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): March 24, 2020

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 2.02 Results of Operations and Financial Condition

On March 24, 2020, T2 Biosystems, Inc. (the "Company") issued a press release announcing preliminary estimated financial results for its fiscal quarter ending March 31, 2020. A copy of the Company's press release is furnished with this report as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 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. Furthermore, such information, including Exhibit 99.1 attached hereto, shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly stated by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

On March 24, 2020, the Company issued a press release announcing its entrance into a license agreement with the Center of Discovery and Innovation at Hackensack Meridian Health (the "Center") pursuant to which the Company has licensed the right to adapt the Center's COVID-19 test to run on the Company's T2Dx® Instrument. A copy of the Company's press release is furnished with this report as Exhibit 99.2.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 and Exhibit 99.2 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. Furthermore, such information, including Exhibit 99.2 attached hereto, shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly stated by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued March 24, 2020 announcing preliminary estimated financial results for the quarter ended March 31, 2020
99.2	Press Release issued March 24, 2020 announcing license agreement with Center of Discovery and Innovation at Hackensack Meridian Health

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: March 24, 2020

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

T2 Biosystems Announces Preliminary First Quarter 2020 Financial Results

Suspends 2020 Financial Guidance

LEXINGTON, Mass., March 24, 2020 (GLOBE NEWSWIRE)—T2 Biosystems, Inc. (NASDAQ:TTOO), a leader in the rapid detection of sepsis-causing pathogens, today announced unaudited, preliminary financial result estimates for the quarter ended March 31, 2020, and suspended full year 2020 financial and operational guidance due to uncertainties from the impact of the novel coronavirus (COVID-19) pandemic.

The Company continues to leverage its technology and scientific expertise to aid in the COVID-19 response while prioritizing the health and safety of its employees and customers. T2 Biosystems recently announced a licensing agreement to support development of a rapid COVID-19 test, developed by the Center of Discovery and Innovation (CDI) at Hackensack Meridian Health, enabling a larger role in the pandemic response.

The licensed coronavirus assay has been used by healthcare professionals within the Hackensack Meridian Health network, under the U.S. Food and Drug Administration's Emergency Use Authorization guidance, to test and treat patients suspected of having coronavirus. T2 Biosystems intends to adapt the newly licensed COVID-19 test to run on its T2Dx® Instrument, the same instrument used for the FDA-cleared T2Bacteria® and T2Candida® Panels, allowing the detection of both coronavirus and associated secondary bacterial or fungal infections that may lead to sepsis.

Preliminary Unaudited First Quarter Financial Results

- Estimated first quarter 2020 total revenue is expected to be in the range of $2.2 million to $2.6 million, compared to $1.8 million in total revenue the first quarter of 2019.
    - Estimated first quarter product revenue is expected to be in the range of $0.9 million to $1.1 million, compared to product revenue of $1.3 million in the prior year period.
    - Estimated first quarter research and grant contribution revenues are expected to be in the range of $1.3 million to $1.5 million, compared to research and grant contribution revenue of $0.5 million in the prior year period.
- Cash and cash equivalents as of March 31, 2020 are expected to be approximately $30.0 million.

"As a result of impacts from the COVID-19 pandemic, we recently began to experience disruption to our commercial operations. We are unsure of the magnitude or duration of these impacts in 2020, and we are making the necessary adjustments to minimize impact to our business," said President and Chief Executive Officer, John Sperzel. "With the newly-licensed coronavirus test being adapted to the T2Dx Instrument, we are working to provide a comprehensive offering to enable the detection and early targeted treatment of COVID-19 patients and the related co-infections and secondary infections that cause sepsis. With our proprietary technology and its

detection capability, we believe we are well positioned to address an urgent healthcare need for rapid diagnostic testing."

2020 Financial Outlook

Due to uncertainties related to the on-going COVID-19 pandemic, the Company has suspended financial and operational guidance for 2020.

The Company expects to provide complete first quarter 2020 financial results in early May.

About T2 Biosystems

T2 Biosystems, a leader in the rapid detection of sepsis-causing pathogens, 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, T2Candida® Panel, the T2Bacteria® Panel, and the T2Resistance™ Panel and are powered by the proprietary T2 Magnetic Resonance (T2MR®) technology. T2 Biosystems has an active pipeline of future products, including products for the detection of additional species and antibiotic resistance markers of sepsis pathogens, and tests for Lyme disease.

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 revenue results and cash balance, the adaptation of the COVID-19 test on the Company's T2Dx® Instrument, additional patients, timing of testing patients, anticipated product benefits, strategic priorities, product expansion or opportunities, growth expectations or targets, timing of FDA filings or clearances and anticipated operating expenses, 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. The preliminary, estimated financial results for the first quarter contained in this document are subject to the completion of management's and the audit committee's final reviews and our other financial closing procedures and are therefore subject to change. Furthermore, statements contained in this document relating to the recent global outbreak of the novel coronavirus disease (COVID-19), the impact of which remains inherently uncertain on our financial results, are forward-looking statements.

