
**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): August 5, 2021

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))

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 August 5, 2021, T2 Biosystems, Inc. (the “Company”) issued a press release announcing its financial results for its second quarter ended June 30, 2021 and held a conference call to discuss those results. A copy of the Company’s press release and a copy of the transcript of the conference call are furnished with this report as Exhibits 99.1 and 99.2, respectively.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 and Exhibits 99.1 and 99.2 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 Exhibits 99.1 and 99.2 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

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 99.1 | Press Release issued August 5, 2021 |
| 99.2 | Transcript of conference call held on August 5, 2021 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

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: August 10, 2021

T2 BIOSYSTEMS, INC.

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



T2 Biosystems Announces Second Quarter 2021 Financial Results

LEXINGTON, Mass., August 5, 2021 (GLOBE NEWSWIRE)—T2 Biosystems, Inc. (NASDAQ:TTOO), a leader in the rapid detection of sepsis-causing pathogens, today announced financial results for the three months ended June 30, 2021.

Recent Highlights

- Achieved second quarter 2021 revenue of \$6.7 million, including product revenue of \$3.7 million, representing growth of 162% and 253%, respectively, compared to the prior year period
- Generated second quarter U.S. sepsis test panel utilization annualized run rate of approximately \$98,000 per legacy sepsis instrument
- Sold 3 T2Dx® Instruments during the second quarter and achieved routine use for T2Bacteria® and T2Candida® Panels in 3 additional accounts following tenders won in Austria, France, and Kuwait
- Received New Technology Add-on Payment (NTAP) extension for the T2Bacteria Panel from the U.S. Centers for Medicare & Medicaid Services (CMS) for fiscal year 2022
- Accelerated new product development initiatives under Option 1 of existing BARDA contract, including the T2Resistance® Panel, additionally the Company plans to initiate a clinical trial for the panel in the first quarter of 2022
- Clinical data on the positive clinical and economic impact of the use of T2 Biosystems' sepsis products presented by thought leaders at multiple global scientific and industry meetings

“Our second quarter performance represents meaningful progress across our three corporate priorities: accelerating our sales, enhancing our operations and advancing our pipeline,” stated John Sperzel, Chairman and CEO of T2 Biosystems. “We are confident that our investments in U.S. commercial expansion and medical and clinical affairs, coupled with increased presence at clinical, scientific and industry meetings, positions us favorably to drive greater awareness and adoption of T2Biosystems' products.”

Second Quarter 2021 Financial Results

Total revenue for the second quarter of 2021 was \$6.7 million, an increase of 162% compared to the prior year period. Product revenue for the second quarter of 2021 was \$3.7 million, an increase of 253% compared to the prior year period, driven by increased test panel sales. Research and contribution revenue for the second quarter of 2021 was \$3.0 million, an increase of 100% compared to the prior year period, driven by increased BARDA contract activity.

Operating expenses for the second quarter of 2021 were \$12.6 million, an increase of \$3.6 million compared to the prior year period, driven by increased BARDA contract research and development activity and increased commercial headcount.

Net loss for the second quarter of 2021 was \$(12.5) million, \$(0.08) per share, compared to a net loss of \$(10.7) million, \$(0.09) per share, in the prior year period.

Cash, equivalents, marketable securities, and restricted cash were \$53.3 million as of June 30, 2021. The final revenue covenant of \$20.0 million for the CRG debt agreement was achieved in June 2021.

2021 Financial Outlook

The Company continues to expect revenue for the full year 2021 to be between \$24.0 million and \$26.0 million. Product revenue is now expected to be between \$14.0 million and \$15.0 million, compared to the previous expectation of between \$16.0 to \$18.0 million, driven by lower T2SARS-CoV-2 Panel sales partially offset by increased sepsis test panel sales. Research and contribution revenue is now expected to be between \$10.0 million and \$11.0 million, compared to the previous expectation of \$8.0 million, driven by accelerated progress under the BARDA contract. The Company continues to expect to enter into at least 30 T2Dx Instrument contracts in 2021.

