

T2 Biosystems, Inc.
Form 8-K
September 11, 2017

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
(State or other jurisdiction
of incorporation)

001-36571
(Commission
File Number)

20-4827488
(I.R.S. Employer
Identification Number)

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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 the T2Bacteria® 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

Exhibit No.	Description
99.1	<u>T2Bacteria® Panel Pivotal Clinical Study Information</u>

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