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 6, 2021

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 May 6, 2021, T2 Biosystems, Inc. (the "Company") held a conference call to discuss its financial results for its fiscal quarter ended March 31, 2021. 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 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 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Transcript of conference call held on May 6, 2021

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: May 11, 2021

T2 BIOSYSTEMS, INC.

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

Philip Taylor

Thank you operator. 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 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 these statements, including the risks and uncertainties described in T2 Biosystems' annual report on Form 10-K filed with the SEC on March 31, 2021, and other filings the company makes with the SEC from time to time. The company undertakes no obligation to publicly update or revise any forward-looking statements, except as required by law.

With that, I would like to turn the call over to President and CEO, John Sperzel. John?

John Sperzel

Thank you for joining our first quarter 2021 earnings conference call. Today, I will review the company's first quarter performance and provide updates on the progress across our three corporate priorities. I will then turn the call over to John Sprague, who will review our financial results for the first quarter, before I make some closing remarks and we open the call for questions and answers.

During the first quarter, the T2 Biosystems team generated total revenue of $7.0 million, an increase of 173% compared to the prior year period. Product revenue during the first quarter was $4.7 million, an increase of 345% compared to the prior year period. In addition to contributions from our COVID-19 diagnostic test, the T2SARS-CoV-2 Panel, which ended the first quarter with annualized test utilization of $214,000 per COVID-19 driven instrument, the annualized test utilization for our U.S. sepsis tests, T2Bacteria and

T2Candida, was robust year-over-year and in sequential quarters. The annualized sepsis test utilization in the first quarter was $111,000 per instrument, up from $60,000 in the prior year period, a year-over-year increase of 85%, and up from $84,000 in the fourth quarter of 2020, a sequential quarterly increase of 32%.

We continue to advance our mission: to fundamentally change the way medicine is practiced through transformative diagnostics that improve the lives of patients around the world. While COVID-19 presented a new and challenging opportunity to demonstrate the capabilities of our technology and our commitment to our mission, I want to reiterate that sepsis is our primary focus. Our novel sepsis test panels – T2Bacteria, T2Candida, and T2Resistance – offer potentially lifesaving benefits for patients and cost saving benefits for hospitals. We believe that the clinical benefits of our sepsis products, and the clear need to improve the standard of care for sepsis management, will lead to greater adoption and increased utilization of our products. We are committed to establishing our T2Dx Instrument and sepsis test panels as the standard of care.

The current standard of care for patients at risk of sepsis relies on broad, empiric protocols to administer antimicrobial therapy, despite the fact that such protocols are only optimal in approximately half of cases. To further complicate matters, the current standard of care for the detection of sepsis-causing pathogens continues to rely on a positive blood culture in order to target therapy for patients that are suspected of sepsis. Blood cultures are diagnostic tests that are intended to identify the presence of a blood stream infection. Due to their poor sensitivity, blood cultures often require multiple samples of blood from critically ill patients, and take anywhere from 1-5 days to achieve the growth necessary for pathogen identification. Additional testing, such as traditional microbiology or post-culture molecular diagnostic tests, may be required for determination of species ID and susceptibility.

The results achieved with this current standard of care are both disheartening and alarming. Sepsis is the leading cause of death in U.S. hospitals – claiming the lives of nearly 270,000 Americans *each year* – and the leading cost of U.S. hospitalization. In

2020, the U.S. Department of Health and Human Services estimated that the cost of sepsis care for patients in hospitals and skilled nursing facilities was more than $62 billion. In addition, the patients who survive sepsis may face hospital readmission due to reoccurrence of sepsis, limb amputation due to complications of sepsis, and long-term physical and psychological affects due to post-sepsis syndrome.

