

**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 20, 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On November 1, 2022, Alec Barclay notified T2 Biosystems, Inc. (the “Company”) of his resignation as Chief Operations Officer of the Company, effective as of November 30, 2022.

**Item 7.01 Regulation FD Disclosure.**

On November 7, 2022, the Company issued a press release announcing the U.S. Department of Health and Human Services (“HHS”) and the Steven & Alexandra Cohen Foundation (“Cohen Foundation”) have selected T2 Biosystems as a Phase 1 winner in the LymeX Diagnostics Prize, a LymeX Innovation Accelerator (“LymeX”) prize competition to accelerate the development of Lyme disease diagnostics. As a Phase 1 winner, the Company will receive \$100,000 and an invitation to participate in a second phase. 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 20, 2022, the Company issued a press release announcing that it has initiated studies to expand the number of pathogens detected on the FDA-cleared T2Bacteria® Panel to include the detection of *Acinetobacter baumannii*.

*A. baumannii* is a cause of bloodstream infections especially in critically ill patients, which can range from a benign transient bacteremia to fulminant septic shock. *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. 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%.

On October 26, 2022, the private investor in the Company’s Series A redeemable convertible preferred stock redeemed all 3,000 shares of the Series A redeemable convertible preferred stock for an aggregate amount of \$0.3 million.

On November 1, 2022, the Company issued a press release announcing that it received written notice from the NASDAQ Stock Market LLC (NASDAQ) on October 31, 2022 informing the Company that it has regained compliance with the minimum bid price requirement under NASDAQ Listing Rule 5550(a)(2) for continued listing on the NASDAQ Capital Market.

As previously reported, the Company was notified by NASDAQ on November 5, 2021 that it was not in compliance with the minimum bid price rule because its common stock failed to meet the closing bid price of \$1.00 for a period of 30 consecutive business days. To regain compliance with the Rule, the Company was required to maintain a minimum closing bid price of \$1.00 or more for at least 10 consecutive trading days. This requirement was met on October 26, 2022, the tenth consecutive trading day when the closing bid price of the Company's common stock was greater than \$1.00, and the matter is now closed.

On November 7, 2022, the Company issued a press release announcing HHS and the Cohen Foundation have selected T2 Biosystems as a Phase 1 winner in the LymeX Diagnostics Prize, a LymeX prize competition to accelerate the development of Lyme disease diagnostics. As a Phase 1 winner, T2 Biosystems will receive \$100,000 and an invitation to participate in a second phase.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release issued November 7, 2022</a>
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: November 7, 2022

**T2 BIOSYSTEMS, INC.**

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



## HHS and the Cohen Foundation Name T2 Biosystems a Phase 1 Winner in LymeX Diagnostics Prize

LEXINGTON, Mass., November 7, 2022 (GLOBE NEWSWIRE) — T2 Biosystems, Inc. (NASDAQ:TTOO) a leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes, announced today that the U.S. Department of Health and Human Services (“HHS”) and the Steven & Alexandra Cohen Foundation (“Cohen Foundation”) have selected T2 Biosystems as a Phase 1 winner in the LymeX Diagnostics Prize, a LymeX Innovation Accelerator (“LymeX”) prize competition to accelerate the development of Lyme disease diagnostics. As a Phase 1 winner, T2 Biosystems will receive \$100,000 and an invitation to participate in a second phase.

The current two-tier serological testing system relies on the presence of antibodies and can only be used accurately four to six weeks after infection. The LymeX Diagnostics Prize’s open innovation model is accelerating discovery and development by offering no-strings-attached funding alongside exclusive access to key resources and collaboration opportunities—helping innovators take their solutions from concept to the healthcare market.

“We appreciate the leadership from HHS and the Cohen Foundation to advance next generation Lyme diagnostics, and we are grateful to receive this support to advance our T2Lyme Panel for the detection of early Lyme disease,” stated John Sperzel, Chairman and CEO of T2Biosystems. “We believe the T2Lyme Panel may allow clinicians to ensure patients receive appropriate therapy faster, and prevent the negative impact of a delay in the delivery of appropriate therapy and the overuse of antibiotics.”

From May to August 2022, Phase 1 received 52 solutions for detecting active Lyme disease infections in people. Solutions incorporated techniques such as radiology imaging, genomics sequencing, and microfluidics; submissions also translated approaches used in diagnosing other infectious diseases, including COVID-19. Technical reviewers initially evaluated this highly competitive field, and then the competition judging panel assessed submissions according to [official evaluation criteria](#).

At the discretion of HHS and the Cohen Foundation, and subject to availability of future funding, at least one additional phase may follow Phase 2. Future phases are expected to focus on clinical and nonclinical validation of diagnostic tests that detect active infection by Lyme-disease-causing bacteria, as well as readiness for regulatory submission and market entry. Thanks to a \$10 million pledge to the LymeX Diagnostics Prize from the Cohen Foundation, \$9 million in additional LymeX prizes are projected to be available in proposed future phases.

Visit [LymeXDiagnosicsPrize.com](https://LymeXDiagnosicsPrize.com) for more information and [subscribe to the competition newsletter](#) to receive future updates.

### About T2Lyme Panel:

The T2Lyme Panel is a direct-from-blood molecular diagnostic test designed to run on the FDA-cleared T2Dx<sup>®</sup> 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. In the last six months, the T2Lyme Panel received Breakthrough Device Designation from the U.S. Food and Drug Administration and received a patent from the U.S. Patent and Trademark Office, both covering the T2Lyme Panel.

**About 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 system.

**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 proprietary T2 Magnetic Resonance (T2MR<sup>®</sup>) technology. T2 Biosystems has an active pipeline of future products, including the T2Biothreat<sup>™</sup> Panel, the T2Cauris<sup>™</sup> Panel, and T2Lyme<sup>™</sup> 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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