Webcast and Conference Call Information

T2's management team will host a conference call today, August 5, 2021, beginning at 4:30pm ET. Investors interested in listening to the call may do so by dialing 1-877-407-9208 for domestic callers or 1-201-493-6784 for International callers. A live and recorded webcast of the call will be available on the "Investors" section of the Company's website at www.t2biosystems.com.

About T2 Biosystems

T2 Biosystems, a leader in the rapid detection of sepsis-causing pathogens, is dedicated to improving patient care and reducing the cost of care by helping clinicians effectively treat patients faster than ever before. T2 Biosystems' products include the T2Dx[®] Instrument, T2Candida[®] Panel, the T2Bacteria[®] Panel, the T2Resistance[®] Panel, and the T2SARS-CoV-2[™] Panel and are powered by the proprietary T2 Magnetic Resonance (T2MR[®]) technology. T2 Biosystems has an active pipeline of future products, including the T2Cauris[™] Panel, and T2Lyme[™] Panel, as well as additional products for the detection of bacterial and fungal pathogens and associated antimicrobial resistance markers, and biothreat pathogens.

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, including, without limitation, statements regarding our revenue results and cash balance, financial outlook, anticipated strategic priorities, product demand, commitments or opportunities, and growth expectations or targets, , as well as statements that include the words "expect," "intend," "plan", "believe", "project", "forecast", "estimate," "may," "should," "anticipate," and similar statements of a future or forward looking nature.. 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, (i) any inability to (a) realize anticipated benefits from commitments, contracts or products; (b) successfully execute strategic priorities; (c) bring products to market; (d) expand product usage or adoption; (e) obtain customer testimonials; (f) accurately predict growth assumptions; (g) realize anticipated revenues; (h) incur expected levels of operating expenses; or (i) increase the number of high-risk patients at customer facilities; (ii) failure of early data to predict eventual outcomes; (iii) failure to make or obtain anticipated FDA filings or clearances within expected time frames or at all; or (iv) the factors discussed under Item 1A. "Risk Factors" in the company's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the U.S. Securities and Exchange Commission, or SEC, on March 31, 2021, and other filings the company makes with the SEC from time to time. 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. 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, unless required by law, it disclaims any obligation to do so, even if subsequent events cause its views to change. Thus, no one should assume that the Company's silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. 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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T2 BIOSYSTEMS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

(Unaudited)

| | June 30, 2021 | December 31, 2020 |
|--|------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 32,708 | \$ 16,793 |
| Marketable securities | 20,080 | 25,396 |
| Accounts receivable | 3,979 | 5,099 |
| Inventories | 4,784 | 3,636 |
| Prepaid expenses and other current assets | 2,308 | 2,660 |
| Total current assets | 63,859 | 53,584 |
| Property and equipment, net | 4,078 | 3,771 |
| Operating lease right-of-use assets | 10,332 | 11,034 |
| Restricted cash | 551 | 551 |
| Marketable securities | — | 10,002 |
| Other assets | 78 | 136 |
| Total assets | <u>\$ 78,898</u> | <u>\$ 79,078</u> |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 2,890 | \$ 2,058 |
| Accrued expenses and other current liabilities | 6,017 | 7,512 |
| Deferred revenue | 438 | 230 |
| Total current liabilities | 9,345 | 9,800 |
| Notes payable | 46,487 | 45,235 |
| Operating lease liabilities, net of current portion | 9,964 | 10,533 |
| Deferred revenue, net of current portion | 146 | 424 |
| Derivative liability | — | 1,010 |
| Other liabilities | 3,947 | 3,350 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2021 and December 31, 2020 | — | — |
| Common stock, \$0.001 par value; 200,000,000 shares authorized; 165,763,776 and 148,078,974 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively | 165 | 148 |
| Additional paid-in capital | 454,950 | 431,544 |
| Accumulated other comprehensive income | 4 | 9 |
| Accumulated deficit | (446,110) | (422,975) |
| Total stockholders' equity | 9,009 | 8,726 |
| Total liabilities and stockholders' equity | <u>\$ 78,898</u> | <u>\$ 79,078</u> |