As a sepsis survivor, I understand the impact our technology can have for patients, hospitals, and the broader healthcare system. Several years ago, following a life-saving heart transplant, I acquired several multidrug-resistant bacterial infections while in the hospital, and I was diagnosed with sepsis. I was treated with broad spectrum antibiotics and, after having suffered severe nerve damage in both legs, spent nearly a month in a rehabilitation hospital where I had to learn how to walk again. I was discharged from the hospital and, after spiking a temperature, I was immediately readmitted to finally receive the appropriate targeted antibiotic treatment. Had the T2Dx Instrument been present in my hospital, the pathogen that led to my sepsis diagnosis could have been identified in 3-5 hours.

I recently published a book about my personal experience to help raise awareness about sepsis, which I am using to shed light on why we must change the standard of care for patients at risk of sepsis. The book is titled “Courage: Powerful Lessons in Leadership, Strength, and the Will to Succeed” and I am donating 100% of the sales to Sepsis Alliance and Donate Life America, the nation’s leading organizations for sepsis and organ donation.

Our aim at T2 Biosystems is to change the standard of care by enabling targeted therapy, faster (i.e., within 3-5 hours of the first blood draw). This is critical as each hour of delayed, targeted treatment can increase patient mortality rates by up to eight percent. Our T2Dx Instrument combined with our sepsis tests, the T2Bacteria and T2Candida Panels, offer the first and only FDA-cleared products able to detect sepsis-causing pathogens directly from whole blood in only 3-5 hours, without the need to wait days for a positive blood culture.

To further T2 Biosystems' mission and create shareholder value, we have outlined three corporate priorities for 2021 that we believe will position the company for long-term success: 1) accelerating our sales, 2) enhancing our operations, and 3) advancing our pipeline.

We'll start off by addressing our first priority – accelerating our sales

On our last call, we identified three commercial priorities intended to accelerate our sales: 1) to transition instruments sold in the U.S. during the second half of 2020 from COVID-19 testing to sepsis testing, 2) to increase sepsis test utilization in our legacy installed base, and 3) to expand our T2Dx Instrument installed base.

To accomplish these objectives and expand our commercial reach, we have rebuilt our U.S. sales team. We understand that driving adoption of our T2Dx Instrument and fully implementing the use of our tests and integrating them into sepsis protocols within U.S. hospitals requires a clinically focused sales team. In late 2020, we created a geographic sales model with 10 Regional Account Managers across the U.S. and we have filled all but one of those positions.

Our U.S. Regional Account Managers are sales professionals with broad experience selling capital equipment into the hospital market across multiple stakeholders, and understand the system-wide sales process. They have completed a training program designed to articulate the clinical and economic value proposition to the whole hospital – clinicians, laboratorians, hospital administrations, antimicrobial stewardship committees and sepsis committees. In combination with our Field Application Specialists and Medical Affairs Specialists, we now feel that we have the right structure and team in place to accelerate adoption and continue to increase the utilization of our sepsis products.

Our newly appointed Chief Medical Officer, Dr. Aparna Ahuja, and the Medical Affairs department are generating evidence to support the clinical and health economic value of our products both internally and through collaborations with industry thought leaders. We

expect to see data published and presented at key medical conferences throughout 2021, which is important as we seek to build greater awareness of our products in the medical and scientific community. Dr. Ahuja is also leading the creation of our scientific advisory board and building our Clinical Affairs team as we prepare to initiate multiple clinical studies.

Expert Review of Medical Devices, a peer reviewed medical journal, recently published a meta-analysis, exemplifying the clinical and economic benefits of our products. We believe this data will be a powerful tool for our sales and marketing teams. This meta-analysis includes data from 14 clinical studies evaluating the use of our sepsis products in the U.S. and internationally. According to the meta-analysis, as compared to blood culture, the use of T2 Biosystems' diagnostic products reduced the time to pathogen detection by 81 hours, reduced the time to species identification by 77 hours, accelerated the time to administration of targeted antimicrobial therapy by 42 hours, accelerated the time to de-escalation of patients from empiric therapy by 7 hours, decreased the length of patients' ICU stay by 5 days, and decreased the length of patients' hospital stay by 4.8 days. The authors conclude that, in addition to significant clinical improvements and efficiencies, this could theoretically reduce hospital costs by as much as $25,000 per patient tested. This independent third-party publication further demonstrates the potential impact that the T2Bacteria and T2Candida Panels can have on improving clinical and health economic outcomes.

