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): May 29, 2018

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))

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 May 29, 2018, T2 Biosystems, Inc. (the "Company") held a conference call to discuss financial guidance for the remainder of fiscal year 2018. A copy of the transcript of the conference call 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 are 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 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Transcript of conference call held by T2 Biosystems, Inc. on May 29, 2018

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 4, 2018

T2 BIOSYSTEMS, INC.

By: /s/ John McDonough
John McDonough
CEO & President

Business Update and Financial Guidance
Conference Call Script

John McDonough – CEO Commentary

John Sprague – CFO Commentary

Zack Kubow (W2O) - Moderator

May 29, 2018 – 8:30 a.m. ET

Leader Dial-In Number: 1-877-808-1531 or 1-201-493-6782
Conference ID: 13680514

Operator:

Good morning, ladies and gentlemen. Thank you for standing by, and welcome to the T2 Biosystems conference call to discuss the FDA clearance of the T2Bacteria Panel. At this time, all participants are in a listen-only mode. Later, we will conduct a question and answer session and instructions will follow at that time. It is now my pleasure to turn the call over to Zack Kubow, of the W2O Organization.

Please go ahead, sir.

Zack Kubow

Thank you, operator, and good morning everyone. Thanks for joining us for the T2 Biosystems conference call to discuss the news issued this morning that the FDA has cleared the T2Bacteria Panel for marketing in the US. On the call today are President and CEO, John McDonough, and Chief Financial Officer, John Sprague. The executive team will open the call with some prepared remarks, followed by a question-and-answer period.

I would like to remind everyone that comments made by management today and answers to questions will include forward-looking statements. Those include statements related to T2 Biosystems' future financial and operating results and plans for developing and marketing new products. Forward-looking statements are not guarantees of future performance and are based on estimates and assumptions as of today and are subject to risks and uncertainties that may cause actual results to differ materially from those expressed or implied by those statements, including the risks and uncertainties described in T2 Biosystems' Annual Report on Form 10-K filed with the SEC on March 19, 2018. The company undertakes no obligation to publicly update or revise any forward-looking statements, except as required by law.

With that, I'd like to turn the call over to President and CEO, John McDonough .. Congratulations John, please go ahead.

John McDonough:

Thank you, Zack. Good morning, everyone, and thank you for joining us to discuss what we believe may be the most important milestone to date at T2 – FDA clearance of the T2Bacteria Panel. We believe this will be a significant growth catalyst for the Company because it allows us to roll out a more complete solution for diagnosing the pathogens associated with sepsis - a solution that we believe is capable of fundamentally improving the process of detecting,

managing and ultimately minimizing the terrible impact of sepsis. This is a significant development for the Company, the hospitals and the healthcare providers serving patients at risk for sepsis.

T2Bacteria is the first and only diagnostic that can identify specific sepsis-causing bacterial pathogens directly from a whole blood specimen in approximately five hours, without the need to wait for the results of a blood culture. This represents a major breakthrough in the field of diagnostics, and more specifically, in the management of patients at risk for sepsis, which continues to be one of the most costly issues – both in terms of mortality rates and actual dollars spent – in the healthcare system today. The T2Bacteria Panel, combined with the already FDA-cleared T2Candida Panel, may allow hospitals to identify up to 90% of the bacterial and fungal infections that are not effectively treated with broad-spectrum antibiotic drugs, a regimen that is typically initiated immediately when a patient is suspected of having an infection.

To appreciate this step forward, it is helpful to understand the limitations to date of the diagnosis and treatment of patients suspected of having a bloodstream infection, which leads to sepsis when not effectively treated. In order to successfully treat such patients with the correct targeted antibiotic, a clinician needs to know the species-specific pathogen responsible for the infection. Blood culture, the only other method to diagnose a bloodstream infection, takes up to five days and even then detects only 50-65% of the infections with the first culture. Because of blood culture's poor rate of diagnosing infections, clinicians often run four blood cultures for each patient, spread out over a period of time, in the hope that they can improve the rate of detection. But even with that marginal accuracy, the time required to run the additional blood cultures further delays the time to result. Meanwhile, for every hour that passes without the correct matching of the pathogen to the targeted medication, the estimated mortality rate for the patient increases by almost eight percent.