T2 BIOSYSTEMS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)
(Unaudited)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|--|--------------------------------|--------------------|------------------------------|--------------------|
| | 2021 | 2020 | 2021 | 2020 |
| Revenue: | | | | |
| Product revenue | \$ 3,678 | \$ 1,041 | \$ 8,328 | \$ 2,086 |
| Research revenue | — | 11 | — | 11 |
| Contribution revenue | 3,016 | 1,500 | 5,322 | 3,000 |
| Total revenue | 6,694 | 2,552 | 13,650 | 5,097 |
| Costs and expenses: | | | | |
| Cost of product revenue | 4,831 | 2,300 | 10,621 | 6,971 |
| Research and development | 5,399 | 3,786 | 10,064 | 8,566 |
| Selling, general and administrative | 7,244 | 5,305 | 13,447 | 11,960 |
| Total costs and expenses | 17,474 | 11,391 | 34,132 | 27,497 |
| Loss from operations | (10,780) | (8,839) | (20,482) | (22,400) |
| Other income (expense): | | | | |
| Interest income | 6 | 1 | 12 | 1 |
| Interest expense | (1,700) | (1,844) | (2,713) | (3,261) |
| Other income, net | (1) | (3) | 48 | 26 |
| Total other expense | (1,695) | (1,846) | (2,653) | (3,234) |
| Net loss | \$ (12,475) | \$ (10,685) | \$ (23,135) | \$ (25,634) |
| Net loss per share — basic and diluted | \$ (0.08) | \$ (0.09) | \$ (0.15) | \$ (0.27) |
| Weighted-average number of common shares used in computing net loss | | | | |
| per share — basic and diluted | 154,885,039 | 120,292,543 | 151,576,606 | 94,464,933 |
| Other comprehensive loss: | | | | |
| Net loss | \$ (12,475) | \$ (10,685) | \$ (23,135) | \$ (25,634) |
| Net unrealized gain on marketable securities arising during the period | — | — | 9 | — |
| Less: net realized gain on marketable securities included in net loss | (12) | — | (14) | — |
| Total other comprehensive loss, net of taxes | (12) | — | (5) | — |
| Comprehensive loss | \$ (12,487) | \$ (10,685) | \$ (23,140) | \$ (25,634) |

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 Chairman and CEO, John Sperzel. John?

John Sperzel

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

During the second quarter, the T2 Biosystems team generated total revenue of \$6.7 million, an increase of 162% compared to the prior year period. Product revenue during the second quarter was \$3.7 million, an increase of 253% compared to the prior year period.

Second quarter product revenue was driven mainly by hospitals' utilization of our test panels. Our U.S. hospital customers continue to increase usage of our sepsis-related diagnostic products compared to prior year periods. In the second quarter, the annualized U.S. test utilization for our sepsis-related diagnostic panels, T2Bacteria and T2Candida, within our legacy sepsis installed base of T2Dx Instruments, was \$98,000 per instrument, a 17% increase compared to the prior year period. The test utilization decreased slightly compared to the first quarter of 2021 as our ability to deliver to customers was impacted by raw material supply shortages, a matter that was resolved early in the third quarter. Long-term, we continue to believe that the annualized U.S. test utilization, for customers routinely using our sepsis-related products, will reach \$200,000 per instrument.

Sales of our COVID-19 diagnostic test, the T2SARS-CoV-2 Panel, were impacted by lower overall infection rates during the second quarter — due to wider vaccination within the U.S. population and changes to testing guidance from local regulatory agencies — as well as hospitals' increased access to testing alternatives. In the second quarter, the annualized U.S. test utilization for our T2SARS-CoV-2 Panel, within our COVID-driven installed base of T2Dx Instruments, was \$148,000 per instrument, compared to \$214,000 per instrument during the first quarter of 2021.

These results reflect the fact that our efforts remain completely focused on our mission *to fundamentally change the way medicine is practiced through transformative diagnostics that improve the lives of patients around the world*. Our opportunity to make the greatest impact is through our sepsis-related products that enable clinicians to improve patient outcomes and reduce the overall cost of care for patients at risk of sepsis. We offer clinicians three potentially lifesaving sepsis-related test panels — T2Bacteria, T2Candida, and T2Resistance — which run on our T2Dx Instrument and address one of the greatest needs for patients at risk of sepsis, rapid detection.