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, 2019, filed with the U.S. Securities and Exchange Commission, or SEC, on March 16, 2020, 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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Exhibit 99.2

T2 Biosystems Announces Worldwide Licensing Agreement of COVID-19, Novel Coronavirus Assay from Hackensack Meridian Health's Center for Discovery and Innovation

New COVID-19 assay will be adapted to run on T2 Biosystems' FDA-cleared T2Dx® Instrument

LEXINGTON, Mass., March 24, 2020 (GLOBE NEWSWIRE)—T2 Biosystems, Inc. (NASDAQ:TTOO), a leader in the rapid detection of sepsis-causing pathogens, today announced that it has entered into a worldwide licensing agreement for a rapid COVID-19, novel coronavirus test developed by the Center of Discovery and Innovation at Hackensack Meridian *Health*, New Jersey's largest and most comprehensive health network.

The licensed coronavirus assay has been used by healthcare professionals within the Hackensack Meridian *Health* network, under the U.S. Food and Drug Administration's Emergency Use Authorization guidance, to test and treat patients suspected of having coronavirus. Under terms of the agreement, T2 Biosystems will adapt the coronavirus test to run on its T2Dx® Instrument, the same instrument used for the FDA-cleared T2Bacteria® and T2Candida® Panels. Hackensack Meridian *Health* will also adopt the T2Dx® Instrument and test panels within its Center of Discovery and Innovation.

"This agreement combines our FDA-cleared T2Dx platform with our joint scientific expertise to benefit patients at risk for both primary coronavirus infections, as well as associated secondary infections that may lead to sepsis," said John Sperzel, President and Chief Executive Officer of T2 Biosystems. "Data from prior flu pandemics indicated bacterial co-infection rates as high as 29%, and sepsis rates above 30% among patients admitted to hospital intensive care units. The ability to detect coronavirus and associated secondary bacterial or fungal infections that may lead to sepsis, without the need to wait days for a diagnostic result, allows clinicians to achieve targeted therapy faster, and can lead to reduced length of stay in the intensive care unit, freeing up beds for incoming patients."

By adding this complementary test to the T2Dx platform, capable of detecting SARS-CoV-2 (novel coronavirus), T2 Biosystems will be able to provide a comprehensive assessment of patients suspected of primary or secondary infections associated with coronavirus, when timely results are most critical. These results will enable clinicians to rapidly quarantine and treat patients suspected of having coronavirus, effectively allocate critical resources, and in the case of a negative result, spare the patient unnecessary time in the hospital, thus reducing risks to additional exposure.

"Our scientists at the Center for Discovery and Innovation have given our health network a crucial tool to treat patients in real-time," said Robert C. Garrett, FACHE, Chief Executive Officer of Hackensack Meridian *Health*. "We are pleased to license the technology to T2 Biosystems and also adopt the T2Dx platform."

The ongoing pandemic has accelerated the need for worldwide testing. The World Health Organization (WHO) has confirmed nearly 335,000 cases globally and the most recent reports indicate a death toll of more than 14,500. In the United States, more than 33,400 cases have been reported across all 50 states, with 400 deaths, according to the Centers for Disease Control and Prevention (CDC).

"We developed a highly sensitive and accurate coronavirus test that provides rapid, definitive results by combining the best elements found in the coronavirus tests developed by CDC and WHO," said David S. Perlin, Ph.D., Chief Scientific Officer and Senior Vice President of the CDI. "The T2Dx® Instrument is the perfect vehicle to expand our innovation to customers around worldwide."

While the majority of confirmed cases have been mild to moderate in severity, nearly 14% of patients have suffered from severe disease, exhibiting signs and symptoms that also meet SIRS criteria, putting those patients at high risk for sepsis. Additionally, 6.1% of patients were found to be critical, suffering from respiratory failure, septic shock, and/or multiple organ dysfunction/failure. These patients are treated in the ICU, where they are exposed to additional risk factors as well as countless antimicrobial agents.

About T2 Biosystems

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About Hackensack Meridian *Health*

Hackensack Meridian *Health* is a leading not-for-profit health care organization that is the largest, most comprehensive and truly integrated health care network in New Jersey, offering a complete range of medical services, innovative research and life-enhancing care. Hackensack Meridian *Health* comprises 17 hospitals from Bergen to Ocean counties, a behavioral health hospital, and two rehabilitation hospitals. Additionally, the network has more than 500 patient care locations throughout the state which include ambulatory care centers, surgery centers, home health services, long-term care and assisted living communities, ambulance services, lifesaving air medical transportation, fitness and wellness centers, rehabilitation centers, urgent care centers and physician practice locations. Hackensack Meridian *Health* has more than 34,100 team members, and 6,500 physicians and is a distinguished leader in health care philanthropy, committed to the health and well-being of the communities it serves. For additional information, please visit www.HackensackMeridianHealth.org**.**

About the Center for Discovery and Innovation

The Center for Discovery and Innovation, a newly established member of Hackensack Meridian *Health*, seeks to translate current innovations in science to improve clinical outcomes for patients with cancer, infectious diseases and other life-threatening and disabling conditions. The CDI, housed in a fully renovated state-of-the-art facility, offers world-class researchers a support infrastructure and culture of discovery that promotes science innovation and rapid translation to the clinic.

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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, 2019, filed with the U.S. Securities and Exchange Commission, or SEC, on March 16, 2020, 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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