Because of the limitations associated with blood culture, physicians and hospitals have had to devise clever, probability-based protocols where they treat patients with drugs before they receive the blood culture results, in the hope that they can administer the right targeted therapy faster than if they were to wait for the blood culture results. If they didn't do so, the mortality rate for sepsis would be far higher. This process, known as empiric therapy, is used because the clinicians know if they can treat the patient with the right targeted therapy sooner, they may save the life of the patient. But these probability-based protocols have issues: targeted therapy for the patient can be delayed by days; many patients never receive the right therapy; and most patients receive drugs they don't actually need, which is expensive to the hospital, can have negative consequences to the patient, and is a primary cause of the growing issue of antimicrobial resistance.

I am happy to say that we believe today's announcement may mark the beginning of the end of the probability-based approach to managing bloodstream infections and sepsis, and its potential replacement with a fact-based system that provides rapid and accurate diagnostic results that can potentially place more than 90% of patients suspected of a bloodstream infection on the right targeted therapy within six to eight hours, reduce related deaths by an estimated 50%,

reduce the long-term side effects for patients that survive, and save billions of dollars for hospitals as the consequences of sepsis become more preventable. Published data suggests that a hospital can save in the range of $25,000 per infection if a patient can be placed on the right targeted therapy within 24 hours of presenting with symptoms. And customers that have adopted our T2Candida product, which provides many of the same benefits as the T2Bacteria Test Panel, have been reporting similar per-infection cost savings.

Before I provide additional color on the benefit of T2Bacteria, our plans for the commercial launch, and our expectations for revenue growth, I want to take a step back to remind everyone of some of the facts about bloodstream infections, sepsis and why we are excited to be able to improve patient care for this condition:

1. We estimate that there are approximately 8.75 million patients in the United States each year that are at a high risk for, or suspected of having, a sepsis-causing pathogen infection, and there are more than 1.6 million diagnosed cases of such infections each year. Based on 8.75 million such patients, we estimate that our total addressable market, in the United States alone, for T2Bacteria and T2Candida together is over $1.5 billion, and over $2 billion on a worldwide basis.
2. Approximately 40% of the diagnosed patients receive ineffective initial therapy. Therapy decisions within hospitals are currently based primarily on probability-based, empiric protocols and would benefit from screening all patients suspected of having an infection with the T2Bacteria Panel, enabling more patients to receive the right targeted therapy faster.
3. Patients with sepsis-causing pathogen infections have a 20% to 40% mortality rate, and as I mentioned, it is estimated that every hour of delayed treatment increases mortality rates nearly 8% - which also means that getting patients on the right targeted therapy faster can reduce mortality rates by that same 8% per hour!
4. Earlier targeted therapy for sepsis-causing pathogens may prevent a bloodstream infection from progressing to sepsis.
5. So, with that as background, it shouldn’t be surprising that sepsis contributes to nearly one in two hospital deaths, with approximately 250,000 deaths per year in the United States.
6. For context, sepsis claims more lives annually than breast cancer, prostate cancer and AIDS, combined.
7. Sepsis is the most expensive hospital-treated condition in the United States, representing $27 billion in annual healthcare costs.

8. Sepsis is the most frequent and costly cause of hospital readmissions, and these readmissions are two to three times more likely and nearly two to three times more costly compared to other causes of hospital readmission.

Our objective is to have T2Bacteria implemented as a part of a hospital's standard sepsis protocol, which is typically used to identify patients suspected of having sepsis and the diagnostic and therapeutic approaches that are automatically taken with those patients. By being a part of the sepsis protocol, physicians would not need to order the test, but instead T2Bacteria would be automatically ordered and, as a result, we believe probability-based approaches, which are currently used to determine what drugs to give these patients, would be improved profoundly.

