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: **September 8, 2017**
(Date of earliest event reported)

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)	(I.R.S. Employer Identification Number)

101 Hartwell Avenue, Lexington, Massachusetts 02421
(Address of principal executive offices and 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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company x

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. x

Item 8.01 Other Events

On August 4, 2017, T2 Biosystems, Inc. (the "Company") completed a pivotal clinical study of the T2Bacteria® Panel, run on the T2Dx® Instrument, which is a qualitative T2 Magnetic Resonance assay designed for the direct detection of bacterial species in human whole blood specimens from patients with suspected bacteremia. The performance characteristics of the T2Bacteria® Panel were evaluated through a series of analytical studies as well as a multi-center clinical study. The clinical trial evaluated the performance of the T2Bacteria® Panel in comparison to the current standard of care, blood culture. The data generated in the analytical and clinical studies were submitted to the United States Food and Drug Administration in a 510(k) application on September 8, 2017.

The Company is filing as Exhibit 99.1 to this Current Report on Form 8-K additional information concerning data generated in the pivotal clinical trial for theT2Bacteria® Panel, which is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	T2Bacteria® Panel Pivotal Clinical Study Information

EXHIBIT INDEX

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99.1	T2Bacteria® Panel Pivotal Clinical Study Information

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: September 11, 2017

T2 BIOSYSTEMS, INC.

By: /s/ Darlene Deptula-Hicks
Darlene Deptula-Hicks
SVP and Chief Financial Officers

T2Bacteria® Panel Pivotal Clinical Study Information

On August 4, 2017, T2 Biosystems, Inc. completed a pivotal clinical study of the T2Bacteria® Panel, run on the T2Dx® Instrument (T2Dx), which is a qualitative T2 Magnetic Resonance (T2MR®) assay designed for the direct detection of bacterial species in EDTA human whole blood specimens from patients with suspected bacteremia. The T2Bacteria Panel is designed to identify six species of bacteria directly from human whole blood specimens: *Acinetobacter baumannii, Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa,* and *Staphylococcus aureus.*

The performance characteristics of the T2Bacteria Panel were evaluated through a series of analytical studies as well as a multi-center clinical study. The clinical study evaluated the performance of the T2Bacteria Panel in comparison to the current standard of care, blood culture. All of the data generated in the analytical studies and the clinical study were submitted to the United States Food and Drug Administration, or FDA, in a 510(k) premarket notification on September 8, 2017.

The clinical study consisted of two arms, a prospective arm and a seeded arm. In the prospective arm, a total of 1,427 subjects were tested at eleven geographically dispersed and demographically diverse sites in the United States. In the seeded arm, 300 specimens of known bacterial composition were evaluated at three sites. Seeded specimens were prepared by spiking whole blood with multiple strains of the bacterial species detected by the T2Bacteria Panel at defined concentrations (CFU/mL). Fifty negative blood samples also were evaluated as part of the seeded arm of the study. In total, 1,777 (1,427 prospective specimens and 350 seeded and negative) clinical samples were tested to evaluate the clinical performance of the T2Bacteria Panel.

The study findings submitted to the FDA include:

- The overall sensitivity for the prospective and seeded arms combined was 95.8% (see Table 1a below);
    - In the seeded arm of the study, the average sensitivity was 96.8% (see Table 2a), with the sensitivity by bacterial target ranging from 90.9%% to 100.0% (see Table 2b);
    - In the prospective arm of the study, the average sensitivity was 89.7% (see Table 3a), with the sensitivity by bacterial target ranging from 81.3%% to 100.0% (see Table 3b);
- The average specificity for the prospective and seeded arms combined was 98.1% (see Table 1a);
    - In the seeded arm of the study, the average specificity of the test was 99.0% (see Table 2a), with the specificity by bacterial target ranging from 97.3% to 100.0% (see Table 2b);
    - In the prospective arm of the study the average specificity of the test was 97.9% (see Table 3a), with the specificity by bacterial target ranging from 95.0% to 99.4% (see Table 3b);
- In the prospective arm of the study, results that were identified as positive by the T2Bacteria Panel but negative by blood culture were evaluated by looking at additional blood culture results obtained +/- 14 days of the paired T2 / blood culture draw. 36% of the T2 positive / blood culture negative results were found to be culture positive for the organism identified by the T2Bacteria Panel within the defined 14 day window (Table 4).
- In the prospective arm of the study, four specimens that were identified as negative by the T2Bacteria Panel but positive by blood culture were evaluated by running a second archived blood sample.. Two of the four samples generated positive results by the T2Bacteria Panel that were in agreement with blood culture, one for *S. aureus* and the other for *E.coli*.

