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 8, 2022

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 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 7.01 Regulation FD Disclosure.

On July 11, 2022, the Company issued a press release announcing that the FDA had informed the Company that its application for Breakthrough Device Designation for the T2Lyme Panel 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 11, 2022, the Company issued a press release announcing that the FDA had informed the Company that its application for Breakthrough Device Designation for the T2Lyme Panel had been granted.

The T2Lyme Panel is a direct-from-blood molecular diagnostic test designed to run on the FDA-cleared T2Dx® Instrument and simultaneously detect the bacteria that cause Lyme disease: *Borrelia burgdorferi*, *Borrelia afzelii*, and *Borrelia garinii*. The T2Lyme Panel is intended to test individuals with signs and symptoms of Lyme disease and aid in the diagnosis of early Lyme disease. According to the U.S. Centers for Disease Control and Prevention (CDC), approximately 476,000 Americans are diagnosed and treated for Lyme disease each year.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued July 11, 2022
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 11, 2022

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

T2 Biosystems Receives FDA Breakthrough Device Designation for the T2Lyme Panel

Molecular Diagnostic Test for Early Detection of Lyme Disease

LEXINGTON, Mass., July 11, 2022 (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 T2Lyme™ Panel.

"We are pleased with the FDA's decision to grant Breakthrough Device Designation for the T2Lyme Panel, as it brings us one step closer to providing clinicians with a valuable tool to detect Lyme disease earlier. Similar to the value proposition of our sepsis panels, we believe the T2Lyme Panel will allow clinicians to ensure patients receive the appropriate therapy faster, and prevent the negative impact of a delay in delivery of appropriate therapy and the overuse of antibiotics," stated John Sperzel, Chairman and CEO of T2Biosystems. "This achievement follows the decision by the U.S. Patent and Trademark Office to grant T2 Biosystems a patent covering the T2Lyme Panel, 'NMR Methods and Systems for the Rapid Detection of Tick-Borne Pathogens' and we look forward to further advancements with our T2Lyme Panel.

The T2Lyme Panel is a direct-from-blood molecular diagnostic test designed to run on the FDA-cleared T2Dx® Instrument and simultaneously detect the bacteria that cause Lyme disease: *Borrelia burgdorferi*, *Borrelia afzelii*, and *Borrelia garinii*. The T2Lyme Panel is intended to test individuals with signs and symptoms of Lyme disease and aid in the diagnosis of early Lyme disease.

Currently, there are no sensitive FDA-cleared diagnostic tests for the detection of early Lyme disease. Laboratory diagnosis of Lyme disease has traditionally used a two-tier process of enzyme immunoassay and western blot for detecting the presence of antibodies against *Borrelia burgdorferi* in a patient's blood. Antibodies are specific proteins produced by the body in response to an infection. In the case of Lyme disease, antibodies can take several weeks to develop, so patients may test negative using current FDA-cleared diagnostics if a patient has been recently infected.

According to the U.S. Centers for Disease Control and Prevention (CDC), approximately 476,000 Americans are diagnosed and treated for Lyme disease each year. Typical symptoms include fever, headache, fatigue and skin rash called *erythema migrans*. If left untreated, infection can spread to joints, the heart and the nervous system.

Lyme disease is a bacterial infection caused by *Borrelia* pathogens and is transmitted to humans through the bite of infected ticks. It is considered the most common vector borne illness in the Northern Hemisphere. *Borrelia burgdorferi* is most commonly associated with Lyme disease in North America, while *Borrelia afzelii* and *Borrelia garinii* cause most Lyme infections in Europe and Asia.

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.

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 T2Cauris™ Panel, and T2Lyme™ Panel, as well as next-generation 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 anticipated product benefits, product expansion or opportunities, and timing of FDA filings or clearances, 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, 2021, filed with the U.S. Securities and Exchange Commission, or SEC, on March 23, 2022, 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:
Philip Trip Taylor, Gilmartin Group
ir@T2Biosystems.com
415-937-5406