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 one-half of cases. To further complicate matters, the current standard of

care continues to rely on a positive blood culture to identify the presence of a blood stream infection and target therapy for patients suspected of sepsis. 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 then be required for determination of species ID and susceptibility.

In contrast, our T2Bacteria and T2Candida Panels are the only FDA cleared diagnostics that can detect sepsis-causing pathogens directly from whole blood samples, producing results in 3-5 hours, compared to days required by the combination of blood culture and post-culture molecular diagnostic products. This time to result advantage provides tremendous benefits to both patients and clinicians, as studies have shown that the mortality rate of patients experiencing septic shock, increase by up to 8% for every hour of delayed appropriate antimicrobial therapy.

Sepsis remains one of the greatest healthcare threats and its impacts are far reaching. It is the leading cause of death in U.S. hospitals, claiming the lives of approximately 270,000 Americans each year. It is also the leading cost of hospitalization in the U.S., costing more than \$62 billion for sepsis care for patients in hospitals and skilled nursing facilities, according to the U.S. Department of Health and Human Services. The morbidity associated with sepsis is significant, as sepsis patients are also prone to developing a number of complications, such as reoccurrence of infection and sepsis, limb amputation, and long-term physical and psychological effects. These complications can lead to longer hospital stays, increased medical costs and a substantial impact on the quality of life for patients. Clearly there is a massive disconnect between the current detection standard and the needs of patients. We believe that today's standard of care represents a failure of our health systems to adequately treat patients at risk of sepsis and is unacceptable. We also believe routine use of our sepsis-related diagnostic products can fundamentally change and improve sepsis management in hospitals around the world.

To advance our mission and create value across our stakeholders, we are focused on three corporate priorities: 1) accelerating our sales, 2) enhancing our operations, and 3) advancing our pipeline. I will now discuss our recent progress and the strategic approach for each of these priorities.

Starting with our first priority – accelerating our sales

Our strategy to accelerate sales consists of three tactical components: 1) transitioning instruments sold in the U.S. during the second half of 2020 from COVID-19 to sepsis testing, 2) increasing sepsis test utilization within our legacy installed base, and 3) expanding our T2Dx Instrument installed base.

In the second quarter, we sold 3 T2Dx Instruments, including two in the U.S., and we also achieved routine use for T2Bacteria and T2Candida Panels in three ex-U.S. hospitals, following tenders won in Austria, France, and Kuwait, which we believe will be among our largest customers.

To accelerate sales, we have increased the size of our U.S. sales team — which now stands at eleven Regional Account Managers — expanded our commercial organization, and focused our commercial strategy to more comprehensively address the needs of our customers. Because our technology addresses one of the most complex healthcare problems, several functional groups in the hospital are involved in the sales process, including clinicians, laboratorians, pharmacists, and administrators. Each of these key stakeholders has unique needs and challenges, and our commercial team has made incredible strides to advance our sales funnel opportunities, by bringing this coalition together and building a hospital specific business, and clinical case.

Our team recently completed an advanced sales training to further expand their knowledge of how to drive change in clinical practice, which includes increased engagement with our customers. At this time, our U.S. sales team has more than 200 hospitals that are officially in the sales funnel and we continue to support their efforts by increasing our clinical marketing efforts to build a larger funnel of potential customers.

In the first quarter of 2021, we appointed Dr. Aparna Ahuja to the newly created position of Chief Medical Officer. Dr. Ahuja has been actively building out our clinical and medical affairs team, with a priority is to enhance the messaging around of the value of our products. This will be accomplished by partnering with both early adopter customers and with Key Opinion Leaders, or KOLs, to generate and share data via scientific journal publications, and at medical conferences, and trade shows.

Dr. Ahuja and her team have been working closely with KOLs with the mission to deepen our presence at key medical conferences and build widespread awareness among the scientific community of the value of our products. Starting in the first quarter, we have had numerous high-profile presentations at a number of conferences, including presentations at the American Society for Microbiology's and Federation of European Microbiological Societies' World Microbe Forum, the Sepsis Alliance's inaugural Sepsis Tech and Innovation 2021 Conference, and the European Society of Clinical Microbiology and Infectious Diseases' 31st European Congress of Clinical Microbiology & Infectious Diseases.