Table 1a: T2Bacteria Panel Overall Performance for Prospective and Seeded Arms

Sensitivity	95% CI	Specificity	95% CI
95.8% (248 / 259)	92.6%-97.6%	98.1% (10,129/10,323)	97.8%-98.4%

Table 1b: T2Bacteria Panel Combined Performance for Prospective and Seeded Arms

	Sensitivity (PPA)		Specificity (NPA)	
Species	Sensitivity	95% CI	Specificity	95% CI
A. baumannii	97.5% (39/40)	87.1% - 99.6%	99.2% (1713/1727)	98.6% - 99.5%
E. coli	90.9% (30/33)	76.4% - 96.9%	95.4% (1637/1716)	94.3% - 96.3%
E. faecium	100.0% (41/41)	91.4% - 100.0%	99.5% (1717/1726)	99.0% - 99.7%
K. pneumoniae	100.0% (46/46)	92.3% - 100.0%	98.6% (1697/1721)	97.9% - 99.1%
P. aeruginosa	97.7% (43/44)	88.2% - 99.6%	97.7% (1682/1722)	96.9% - 98.3%
S. aureus	89.1% (49/55)	78.2% - 94.9%	98.4% (1683/1711)	97.6% - 98.9%

- PPA (sensitivity) calculated against samples with titer levels at or above limit of detection (LoD) in Seeded Arm and blood culture positives in Prospective Arm
- NPA (specificity) calculated from all samples (including below LoD and unspiked negative samples) as the total number of negative channels divided by total number of non-spiked channels in Seeded Arm and blood culture negatives in Prospective Arm.

Table 2a: T2Bacteria Panel Seeded Sample Performance

Sensitivity (PPA)		Specificity (NPA)	
PPA	95% CI	NPA	95% CI
96.8% (213/220)	93.6 - 98.5%	99.0% (1782/1800)	98.4 - 99.4%

- PPA (sensitivity) calculated against samples with titer levels at or above limit of detection (LoD)

Table 2b: T2Bacteria Panel Seeded Sample Performance

	Sensitivity (PPA)		Specificity (NPA)	
Species	**PPA**	**95% CI**	**NPA**	**95% CI**
A. baumannii	97.5% (39/40)	87.1 - 99.6%	99.7% (299/300)	98.1 - 99.9%
E. coli	90.9% (20/22)	72.2 - 97.5%	97.3% (292/300)	94.8 - 98.6%
E. faecium	100% (40/40)	91.2 - 100%	100% (300/300)	98.7 - 100%
K. pneumoniae	100% (40/40)	91.2 - 100%	99.3% (298/300)	97.6 - 99.8%
P. aeruginosa	97.4% (38/39)	86.8 - 99.5%	97.7% (293/300)	95.3 - 98.9%
S. aureus	92.3% (36/39)	79.7 - 97.3%	100% (300/300)	98.7 - 100%

· PPA (sensitivity) calculated against samples with titer levels at or above limit of detection (LoD)

Table 3a: T2Bacteria Panel Overall Performance for Prospective Arm

Sensitivity	95% CI	Specificity	95% CI
89.7% (35/39)	76.4%-95.9%	97.9% (8,347/8,523)	97.6%-98.2%

Table 3b: T2Bacteria Panel Performance as Compared to Blood Culture — Prospective Arm

	Sensitivity (PPA)		Specificity (NPA)	
Species	**Sensitivity**	**95% CI**	**Specificity**	**95% CI**
A. baumannii	— (0/0)	—	99.1% (1414/1427)	98.4 - 99.5%
E. coli	90.9% (10/11)	62.3 - 98.4%	95.0% (1345/1416)	93.7 - 96.0%
E. faecium	100.0% (1/1)	20.7 - 100%	99.4% (1417/1426)	98.8 - 99.7%
K. pneumoniae	100.0% (6/6)	61.0 - 100%	98.5% (1399/1421)	97.7 - 99.0%
P. aeruginosa	100.0% (5/5)	56.6 - 100%	97.7% (1389/1422)	96.8 - 98.3%
S. aureus	81.3% (13/16)	57.0 - 93.4%	98.0% (1383/1411)	97.1 - 98.6%

Table 4: Percentage of Positive results with negative paired Blood Cultures that were Found to be Culture Positive +/- 14 Days of Paired T2/Blood Culture Draw

Bacteria	Percentage of T2(+)/BC(-) results with other Positive Cultures*
A. baumannii	0/13
E.coli	23/70 (33%)
E. faecium	4/9 (44%)
K. pneumoniae	8/21 (38%)
P. aeruginosa	7/32 (22%)
S. aureus	21/28 (75%)
Total	**63/173 (36%)**
