with a European distributor for 7 T2Dx Instruments and sepsis test panels for Poland – including T2Bacteria<sup>®</sup> Panel, T2Candida<sup>®</sup> Panel, and T2Resistance<sup>®</sup> Panel.
- Implemented a restructuring program in May 2023, including a workforce reduction of nearly 30%.
- Strengthened balance sheet by converting \$10.0 million, or approximately 20%, of term loan debt with CRG Servicing LLC ("CRG") in exchange for 48,345,798 shares of T2 Biosystems common stock and Series B Convertible Preferred Stock convertible into 93,297,259 shares of common stock.
- Completed Nasdaq listing compliance hearing and a response is expected within 30 days.
- Cash and cash equivalents totaled \$16.1 million as of June 30, 2023, including \$18.5 million of net proceeds from the sale of shares through the ATM facility in the second quarter.
- Completed patient enrollment in the U.S. clinical trial for the T2Resistance Panel.
- Filed FDA submission for T2Biothreat<sup>™</sup> Panel, a direct-from-blood diagnostic test that runs on the FDA-cleared T2Dx Instrument and detects six biothreat pathogens identified as threats by CDC.
- Submitted for FDA Breakthrough Device Designation for a direct-from-blood diagnostic test to detect *Candida auris*, a multidrug-resistant fungal pathogen identified by CDC as an urgent threat.
- Established a clinical collaboration with Vanderbilt University Medical Center to implement the T2Bacteria Panel and assess its impact on antibiotic usage and clinical interventions.

### *ATM Update*

On March 31, 2021, the Company entered into an Equity Distribution Agreement, or the Distribution Agreement, with Canaccord Genuity LLC, or Canaccord, relating to the offer and sale of shares of the Company's common stock. As of the date of this current report on Form 8-K, the Company

has sold shares of our common stock pursuant to a prospectus supplement for gross proceeds of approximately \$71.3 million under the Distribution Agreement. The Company is filing an amendment to the prospectus supplement increasing the dollar amount of shares available to be sold pursuant to the Distribution Agreement to \$65.0 million from and after the date hereof. This current report on Form 8-K includes an opinion related to the \$65.0 million of shares that may be sold pursuant to the amendment to the prospectus supplement.

## **Item 9.01 Financial Statements and Exhibits**

### (d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
5.1	<a href="#">Opinion of Latham &amp; Watkins LLP</a>
23.1	<a href="#">Consent of Latham &amp; Watkins LLP (contained in Exhibit 5.1)</a>
99.1	<a href="#">Press Release issued July 12, 2023</a>
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 Company's ability to sell shares of common stock pursuant to the Distribution Agreement, revenue results and cash balance, financial outlook, cost improvement measures, timing of completion of clinical trials, timing regarding a response from Nasdaq related to delisting, anticipated strategic priorities, status of product development pipeline and collaborations, FDA feedback, 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 fourth quarter and fiscal year 2022 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 as of and for the quarter ended June 30, 2023, including all disclosures required by U.S. generally accepted accounting principles. 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

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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 heading “Risk Factors” in the company’s Annual Report on Form 10-K for the year ended December 31, 2022 and Quarterly Report on Form 10-Q for the period ended 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.

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**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: July 12, 2023

**T2 BIOSYSTEMS, INC.**

By: /s/ John Sprague

Name: John Sprague

Title: Chief Financial Officer

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**LATHAM & WATKINS** LLP

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File No. 042073-0033

July 12, 2023

T2 Biosystems, Inc.  
 101 Hartwell Ave.  
 Lexington, MA 02421

Re: Registration Statement on Form S-3; Shares of Common Stock par value \$0.001 per share, having an aggregate offering price of up to \$65,000,000

Ladies and Gentlemen:

We have acted as special counsel to T2 Biosystems, Inc., a Delaware corporation (the “**Company**”), in connection with the sale by the Company of shares (the “**Shares**”) of common stock of the Company, par value \$0.001 per share (the “**Common Stock**”), having an aggregate offering price of up to \$65,000,000, pursuant to (i) a registration statement on Form S-3 under the Securities Act of 1933, as amended (the “**Act**”), filed with the Securities and Exchange Commission (the “**Commission**”) on March 31, 2021 (as so filed and as amended, the “**Registration Statement**”), (ii) the base prospectus included in the Registration Statement (the “**Base Prospectus**”), (iii) the prospectus supplement included in the Registration Statement, as amended by Amendment No. 1 to the prospectus supplement, dated July 12, 2023, (together with the Base Prospectus, the “**Prospectus**”), and (iv) that certain Equity Distribution Agreement, dated as of March 31, 2021, by and between the Company and Canaccord Genuity LLC (the “**Sales Agreement**”).

This opinion is being furnished in connection with the requirements of Item 601(b)(5) of Regulation S-K under the Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement or the Prospectus, other than as expressly stated herein with respect to the issue of the Shares.

As such counsel, we have examined such matters of fact and questions of law as we have considered appropriate for purposes of this letter. With your consent, we have relied upon certificates and other assurances of officers of the Company and others as to factual matters without having independently verified such factual matters. We are opining herein as to the General Corporation Law of the State of Delaware (the “**DGCL**”), and we express no opinion with respect to the applicability thereto, or the effect thereon, of the laws of any other jurisdiction or, in the case of Delaware, any other laws, or as to any matters of municipal law or the laws of any local agencies within any state.