At the European Congress of Clinical Microbiology & Infectious Diseases, several studies were presented by independent investigators that evaluated our products compared to blood culture and post-blood culture molecular platforms, including diagnostic accuracy, time to results, and clinical impact. In a prospective observational study conducted by Dr. Paggi at the University of Perugia, the T2Bacteria Panel demonstrated a sensitivity of 100% and negative predictive value, or NPV, of 100%, as compared to blood culture sensitivity of 57.1% and NPV of 81.8%. The time to report T2Bacteria results was 4.17 hours, as compared to blood culture time to result of 36.34 hours. Most importantly, a positive T2Bacteria resulted in a change from empiric therapy to directed therapy in 29.2% of patients on the same day as the T2Bacteria sample drawing, and a negative T2Bacteria resulted in a change from empiric therapy to directed therapy in 8% of patients.

We believe commercial success requires clinical data, bolstered by economic evidence, and is a key to accelerating sales — including transitioning instruments from COVID-19 to sepsis diagnostic testing, increasing test utilization among our current sepsis accounts, and expanding our installed base. Demonstrating and messaging these improved clinical outcomes and reductions in the cost of care achieved by our customers through routine use of our products is very compelling. We have placed a higher priority on adding to and organizing these data for use by our commercial team. This strategy is already generating additional interest and deeper customer conversations. In what we view as a validation, CMS has again decided to extend the New Technology Add-on Payment, or NTAP, for our T2Bacteria Panel through fiscal year 2022. This favorable reimbursement further increases the economic value of the test to hospitals. Our commercial team will continue to leverage this designation and educate customers on the benefits.

Now I want to circle back to the tactical components of our sales strategy. Early in the COVID-19 pandemic, we recognized a need among our U.S. hospital customers, the same ones that could potentially use our sepsis products, to detect SARS-CoV-2 quickly and accurately. In a short period of time, we were able to leverage our technology to develop a test that met these needs. As the SARS-CoV-2 virus continues to evolve, we have been diligent in our efforts to ensure that our test is able to detect emerging variants. In fact, we recently announced that our T2SARS-CoV-2 Panel is capable of detecting all variants of interest and concern as noted by the CDC — including the alpha, beta, gamma, delta and lambda variants of the virus — based on sequence and *in silico* analysis. Offering this test opened the door to many new customers for T2 Biosystems. As part of the sales process, we were disciplined in prequalifying potential COVID-19 customers based on their willingness to explore adoption of our sepsis diagnostic panels following the pandemic. Executing on this opportunity, we more than doubled our U.S. installed base of instruments during the second half of 2020.

As a company that focuses on making a difference in the lives of sepsis patients, rapidly detecting the pathogens that cause sepsis remains our number one focus and underpinned our decision to develop and commercialize a COVID-19 test. Although

COVID-19 testing volumes in the U.S. declined in the second quarter with the adoption of vaccines, as of the end of June, our sales team have been granted access to visit many of our current customers and potential new customers to actively engage in face-to-face discussion around the adoption of our sepsis-related products. This is generally in-line with our previously stated expectation that hospital access was going to be limited in the first half of the year with access opening up in the second half. At this time, we feel that U.S. hospitals now have the necessary precautions and procedures in place for continued interactions through the second half of the year, allowing us to continue to drive new sepsis opportunities through our sales funnel.

Overall, the impacts of COVID-19 remain a headwind to the adoption of our sepsis products. We remain optimistic that we will continue to have open access to our hospital customers through the second half of the year, as well as an increasing mindshare of personnel within hospitals.

Accordingly, we continue to expect total revenue for the full year 2021 to be between \$24.0 million and \$26.0 million, and we are adjusting our expectation for the mix of product and research revenues. We now expect product revenue of \$14.0 million to \$15.0 million, down from \$16.0 to \$18.0 million, driven by lower T2SARS-CoV-2 Panel sales but partially offset by increased sepsis test panel sales. At the same time, due to updated expectations around timing of milestones and options under the BARDA contract, which I will discuss later, we now expect research contribution revenues of \$10.0 to \$11.0 million, up from \$8.0 million. Also, we continue to expect to enter into at least 30 T2Dx Instrument contracts in 2021.