So clearly, there is a need and a benefit to the key stakeholders in the healthcare system – the patient, the hospital and the payor. But we have the experience to know that while there are institutions that have been waiting for the approval, the T2Bacteria Panel will not sell itself and we therefore have a commercial plan in place that is being implemented as we speak.

We have been preparing for the launch of T2Bacteria for two years and are confident that we have the team and strategy in place to hit the ground running. Here are a few elements of that plan and facts we look to as positive signs of market interest:

- We will support the T2Bacteria launch with focused marketing efforts that include medical education and awareness to key stakeholders including webinars, live speaking events and major conferences. We will have our first major opportunity to showcase T2Bacteria as a commercial product at the American Society for Microbiology meeting which is timely for us as it begins on June 7th. We will have a strong presence at the conference to drive traffic to our booth along with new "late-breaker" data. We are pleased that there will be five poster presentations on T2 products at the meeting, including four on T2Bacteria, from clinical and scientific experts highlighting the T2 product performance and technology platform.
- Our sales team is fully trained and ready to go. A pipeline of hospitals have expressed a keen interest in adopting our technology.
- We have a total sales team of 20 people in the United States and will likely add 3 to 5 additional people in the coming months – this is on par with other successful laboratory system launches and we believe it is adequate to cover the high-throughput hospitals that represent our initial target market.
- Our sales and marketing focus will initially be on the top 1,200 hospitals in the United States, and each member of the sales team has identified target accounts.
- Our sales team is focused heavily on our existing base of T2Candida customers who already have T2Dx instruments in place that can run T2Bacteria. We expect to convert a high percentage of these customers over the coming quarters since we believe the majority of T2Candida users are satisfied with its results and understand the value in adopting both tests.

- Our sales funnel activity has accelerated over the past six months based on interest in the pending FDA clearance of T2Bacteria, as evidenced by the three times increase in the number of customer proposals in Q4 and Q1 combined as compared to the previous two years. We are squarely focused on closing those opportunities as fast as possible.

As John Sprague will discuss, we believe the FDA clearance of the T2Bacteria Panel and the launch of a more complete Sepsis Solution will drive an acceleration in the adoption and utilization of the T2Dx system that will allow us to double our revenue in each of the next two to three full years. Let me walk you through the reasons we are confident that we will be successful in doing so.

1) T2Bacteria and T2Candida represent a potential game changer in the management of patients suspected of sepsis. We have the only FDA-cleared products that identify specific sepsis-causing pathogens directly from a whole blood specimen, without the need to wait for the results of a blood culture, and hence provide a huge time and accuracy advantage over every other approach in the market. Let me pause here to emphasize that fact as we continue to hear confusing messages in the marketplace. We are the ONLY technology that can detect and identify these infections from a whole blood sample without waiting for it to culture. We are not aware of any other technology that has produced even close to the quality of clinical data showing the ability that we have, and our technology is protected by over 60 issued patents with 40 additional patents in process.

2) We estimate that the total addressable worldwide market for T2Bacteria and T2Candida combined is over $2 billion. We understand that adoption will follow a typical new technology adoption curve and that data, publications and customer testimonials will drive new placements and revenue growth. But we believe the need for our products is extraordinary due to the value we provide for patients and hospital economics.

3) Our approach of detecting pathogens directly from blood and without the need for blood culture has already been proven with the T2Candida Panel, where we have seen hospitals report improved sepsis management and millions of dollars of annual costs savings by getting patients aligned to the right treatment sooner. This data and these testimonials will be helpful in driving adoption of T2Bacteria.

4) As we have already reported over the past two quarters, there has been robust interest in the T2Bacteria Panel from new and existing customers, resulting in a meaningful increase in proposals delivered, two existing Candida customers have already signed contracts for T2Bacteria, and 11 research use only systems are already in the field. We expect with FDA clearance in hand, we will be able to begin converting many of these proposals to installations while also driving continued development of our sales pipeline.

