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): August 9, 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 August 9, 2022, the Company issued a press release announcing plans to explore the potential to develop a rapid molecular diagnostic test for detection of the monkeypox virus, including technical and commercial feasibility.. 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 August 9, 2022, the Company issued a press release announcing plans to explore the potential to develop a rapid molecular diagnostic test for detection of the monkeypox virus, including technical and commercial feasibility.

Monkeypox is a rare disease caused by infection with the monkeypox virus that is part of the orthopoxvirus family of viruses, which also contains smallpox. The main symptom of monkeypox is a rash, but individuals may also present with flu like symptoms. A rapid and accurate diagnosis of monkeypox is essential to expedite treatment and to limit exposure and spread of the disease.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued August 9, 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: August 9, 2022

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

T2 Biosystems to Explore Potential to Develop Rapid Molecular Diagnostic Test for Monkeypox Virus

LEXINGTON, Mass., August 9, 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 explore the potential to develop a rapid molecular diagnostic test for detection of the monkeypox virus, including technical and commercial feasibility. Monkeypox is a rare disease caused by infection with the monkeypox virus that is part of the orthopoxvirus family of viruses, which also contains smallpox. The main symptom of monkeypox is a rash, but individuals may also present with flu like symptoms. A rapid and accurate diagnosis of monkeypox is essential to expedite treatment and to limit exposure and spread of the disease.

On July 23, 2022, the World Health Organization declared the global monkeypox outbreak a Public Health Emergency of International Concern, which is the highest level of global health alert under International Health Regulations. On August 4, 2022, the United States declared monkeypox a public health emergency, a move that is expected to free up additional funding and tools to fight the disease.

“Our team has demonstrated the scientific expertise to develop new tests on our proprietary platform, including direct-from-blood and swab tests, and we believe the development of a molecular diagnostic test for the monkeypox virus is possible on our platform,” stated John Sperzel, Chairman and CEO of T2Biosystems. “Given the urgent nature of the monkeypox virus, and the potential for global transmission, we have communicated with the FDA and CDC and we are exploring the potential to develop and commercialize a test for the monkeypox virus.”

The U.S. Centers for Disease Control and Prevention (CDC) has the only FDA-cleared test that can detect monkeypox by a swab from a monkeypox lesion (rash or growth). This test is being offered through the CDC’s public health Laboratory Response Network. Additionally five large commercial laboratories have developed the CDC test on their platform or developed a Lab Developed Test (LDT). The FDA is working closely with the CDC to increase diagnostic testing availability for monkeypox.

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 the feasibility of developing a rapid molecular diagnostic test for detection of the

monkeypox virus, T2 Biosystems' ability to successfully develop and commercialize a molecular diagnostic test for detection of the monkeypox virus, the commercial demand for a rapid molecular diagnostic test for detection of the monkeypox virus, and the likelihood of receiving regulatory approval to market a molecular diagnostic test for detection of the monkeypox virus;, 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.

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