

**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): **July 7, 2016**

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
(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))

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

(c) On July 6, 2016, the Board of Directors (the "Board") of T2 Biosystems, Inc. (the "Company") appointed Dr. Joanne Spodoro, Ph. D., to serve as the Company's Chief Operations Officer, effective upon the date she commences employment with the Company, but no later than September 6, 2016 (the "Appointment Date"). Prior to joining the Company, Dr. Spodoro, 57 years old, was at Immucor from 2010 to March, 2016, her most recent positions being Chief Scientific Officer and Vice President of Worldwide Operations. Dr. Spodoro received her bachelor's degree from Douglass College and her Ph.D. in cell biology from the University of Connecticut.

(e) In connection with her appointment, on June 30, 2016, the Company entered into an offer letter agreement with Dr. Spodoro. Under the terms of Dr. Spodoro's offer letter agreement, she will receive an initial annual base salary of \$350,000 and will be eligible to receive an annual cash bonus award targeted at 45% of her annual base salary (pro-rated for 2016), subject to the attainment of Company and individual performance goals as determined by the Board. Dr. Spodoro will also be eligible to receive relocation assistance, including reimbursement of certain moving, temporary housing and travel expenses as well as reimbursement of taxes incurred on the relocation assistance, in an amount not to exceed \$115,000. Effective as of the Appointment Date, the Company will grant Dr. Spodoro an option under the Company's 2014 Incentive Award Plan to purchase 146,600 shares of common stock of the Company at an exercise price per share equal to the stock's closing price on the NASDAQ market on the grant date. The option will vest as to 25% of the shares subject to the option on the first anniversary of Dr. Spodoro's employment start date and as to the remaining shares in substantially equal monthly installments over the following 36 months, subject to Dr. Spodoro's continued service on the applicable vesting date. Dr. Spodoro has also entered into a Non-Competition, Non-Disclosure and Invention Assignment Agreement with the Company pursuant to which she has agreed to refrain from disclosing the Company's confidential information indefinitely and from competing with the Company or soliciting its employees or consultants for 12 months following termination of her employment.

In addition, on July 7, 2016, Dr. Spadaro and the Company entered into a change of control severance letter agreement. The agreement provides that, if Dr. Spadaro's employment is terminated by the Company without cause within three months preceding or 12 months following a change of control or by Dr. Spadaro for good reason within 12 months following a change of control (with the terms "cause," "change of control" and "good reason" defined in the change of control severance letter agreement), Dr. Spadaro will be entitled, subject to her signing and not revoking a general release of claims in the Company's favor, to receive:

- an amount equal to her annual base salary, payable over a 12-month period following her termination,
- reimbursement for a portion of the COBRA premiums (based on the then-current cost-sharing rates for active employees) for continued medical coverage for up to 12 months following her termination,
- if the termination occurs prior to the first anniversary of her start date, accelerated vesting of the pro-rated portion of her equity awards that would have otherwise vested had she remained employed for one year (with such proration based on the number of months during which she was actually employed) and, after giving effect to such accelerated vesting, accelerated vesting of an additional 25% of her outstanding unvested equity awards, and

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- if the termination occurs on or after the first anniversary of her start date, full accelerated vesting of all of her outstanding equity awards.

Item 7.01 Regulation FD

On July 7, 2016, T2 Biosystems, Inc. (the "Company") issued a press release in connection with the announcements discussed in Item 5.02 above and Item 8.01 below. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 8.01 Other Events

On July 7, 2016, the Company announced its plans to initiate a voluntary recall and replacement of its T2Candida cartridges at certain customer sites. The Company has delayed shipments of new T2Candida cartridges since the last week of the second quarter of 2016 and intends to commence shipping replacement cartridges and replace existing cartridges by no later than the week of July 11, 2016. The cost of these activities is currently estimated to be less than \$750,000, which amount will be incurred as a one-time charge in the second quarter 2016 for recall-related expenses, including inventory impairment.

The Company also announced that it is now expecting to complete the pivotal trial for its T2Bacteria Panel and file with the U.S. Food and Drug Administration (the "FDA") in mid- 2017. The Company now hopes to commercially launch its T2Bacteria Panel in the second half of 2017, as opposed to the first half of 2017 as previously disclosed.

The Company has notified the FDA and other health authorities as required and has issued a press release informing consumers of the foregoing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated July 7, 2016

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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: July 7, 2016

T2 BIOSYSTEMS, INC.

By: /s/ John McDonough
John McDonough
President and Chief Executive Officer

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**Exhibit
No.**

Description

99.1

Press release issued July 7, 2016



T2 Biosystems Announces Preliminary Second Quarter Commercial, Clinical and Executive Personnel Updates

LEXINGTON, Mass., July 7, 2016 — T2 Biosystems, Inc. (NASDAQ: T2OO), a company developing innovative diagnostic products to improve patient health, today announced preliminary commercial metrics for its second quarter, news regarding replacement of products at customer sites, an update on the timing for completing clinical trials for the T2Bacteria® Panel, news from the recent ASM Microbe 2016 conference and the planned appointment of a veteran operations executive to the position of chief operations officer (COO).