5) Finally, we had an existing installed base of 70 instruments placed or contracted to be placed as of March 31st, covering 162 hospitals in the United States and worldwide, providing access to an estimated almost 520,000 high-risk patients that could be tested with T2Candida and T2Bacteria. The majority of this opportunity will be for T2Bacteria – so clearly we have a robust opportunity with our current customers alone.

With that as a background, I will turn the call over to John Sprague to discuss our financial guidance. John…

John Sprague:

Thank you, John.

The following forward-looking statements reflect estimates based on information as of May 29, 2018 and are subject to uncertainty. Additional information is available under the heading “Forward-Looking Statements.”

With the FDA clearance of the T2Bacteria Panel, we are now prepared to provide guidance for the full year 2018.

We expect total 2018 revenue to be $10.0 million to $12.0 million, with product revenue in the range of $4.5 million to $5.9 million. Research revenue is expected to be in the range of $5.5 million to $6.1 million.

We expect revenue to double in each of 2019 and 2020 and to achieve total revenue in 2020 in the range of at least $50 million.

In the second half of 2018, we expect to close contracts for the placement of 20 to 25 instruments that provide access to at least 75,000 patients suspected of sepsis. We expect approximately 70% of these instruments to be placed in the United States.

For new instrument placements, it typically takes three to six months before systems go live and patient testing commences as hospitals are required to validate any new diagnostic tests or instruments. During this period, the Company typically receives nominal revenue unless the instrument has been purchased by the hospital, which in the United States occurs about 15% of the time. International distributors typically purchase instruments at a 30% discount off the list price of $100,000 per instrument.

We expect the average sales price for T2Bacteria to be $150 and for T2Candida to hold at $200 per test. International distributors typically receive about a 30% discount.

We estimate that a single T2Dx instrument is capable of running about 3,000 tests per year. Over time, as patient testing grows in the hospital, we expect each T2Dx instrument to generate about $300,000 in annual revenue from the combination of T2Bacteria and T2Candida testing.

We estimate that we will achieve cash flow break-even between $65 million and $75 million in annual revenue. We expect our gross margins to be approximately 45% to 50% at these revenue levels.

Regarding operating expenses, as discussed on our last call, we expect second quarter 2018 operating expenses, excluding cost of product revenue, to be $10.0 million to $10.5 million, including non-cash stock based compensation and depreciation expenses of $2.0 million. We expect quarterly operating expenses to stay in the range of $10.0 million to $11.0 million per quarter in the second half of 2018, including non-cash stock based compensation and depreciation expenses of approximately $2.0 million each quarter.

Thank you and back to John McDonough for closing remarks.

John McDonough:

Thank you, John. In summary, with the FDA clearance of T2Bacteria, we are now poised to enter the next chapter at T2 Biosystems. Sepsis is a significant issue in the United States and around the world, and we believe the combination of T2Bacteria and T2Candida represents a breakthrough in the ability of physicians and hospitals to finally manage patients at risk for sepsis using accurate, fact-based assessments and not probabilities alone. Our vision is to drive broad adoption of T2Bacteria, which we believe can have the following positive effects:

1. A potential reduction in patient mortality by as much as 50%.
2. A 25% or greater reduction in the cost of sepsis to hospitals.
3. A reduction in the use of antibiotic drugs, which is the primary cause of resistance and the emergence of superbugs.
4. For sepsis survivors, an improvement in their long term health as the after-effects of sepsis can linger for months, years or the rest of the patient's life.

Given this significant opportunity to impact patient care, we believe the FDA clearance of T2Bacteria will put T2 Biosystems on a new and accelerated growth trajectory as the number of installed systems grows and testing at hospitals grows in multiples, which should then result in a significant inflection in our revenue ramp. This will also position us to continue advancing our exciting pipeline of diagnostics that meet critical unmet needs in healthcare, including the T2Lyme Panel, which officially tested the first patient in the beginning of an FDA clinical trial this quarter.

Thank you for your participation in today's call and for your continued interest in T2 Biosystems. That concludes our prepared remarks. Operator, we'll now open the call for questions.