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 20, 2023

T2 BIOSYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36571**	**20-4827488**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

101 Hartwell Avenue, Lexington, Massachusetts 02421
(Address of principal executive offices, including Zip Code)

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

N/A
(Former Name or Former Address, if Changed Since Last Report)

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

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

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

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

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

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

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

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

Emerging growth company ☐

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

Item 7.01 Regulation FD Disclosure.

On July 20, 2023, the Company issued a press release announcing that the FDA had informed the Company that its application for Breakthrough Device Designation for the Company's *Candida auris* direct-from-blood molecular diagnostic test had been granted. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

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

Item 8.01 Other Events

On July 20, 2023, the Company announced that the FDA had informed the Company that its application for Breakthrough Device Designation for the Company's *Candida auris* direct-from-blood molecular diagnostic test had been granted.

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

Forward-Looking Statements

This Current Report on Form 8-K ("Current Report") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding the potential that the Breakthrough Device designation will accelerate the FDA clearance of the *Candida auris* test or the Company's commercialization of the *Candida auris* test, the ability of the *Candida auris* test to successfully detect *Candida auris*, 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 Current Report. Any such forward-looking statements represent management's estimates as of the date of this Current Report. 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.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued July 20, 2023
104	Cover Page Interactive Data File (embedded within the inline XBRL document

SIGNATURES

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

Date: July 20, 2023

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

FOR IMMEDIATE RELEASE

T2 Biosystems Receives FDA Breakthrough Device Designation for *Candida Auris* Diagnostic Test

LEXINGTON, Mass., July 20, 2023 (GLOBE NEWSWIRE)—T2 Biosystems, Inc. (NASDAQ:TTOO), a leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes, announced today the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device designation for the Company's *Candida auris* (*C. auris*) direct-from-blood molecular diagnostic test.

This marks the third T2 Biosystems' product to receive FDA Breakthrough Device designation, as the Company was previously granted FDA Breakthrough Device designation for its T2Resistance® Panel and T2Lyme™ Panel. The Company plans to expand the test menu on its FDA-cleared T2Dx® Instrument by adding the *C. auris* diagnostic test that is designed to detect *C. auris* species directly from blood in just 3-5 hours, without the need to wait days for a positive blood culture.

"We are pleased with the FDA's decision to grant Breakthrough Device designation for our *Candida auris* test, which provides greater and more frequent access to the FDA and may accelerate our path to FDA clearance," stated John Sperzel, Chairman and CEO of T2 Biosystems. "We believe adding *Candida auris* to the test menu on our FDA-cleared T2Dx Instrument will provide clinicians with a valuable tool to rapidly detect a dangerous, multidrug-resistant fungal pathogen much faster than blood culture-based methods, strengthening our value proposition and increasing the attractiveness of our products to U.S. hospitals."

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

The Company currently markets and sells the T2Candida® Panel, the only FDA-cleared diagnostic test able to detect sepsis-causing fungal pathogens directly from blood, without the need to wait days for a positive blood culture. The T2Candida Panel runs on the fully-automated T2Dx Instrument and simultaneously detects five *Candida* species, including *Candida albicans*, *Candida tropicalis*, *Candida parapsilosis*, *Candida krusei*, and *Candida glabrata*. Rapid detection of these pathogens, as well as *Candida auris*, is essential to getting infected patients on appropriate antifungal therapy and improving clinical outcomes.

About FDA Breakthrough Devices Program

The FDA Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. It is available for devices and device-led combination products which are subject to review under a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request (De Novo request). This program is intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standards for PMA approval, 510(k) clearance, and De Novo marketing authorization, consistent with the FDA's mission to protect and promote public health. For more information, please visit: https://www.fda.gov/media/108135/download.

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 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 T2Biothreat™ Panel, the *Candida auris* test, and 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.

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