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): June 30, 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 June 30, 2020, T2 Biosystems, Inc. (the "Company") issued a press release announcing preliminary estimated financial results for its fiscal quarter ending June 30, 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 June 30, 2020, the Company issued a press release announcing the completion of validation and the US launch of its COVID-19 molecular diagnostic test, the T2SARS-CoV-2 Panel. 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 8.01 Other Events.

On June 30, 2020, the Company reported the following preliminary unaudited second quarter 2020 financial results:

- Estimated second quarter total revenue is expected to be in the range of $2.4 million to $2.6 million, compared to $1.8 million in the prior year period.
- Estimated second quarter product revenue is expected to be in the range of $1.0 million to $1.1 million, compared to $1.3 million in the prior year period.
- Estimated second quarter research and grant contribution revenues are expected to be in the range of $1.4 million to $1.5 million, compared to $0.5 million in the prior year period.
- During the second quarter of 2020, the Company raised $8.4 million of net proceeds from the sale of 6.4 million shares through its ATM facility.
- Cash and cash equivalents as of June 30, 2020 are expected to be approximately $36.5 million.

On June 30, 2020, the Company also announced the completion of validation and US launch of its COVID-19 molecular diagnostic test. The test was developed by the Company under a license agreement with the Center of Discovery and Innovation at Hackensack Meridian Health and is being commercially distributed after validation for an Emergency Use Authorization request to FDA.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report on Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding the T2SARS-CoV-2 panel's results, the T2Dx® Instrument's simultaneous testing capacity, the ability to target patients under intensive care, the benefit of early identification of bacterial or fungal infections, 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. The preliminary, estimated financial results for the first quarter contained in this Current Report on Form 8-K contain forward-looking statements and 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. You should not place undue reliance on such preliminary information and estimates because they may prove to be materially inaccurate. The preliminary information and estimates have not been compiled or examined by our independent auditors and they are subject to revision as we prepare our financial statements as of and for the quarter ending June 30, 2020, including all disclosures required by U.S. generally accepted accounting principles, and as our auditors conduct their review of these financial statements. While we believe that such preliminary information and estimates are based on reasonable assumptions, actual results may vary, and such variations may be material.

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 Current Report on Form 8-K. Any such forward-looking statements represent management's estimates as of the date of this Current Report on Form 8-K. 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 Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued June 30, 2020 announcing preliminary estimated financial results for the quarter ended June 30, 2020
99.2	Press Release issued June 30, 2020 announcing completion of validation and US launch of its COVID-19 molecular diagnostic test, the T2SARS-CoV-2 Panel

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: June 30, 2020

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

T2 Biosystems Announces Preliminary Second Quarter 2020 Financial Results

Launches the T2SARS-CoV-2™ Panel under FDA EUA Guidelines

LEXINGTON, Mass., June 30, 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 June 30, 2020. In addition, the Company announced the U.S. launch of the T2SARS-CoV-2 ™ Panel, the new molecular diagnostic test for the detection of SARS-CoV-2, the virus that is responsible for COVID-19 infections.

Preliminary Unaudited Second Quarter Financial Results:

- Estimated second quarter 2020 total revenue is expected to be in the range of $2.4 million to $2.6 million, compared to $1.8 million in the prior year period.
    - Estimated second quarter product revenue is expected to be in the range of $1.0 million to $1.1 million, compared to $1.3 million in the prior year period.
    - Estimated second quarter research and grant contribution revenues are expected to be in the range of $1.4 million to $1.5 million, compared to $0.5 million in the prior year period.
- During the second quarter of 2020, the Company raised $8.4 million of net proceeds from the sale of 6.4 million shares through its ATM facility.
- Cash and cash equivalents as of June 30, 2020 are expected to be approximately $36.5 million.