Moving to our second priority – enhancing our operations

At the beginning of 2021, we set the goal of enhancing our business operations with a focus on product gross margins, operating cost structure, and efficiency. We reviewed all business and manufacturing processes, as well as our business tools. During this review, each cost line item was carefully scrutinized to ensure that expenses or investments were aligned with our 2021 priorities, including our growth objectives.

We continue to focus on scaling our manufacturing capabilities and strengthening our supply chain. Over the last year, we have scaled our manufacturing from being able to produce 2,000 tests a week to over 7,000 test a day. We did this by scrutinizing every aspect of the manufacturing process, eliminating waste and adding efficiencies. The increased volume and efficiencies added to our processes have had a favorable impact on product gross margins.

We also examined the tool sets we use across our business to weed out any inhibitors to growth and make the business more efficient. One key element of efficiency improvement will be the roll out of a new ERP system we expect to go live in the coming months. This updated tool will allow us to better track all our manufacturing processes, improve our customer service, better understand and predict customer's ordering patters, and identify additional opportunities for improvement.

Lastly, moving to our third priority – advancing our pipeline

While our long term goal is to change the standard of care for patients at risk of sepsis, our immediate goal is to deepen our market penetration by continuing to enhance our product offering. In 2019, we were awarded a product development contract by the Biomedical Advanced Research Development Authority, or BARDA, that is valued at up to \$69 million, based upon the achievement of certain milestones. In collaboration with the team ay BARDA, we continue to make great progress and are confident in our ability to meet all of the milestones defined in Option 1 by October 2021. Given this progress, we are optimistic about the opportunity to gain approval for Option 2.

On our first quarter earnings call, we had announced that after discussions with BARDA, we had mutually agreed to modify the terms of the existing contract to accelerate certain milestones, including for the development of the comprehensive sepsis panel, the next generation instrument, and the biothreat panel. Additionally, BARDA has agreed to add milestones for the T2Resistance Panel, which provides funding and assistance to conduct clinical trials and pursue U.S. regulatory approval.

While the T2Resistance Panel is currently being sold in Europe under a CE Mark, additional verification and validation studies are needed to initiate the clinical trial required to pursue U.S. FDA 510k clearance. The T2Resistance Panel was granted Breakthrough Device designation by the FDA, which has expedited communications with the agency on proposed analytical and clinical requirements. We plan to initiate the U.S. clinical trial for the T2Resistance Panel during the first quarter of 2022.

Initial findings from a multi-center Prospective Study of the T2 Resistance Panel for the detection of resistance markers in blood samples from patients suspected with blood stream infections were presented at the European Congress of Clinical Microbiology & Infectious Diseases. The objective of this study was to compare the T2Resistance Panel with blood culture and molecular and phenotypic resistance testing, evaluating sensitivity and specificity, as well as time to detection of resistance markers in patients with bacterial blood stream infections.

The T2Resistance Panel mean time to results was 4.4 hours compared to 101.4 hours for final reporting of positive blood cultures with antibiotic susceptibility testing. Time for data from molecular resistance assay results following blood cultures was 33.7 hours. When monitored for the impact of significant antibiotic changes at one site, the use of T2Resistance allowed 22 events of discontinuation of unnecessary antibiotics and 10 events of escalation of antibiotics. In summary, the T2Resistance molecular markers were sensitive and specific for the detection of drug resistance genes in patients with resistant bacterial bloodstream infections when compared with standard molecular resistance detection systems and phenotypic identification assays, while also significantly reducing time to detection of resistance genes compared to standard methodology by approximately 90%.

The biothreat panel is designed to be a highly sensitive, direct-from-blood panel able to detect six major biothreat pathogens from a single blood sample. This panel will be run on our FDA cleared T2Dx Instrument. We have completed development for this panel

and have demonstrated preliminary detection of all targeted biothreat pathogens directly in whole blood at less than 25CFU/ml. I am pleased to inform you that we plan to initiate the U.S. clinical trial for the biothreat panel during the first quarter of 2022.