While U.S. COVID-19 cases have decreased since the peak in January, our T2SARS-CoV-2 Panel continues to be a valuable tool for our U.S. hospital customers. We believe U.S. hospitals will continue their COVID-19 testing efforts during 2021, especially as new COVID-19 variants emerge, like the B.1.617 variant currently spreading in India. We previously announced that the T2SARS-CoV-2 Panel is capable of detecting the Brazil, U.K. and South Africa variants – based on sequence and in silico analysis – and I am pleased to confirm that the T2SARS-CoV-2 Panel is also capable of detecting the India B.1.617 variant based on the same analysis.

While the COVID-19 pandemic has limited access to hospitals, we anticipate increased access to hospital personnel as the year progresses, and to a greater extent during the second half of this year. We believe this provide greater opportunity to sell new T2Dx Instruments for sepsis testing, add sepsis test panels to customers that are currently utilizing only the T2SARS-CoV-2 Panel, and to drive broader adoption of sepsis test panels in legacy sepsis accounts. This is why we expect 70% of 2021 T2Dx Instrument sales to occur in the second half of the year, and to be used primarily for sepsis testing.

This has been our strategy since the onset of the pandemic, and the reason we have only been selling our instruments to prequalified U.S. hospital microbiology lab customers with a stated interest in evaluating the use of T2Bacteria and T2Candida Panels for integration into their sepsis treatment protocols.

As previously stated, our commercial focus in 2021 remains on driving adoption and utilization of our sepsis products. We remain on track to close at least 30 T2Dx Instrument contracts during 2021. Our new U.S. salesforce is actively calling on targeted customers, both virtually and in person, and we are advancing toward our 2021 sales objectives. I am pleased to report that during April we sold T2Dx Instruments to two of the leading U.S. hospitals, which will be used for routine sepsis testing.

Moving on to our second priority: enhancing our operations

In 2021, we will continue to prioritize enhancing operations across our business, including improvement in product gross margins and operating cost structure.

Over the last 12 months, we have significantly scaled our manufacturing capabilities and strengthened our supply chain relationships. We believe this is important for the future success of the company, as we advance our product pipeline and continue to enhance our operations. While the increased volume has a favorable impact on overhead absorption, we are continuing to pursue a number of cost improvements initiatives aimed at improving product gross margins and increasing the company’s overall efficiency.

Finally, I will now address our third strategic priority: advancing our pipeline

We intend to extend our technology lead by broadening our capabilities for the detection of sepsis-causing pathogens from whole blood samples. Our ongoing focus has been on advancing the programs outlined in our product development contract awarded in 2019 by the Biomedical Advanced Research Development Authority (BARDA). The total value of the contract is up to $69 million paid upon the achievement of certain milestones and defined contract phases.

We completed the Base Phase of the contract during the third quarter of 2020, and we are currently working toward fulfilling the milestones under Option 1 of the contract. As I previously stated, our new product development programs have been running ahead of schedule and under budget, which provided an opportunity to revisit the terms with the BARDA team, including the schedule.

Today, we announced that we have modified the terms of our existing BARDA contract that will allow us to accelerate our project milestones in Option 1 for our comprehensive sepsis panel, the next generation instrument, and the biothreat panel. We have recently hired a number of employees to accelerate these programs under the terms of the BARDA contract, including the schedule and funding.

The comprehensive sepsis panel is a direct-from-blood test panel designed to detect approximately 99% of all bloodstream infections caused by bacterial and *Candida* species and antibiotic resistant markers identified as threats by the CDC, in a single test with a time to result of approximately three hours. We believe this comprehensive sepsis panel has the potential to totally disrupt the traditional blood culture workflow and become the new standard of care.

The next generation instrument is designed to be fully automated and random access, like our current T2Dx Instrument. The instrument is being designed in parallel with the comprehensive panel, to detect an increased number of pathogens and resistance genes from a single, whole blood sample independent of blood culture.