Subject to the foregoing and the other matters set forth herein, it is our opinion that, as of the date hereof, upon the completion of all Corporate Proceedings (as defined below) relating to the Shares, when the Shares shall have been duly registered on the books of the transfer agent and registrar therefor in the name or on behalf of the purchasers, upon issuance, delivery and payment therefor in an amount not less than the par value thereof in accordance with the Corporate Proceedings and the terms of the Sales Agreement, the Shares to be issued and sold by the Company pursuant to the Sales Agreement will be duly authorized by all necessary corporate action of the Company, and such Shares will be validly issued, fully paid and nonassessable. In rendering the foregoing opinion, we have assumed that (i) the Company will comply with all applicable notice requirements regarding uncertificated shares provided in the DGCL, (ii) upon the issue of any of the Shares, the total number of shares of Common Stock issued and outstanding will not exceed the total number of shares of Common Stock that the Company is then authorized to issue under its Restated Certificate of Incorporation and (iii) certain terms of the Shares to be issued by the Company from time to time will be authorized and approved by the Board of Directors of the Company or one or more committees thereof established by the Board of Directors with the authority to issue and sell Shares pursuant to the Sales Agreement in accordance with the DGCL, the Restated Certificate of Incorporation of the Company, the Amended and Restated Bylaws of the Company and certain resolutions of the Board of Directors and one or more committees thereof (with such approvals referred to herein as the “**Corporate Proceedings**”) prior to issuance thereof.

This opinion is for your benefit in connection with the Registration Statement and may be relied upon by you and by persons entitled to rely upon it pursuant to the applicable provisions of the Act. We consent to your filing this opinion as an exhibit to the Company’s Form 8-K dated July 12, 2023 and to the reference to our firm contained in the Prospectus under the heading “Legal Matters.” In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Act or the rules and regulations of the Commission thereunder.

Very truly yours,

/s/ Latham & Watkins



## T2 Biosystems Announces Preliminary Second Quarter 2023 Financial Results

*Received record quarterly sepsis test panel orders and strengthened balance sheet*

LEXINGTON, Mass., July 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 preliminary unaudited financial and operational results for the second quarter 2023.

### Recent Financial and Operational Highlights (unaudited)

- Achieved second quarter total revenue of \$2.0 million, comprised entirely of product revenue.
- Achieved sepsis test panel revenue of \$1.3 million, representing an increase of 7% compared to the prior year period, despite ending the second quarter with a \$0.4 million sepsis test backorder.
- Executed contracts for 11 T2Dx<sup>®</sup> Instruments during the second quarter, including 4 in the U.S. and 7 internationally.
- Secured multi-year contract with a European distributor for 7 T2Dx Instruments and sepsis test panels for Poland – including T2Bacteria<sup>®</sup> Panel, T2Candida<sup>®</sup> Panel, and T2Resistance<sup>®</sup> Panel.
- Implemented a restructuring program in May 2023, including a workforce reduction of nearly 30%.
- Strengthened balance sheet by converting \$10.0 million, or approximately 20%, of term loan debt with CRG Servicing LLC (“CRG”) in exchange for 48,345,798 shares of T2 Biosystems common stock and Series B Convertible Preferred Stock convertible into 93,297,259 shares of common stock.
- Completed Nasdaq listing compliance hearing and a response is expected within 30 days.
- Cash and cash equivalents totaled \$16.1 million as of June 30, 2023, including \$18.5 million of net proceeds from the sale of shares through the ATM facility in the second quarter.

### Recent Pipeline and Clinical Highlights

- Completed patient enrollment in the U.S. clinical trial for the T2Resistance Panel.
- Filed FDA submission for T2Biothreat<sup>™</sup> Panel, a direct-from-blood diagnostic test that runs on the FDA-cleared T2Dx Instrument and detects six biothreat pathogens identified as threats by CDC.
- Submitted for FDA Breakthrough Device Designation for a direct-from-blood diagnostic test to detect *Candida auris*, a multidrug-resistant fungal pathogen identified by CDC as an urgent threat.
- Established a clinical collaboration with Vanderbilt University Medical Center to implement the T2Bacteria Panel and assess its impact on antibiotic usage and clinical interventions.

“We achieved a number of significant milestones during the second quarter, including record demand for our sepsis test panels, the second largest sepsis-driven instrument order in company history, the FDA 510(k) submission for the T2Biothreat Panel, and the FDA Breakthrough Device Designation application for our *Candida auris* test,” stated John Sperzel, Chairman and CEO of T2 Biosystems. “In addition, we recently strengthened our balance sheet through sales of common stock and the conversion of \$10 million of debt to equity, extending our cash runway to pursue strategic initiatives.”

The Company’s second quarter 2023 financial results are preliminary and are subject to the completion of the audit of the Company’s second quarter 2023 financial statements. Complete second quarter 2023 financial results will be announced in August.



## 2023 Financial Outlook

The Company now expects full year 2023 total sepsis and related product revenue of \$9.5 million to \$10.5 million, representing growth of 13% to 25%, compared to \$8.4 million in 2022.

## 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<sup>®</sup> Instrument, the T2Bacteria<sup>®</sup> Panel, the T2Candida<sup>®</sup> Panel, the T2Resistance<sup>®</sup> Panel, and the T2SARS-CoV-2<sup>™</sup> Panel and are powered by the Company's proprietary T2 Magnetic Resonance (T2MR<sup>®</sup>) technology. T2 Biosystems has an active pipeline of future products, including the *Candida auris* test, the T2Lyme<sup>™</sup> Panel, the T2Biothreat<sup>™</sup> Panel, as well as additional products for the detection of bacterial and fungal pathogens and associated antimicrobial resistance markers.

## 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 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. 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. 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:**

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