

**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 13, 2022

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
(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 October 13, 2022, the Company issued a press release announcing plans to develop and commercialize a rapid molecular diagnostic test for detection of early Lyme disease. 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 October 13, 2022, the Company issued a press release announcing plans to develop and commercialize a rapid molecular diagnostic test for detection of early Lyme disease.

Lyme disease is a bacterial infection caused by the genes *Borrelia* and is transmitted to humans through the bite of infected ticks. It is considered the most common vector borne illness in the United States. *Borrelia burgdorferi* is spread by deer ticks (*Ixodes scapularis*) in the northeastern, mid-Atlantic and north-central regions of the U.S., and by the western blacklegged tick (*Ixodes pacificus*) on the Pacific Coast. According to the U.S. Centers for Disease Control and Prevention (CDC), approximately 476,000 Americans may get Lyme disease each year in the United States. 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 systems.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued October 13, 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: October 13, 2022

T2 BIOSYSTEMS, INC.

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



T2 Biosystems Announces Plan to Commercialize a Diagnostic Test for Early Lyme Disease

Plans to Initiate Marketing and Sales in the U.S. as a Laboratory Developed Test in 2023

LEXINGTON, Mass., October 13, 2022 (GLOBE NEWSWIRE) — T2 Biosystems, Inc. (NASDAQ:TTOO) a leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes, announced today plans to complete development of, and commercialize, a diagnostic test for the detection of early Lyme disease, with the goal of initiating marketing and sales in the United States as a Laboratory Developed Test (LDT) in 2023.

“We believe there is a significant market opportunity for a sensitive diagnostic test to detect early Lyme disease, and initial performance data on the T2Lyme Panel is very encouraging. Our decision to advance toward commercialization in 2023 follows two recent achievements: the receipt of a patent from the U.S. Patent and Trademark Office and the receipt of FDA Breakthrough Device Designation, both covering the T2Lyme Panel,” stated John Sperzel, Chairman and CEO of T2Biosystems. “While we plan to commence marketing and sales as an LDT in 2023, we intend to subsequently initiate a U.S clinical trial for the purpose of pursuing FDA clearance of the T2Lyme Panel. We believe the T2Lyme Panel will potentially allow clinicians to ensure patients receive appropriate therapy faster, and prevent the negative impact of a delay in delivery of appropriate therapy and the overuse of antibiotics.”

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

Laboratory diagnosis of Lyme disease has traditionally used a two-tier process for detecting the presence of antibodies against *Borrelia burgdorferi* in a patient’s blood. Antibodies are proteins present in the blood when the body is responding to a specific 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.

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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 our plan to develop and commercialize a diagnostic test for the detection of early Lyme disease, the capability of the T2Lyme Panel to detect early Lyme disease, the market opportunity for a diagnostic test for early Lyme disease, , timing of development of an LDT for Lyme disease, status of product development pipeline, product demand, and commitments or opportunities, , 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:

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