The biothreat panel is a direct-from-blood panel designed to detect six biothreat pathogens from a single patient sample, and run on the FDA cleared T2Dx Instrument.

Today, we also announced that BARDA has agreed to include milestones for the T2Resistance Panel that will enable T2 Biosystems to commercialize this product in the U.S. market. While we are currently selling the T2Resistance Panel in Europe under CE mark, we need to conduct additional verification and validation studies, as outlined by the FDA through the pre-submission process, to initiate the clinical trial needed to pursue FDA 510k clearance.

To frame the opportunity, more than 2.8 million antibiotic-resistant infections occur in the U.S. each year, and more than 35,000 people die as a result. Unfortunately, these patients are typically on empiric therapy or therapies that do not adequately treat the resistant infection in a timely manner, as the current standard of care for identifying these resistance markers also relies on blood culture workflow. We believe the T2Resistance Panel can be a game-changer for many of these patients, providing results in hours instead of days, enabling clinicians to target therapy for patients with resistant infections faster than ever before.

In 2017, CARB-X (which is funded by both BARDA and the Wellcome Trust), awarded T2 Biosystems $2.0 million to support the development of the T2Resistance Panel, designed to detect 13 resistance genes from both gram-positive and gram-negative pathogens directly from a whole-blood specimen, without the need for blood cultures. In 2019, the FDA granted “Breakthrough Device” designation for the T2Resistance Panel, reflecting the purpose of the test panel to rapidly identify resistant infections. We believe this test will enable more patients to get on the right targeted therapy faster, potentially reducing mortality and hospitalization cost and we are excited to continue our partnership with BARDA on this critical product.

With that, I will now turn the call over to John Sprague to go over the details of our first quarter financial results.

John Sprague

Thank you, John.

Total revenue for the first quarter of 2021 was $7.0 million, an increase of 173% compared to the prior year period. Product revenue was $4.7 million, an increase of 345% compared to the prior year period driven primarily by increased sepsis and COVID-19 test sales. Research contribution revenue was $2.3 million, an increase of 54% compared to the prior year period driven by increased BARDA contract activities.

For the first quarter of 2021 product costs were $5.8 million, an increase of $1.1 million compared to the prior year period, driven by increased sales. Research and development expenses were $4.7 million, an increase of $0.4 million driven by increased BARDA contract activities. Selling, general and administrative expenses were $6.2 million, a decrease of $1.0 million driven by lower headcount.

Net loss for the first quarter of 2021 was $(10.7) million, ($0.07) per share, compared to a net loss of $(14.9) million, ($0.22) per share for the prior year period.

Total cash was $43.9 million as of March 31, 2021, including marketable securities and restricted cash. We filed a new Form S-3 registration statement and established an ATM facility in March to allow the Company to sell common stock; to date we have not sold any stock under the facility.

Reiterating guidance, we continue to expect total revenue for the full year 2021 of $24.0 million to $26.0 million, including product revenues of $16.0 million to $18.0 million and research and contribution revenues of $8.0 million, and we expect to close at least 30 T2Dx Instrument contracts in 2021.

Thank you and back to John Sperzel for closing remarks.

John Sperzel

Entering 2021, we set forth three corporate priorities: accelerating our sales, improving our operations, and advancing our pipeline. We are very pleased with our progress during the first quarter, which included total revenue growth of 173% and product revenue growth of 345%, compared to the prior year period.

Most importantly, our sepsis test sales continue to increase, with an 85% increase compared to the prior year period, and a 32% sequential increase compared to the prior quarter. We have rebuilt a clinically focused U.S. sales team to drive greater adoption of our novel sepsis products and we are strengthening our medical and clinical affairs teams to generate additional clinical and economic data and to support our customers.

We continue to enhance our internal operations which have resulted in a more favorable cost structure and we remain excited about our product pipeline, including the T2Resistance Panel, and our opportunity to lead the change in the standard of care for the management of patients suspected of sepsis.

We will now open it up to questions. Operator?