The next generation instrument will utilize a single, whole blood sample independent of blood culture, and is designed to be fully automated, on-demand, and random access, similar to our T2Dx Instrument, but with faster turnaround times and a much larger target menu. It is being developed in parallel with the comprehensive sepsis panel to detect an increased number of pathogens and resistance genes at the same level of sensitivity our customers have come to expect. We are pleased to announce that we have completed building our Alpha prototypes, which we are testing against our requirements. From this testing, we have begun final design iterations for our Beta prototypes, at which point it will merge with the assay and start full scale on system wet testing.

The comprehensive sepsis panel is designed to detect approximately 99% of all bloodstream infections caused by bacterial and Candida species, as well as all blood-borne antibiotic resistant threats identified by the CDC, in a single test with a time to result of approximately 3 hours. The test will build on existing technology and detect pathogens and resistance markers directly from blood samples, without the need to wait for a positive blood culture. We believe this comprehensive sepsis panel has the potential to completely disrupt the traditional blood culture workflow and become a standard of care. Early development studies with the comprehensive sepsis panel utilizing manual testing has demonstrated our ability to detect all panel targets directly in whole blood at levels below 50 CFU/mL. As we move forward with development studies, we will continue to optimize our manual workflow conditions, utilizing processes and subassemblies from Alpha and Beta prototypes, to increase sensitivity and ensure smooth migration onto the automated system.

Finally I'd like to share an update that was previously discussed at our shareholder meeting, John McDonough has resigned from our Board of Directors. On behalf of the Board, I want to thank John for his service to T2 Biosystems over the last 14 years and

we wish him the best in the future. Our Board has determined that it is in the best interest of the company and its stockholders to combine the roles of Chairman and CEO and to appoint a lead independent director. Accordingly, I have been appointed as Chairman of the Board of Directors and Jack Cumming, former Chairman and CEO of Hologic, will continue to serve as lead independent director.

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 second quarter of 2021 was \$6.7 million, an increase of 162% compared to the prior year period. Product revenue was \$3.7 million, an increase of 253% compared to the prior year period driven primarily by increased sepsis and COVID-19 test sales. Research contribution revenue was \$3.0 million, an increase of 100% compared to the prior year period driven by increased BARDA contract activities.

Product costs for the second quarter of 2021 were \$4.8 million, an increase of \$2.5 million compared to the prior year period, driven by increased sales. Research and development expenses were \$5.4 million, an increase of \$1.6 million driven by increased BARDA contract activities. Selling, general and administrative expenses were \$7.2 million, an increase of \$1.9 million driven by increased Commercial team headcount.

Net loss for the second quarter of 2021 was \$(12.5) million, (\$0.08) per share, compared to a net loss of \$(10.7) million, (\$0.09) per share for the prior year period.

Total cash was \$53.3 million as of June 30, 2021, including marketable securities and restricted cash. In the second quarter of 2021, we strengthened our balance sheet by selling 16.8 million shares for net proceeds of \$20.2 million through the ATM facility. We also achieved the final revenue covenant of \$20.0 million for the CRG debt agreement in June 2021.

As John mentioned for guidance, we continue to expect total revenue for the full year 2021 of \$24.0 million to \$26.0 million, but we are adjusting the mix of product and research contribution revenues. We now expect product revenue of \$14.0 million to \$15.0 million and research contribution revenues of \$10.0 to \$11.0 million. We continue to expect to enter into at least 30 T2Dx Instrument contracts in 2021.

Thank you and back to John Sperzel for closing remarks.

John Sperzel

Our team continues to make meaningful progress across our three corporate priorities: accelerating our sales, enhancing our operations, and advancing our pipeline.

Our sales have accelerated considerably compared to the prior year period, with total revenue growth of 162% and product revenue growth of 253%. We anticipate that the second half of the year will provide a more favorable opportunity to accelerate product sales, as hospitals loosen restrictions and grant increased access to our expanded sales team. Simultaneously, we continue to strengthen our medical and clinical affairs teams to generate additional clinical and economic data to support the adoption of our products, build relationships with key opinion leaders, increase our presence at scientific meetings, and provide support to our customers.

Our efforts to improve our internal operations are beginning to yield encouraging results, and we remain committed to the development of our pipeline products of revolutionary diagnostics, including the T2Resistance Panel. We are very excited about the opportunity to change the standard of care for patients at risk of sepsis and we look forward to updating you on our next call.