For the second quarter ended June 30, 2016, the Company closed six commitments, four domestically and two in international markets. Among these were a leading US academic medical center with multiple affiliated hospitals and another large US regional hospital system. The two international commitments are large and prestigious medical centers in their respective regions. Full results for the second quarter are scheduled to be announced at the close of market on August 2, 2016.

“There is an active, robust pipeline of almost 400 hospital and hospital system prospects, of which approximately 5% are in the late stages of the sales process. That activity, coupled with the growth in the size of our salesforce, has us optimistic about the second half of the year,” said John McDonough, president and CEO of T2 Biosystems. “The approval process for bringing in new diagnostic tests continues to evolve at many hospitals and hospital systems. As we noted following the first quarter, we are also evolving our tactics to further emphasize customer success stories, which we believe are critical to the selling process. While it remains difficult to predict the precise closing dates for contracts each quarter, we believe we can still achieve our goal of closing 45 commitments and contracts this year, the lower end of our previously stated goal for 2016. However, we fully appreciate that the predictability around the timing on closing contracts introduces a degree of uncertainty to achieving that goal, and we will provide an update on our goals in the future, if appropriate.”

T2 Biosystems also is currently reporting to users of the Company’s T2Candida® Panel, that the T2Candida cartridge has recently realized higher than normal “invalid” test results as the cartridge ages. Based on investigative data along with the design of the test, the Company does not believe the identified issue impacts the accuracy of positive and negative test results or has any relationship with the core T2MR® testing technology. While the Company determined that the possible increased invalid test result rate does not present an increased risk to patient health, an abundance of caution led the Company to hold shipment of the cartridges beginning the last week of June. The Company is going to remove current customer inventory in the field and replace it with cartridges that are made using a prior manufacturing process. The Company plans to commence shipping new cartridges within 2 to 5 business days. The Company currently estimates the cost of these activities to be less than \$750,000.

In addition, the shift of internal resources towards reconvening cartridge shipments, along with the scaling of our operations to support multiple products, will impact the

timing for completing the T2Bacteria Panel pivotal trial. To be prudent, the Company is pushing out the expected timeline for the completion of that trial and now is targeting completing the trial and filing with the FDA in mid-2017.

McDonough continued, “In addition to the operational activity at the close of the quarter, two significant activities also bear noting. First, customer presentations at the ASM event in June were exceptionally positive and confirm the clinical and economic value our technology is delivering to patients and those institutions adopting the system. Both oral as well as poster presentations presented by early T2Candida Panel adopters communicated the kind of case studies, experiences and data that lead to peer-to-peer selling — an important element as we pursue a commercial tipping point. In addition, our own symposium, which attracted 75 attendees in 2015, grew this year to more than 200 attendees.

“Finally, and importantly, I am happy to report that Joanne Spadaro, Ph.D., has agreed to join T2 Biosystems as chief operations officer,” McDonough added. “Joanne has been a key contributor at T2 for many years — first as a member of our Scientific Advisory Board and most recently as an operational consultant. Prior to joining T2, Joanne was the chief scientific officer and vice president of worldwide operations at Immucor and senior vice president at Roche Molecular Systems heading its global development and operations functions. Joanne will continue as a full-time consultant over the coming six to eight weeks and will become COO thereafter.”

Conference Call

T2 Biosystems’ management will provide commentary including a Q&A session to discuss the stop shipment issue as well as today’s commercial and regulatory update on a conference call beginning at 4:30 p.m. Eastern Time today, Thursday, July 7. To join the call, participants may dial 1-877-407-4018 (US) or 1-201-689-8471 (International). To listen to the live call via T2 Biosystems’ website, go to www.t2biosystems.com, in the Events & Presentations section. A webcast replay of the call will be available for 30 days following the conclusion of the call in the Events & Presentations section of the website.

About The T2Candida Panel

The T2Candida Panel is the first sepsis pathogen diagnostic that provides species-specific results in three to five hours without the need for blood culture, which can take up to six days to provide a result. The rapid detection of *Candida* enables physicians to provide targeted treatment quickly, and research has shown this can reduce a positive sepsis patient’s length of stay in the hospital by almost nine days at a cost savings of approximately \$26,887. A rapid negative result can prevent unnecessary administration of antimicrobials, further reducing costs. In addition, a rapid negative result can prevent or reduce antimicrobial resistance, which the Centers for Disease Control and Prevention has designated a Serious Threat.

About T2 Biosystems

T2 Biosystems is focused on developing innovative diagnostic products to improve patient health. With two FDA-cleared products targeting sepsis and a range of additional products in development, T2 Biosystems is an emerging leader in the field of *in vitro* diagnostics. The Company is utilizing its proprietary

T2 Magnetic Resonance platform, or T2MR®, to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical

professionals make targeted treatment decisions earlier. T2MR enables the fast and sensitive detection of pathogens, biomarkers and other abnormalities in a variety of unpurified patient sample types, including whole blood, eliminating the time-consuming sample prep required in current methods. For more information, please visit www.t2biosystems.com.

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. 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, the performance of the Company's diagnostic products and the ability to bring such products to market. 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. For more information on risk factors for T2 Biosystems, Inc.'s business, please refer to the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 9, 2016, under the heading "Risk Factors," and other filings the Company makes with the Securities and Exchange Commission from time to time. 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, it disclaims any obligation to do so, even if subsequent events cause its views to change. 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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