“Amid the COVID-19 pandemic, we have seen increased test utilization at existing U.S. customer sites, a clear sign of the clinical utility of our sepsis-related products,” said John Sperzel, President and Chief Executive Officer of T2 Biosystems. “I am extremely proud of the speed at which our team developed and validated a high-quality SARS-CoV-2 molecular diagnostic test. We are pleased to have met our expedited launch timeline to provide our U.S. customers with a fast and accurate test to assist in the management of COVID-19 patients. Our platform is now able to identify acute COVID-19 infections, and support patients under intensive care who may be susceptible to bacterial or fungal infections.”

The Company expects to provide complete second quarter 2020 financial results in early August.

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, 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 T2Cauris™ Panel, and T2Lyme ™ Panel, as well as additional products for the detection of bacterial and fungal pathogens and associated antimicrobial resistance markers, as well as biothreat pathogens.

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 T2SARS-CoV-2 panel’s results, the T2Dx® Instrument’s simultaneous testing capacity, the ability to target patients under intensive care, the benefit of early identification of bacterial or fungal infections,, 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. The preliminary, estimated financial results for the first quarter contained in this press release contain forward-looking statements and 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. You should not place undue reliance on such preliminary information and estimates because they may prove to be materially inaccurate. The preliminary information and estimates have not been compiled or examined by our independent auditors and they are subject to revision as we prepare our financial statements as of and for the quarter ending June 30, 2020, including all disclosures required by U.S. generally accepted accounting principles, and as our auditors conduct their review of these financial statements. While we believe that such preliminary information and estimates are based on reasonable assumptions, actual results may vary, and such variations may be material.

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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415-937-5406

Exhibit 99.2

T2 Biosystems Announces U.S. Launch of COVID-19 Diagnostic Test

The T2SARS-CoV-2™ Panel will run on the FDA cleared T2Dx® Instrument

LEXINGTON, Mass., June 30, 2020 (GLOBE NEWSWIRE)—T2 Biosystems, Inc. (NASDAQ:TTOO), a leader in the rapid detection of sepsis-causing pathogens, today announced the completion of validation of its COVID-19 molecular diagnostic test, the T2SARS-CoV-2 Panel. The test was developed by T2 Biosystems under a license agreement with the Center of Discovery and Innovation at Hackensack Meridian Health and is being commercially distributed after validation meeting requirements for an Emergency Use Authorization (EUA) request to FDA.

The T2SARS-CoV-2 Panel is designed to detect SARS-CoV-2, the virus that is responsible for COVID-19 infections. The T2SARS-CoV-2 Panel provides sample-to-answer results in less than two hours, utilizing a nasopharyngeal swab sample. Clinical testing on known positive and negative patient samples showed a sensitivity of 95% and specificity of 100%. The T2SARS-CoV-2 Panel runs on the Company's FDA-cleared T2Dx® Instrument, which is a fully-automated, random access system capable of performing seven tests simultaneously.

"We are proud to announce the U.S. launch of our molecular diagnostic test, the T2SARS-CoV-2 Panel, which has demonstrated excellent clinical performance. Adding this test to our existing sepsis-related portfolio illustrates our commitment to transformative diagnostics that improve the lives of patients," said John Sperzel, President and Chief Executive Officer of T2 Biosystems. "Given the susceptibility of critically-ill COVID-19 patients to develop bacterial or fungal co-infections and secondary infections that can lead to sepsis, we believe our platform can be used to identify acute COVID-19 infections, and optimize outcomes for patients under intensive care."

The T2Dx Instrument can also run the Company's FDA-cleared T2Bacteria® Panel and T2Candida® Panel. These panels can detect sepsis-causing pathogens, both bacterial and fungal respectively, directly from whole blood in three to five hours, without the need to wait for a blood culture, which typically takes days to provide results and is not as sensitive. By providing quicker results, the panels enable clinicians to target therapy faster than ever for their patients suspected of sepsis, leading to better patient outcomes, improved antibiotic stewardship, and reductions in length of stay in the hospital.

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