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 15, 2022

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 August 15, 2022, the Company issued a press release announcing its financial results for its fiscal quarter ended June 30, 2022, 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

Exhibit No.	Description
99.1	Press Release issued August 15, 2022
99.2	Transcript of conference call held on August 15, 2022
104	Cover page Interactive data file (embedded with in 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 17, 2022

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

T2 Biosystems Announces Second Quarter 2022 Financial Results

T2Dx Instrument contracts increased by 300% compared to the prior year period

LEXINGTON, Mass., August 15, 2022 (GLOBE NEWSWIRE)—T2 Biosystems, Inc. (NASDAQ:TTOO) (the "Company"), a leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes, today announced financial results for the second quarter ended June 30, 2022.

Recent Highlights

- Achieved second quarter total revenue of $5.9 million, including product revenue of $2.6 million, representing decreases of 12% and 30% respectively, compared to the prior year period, driven by lower sales of T2SARS-CoV-2 tests.
- Executed contracts for 12 T2Dx® Instruments during the second quarter, including 6 in the U.S. and 6 outside the U.S., an increase of 300% compared to the prior year period.
- Generated core sepsis test revenue of $1.2 million during the second quarter, a decrease of 3% compared to the prior year period.
- Received a $0.6 million order in July, the largest single sepsis order in company history, including 4 T2Dx Instruments that are expected to ship in the second half of 2022, and sepsis test panels.
- Received Breakthrough Device Designation from the U.S. Food and Drug Administration for the T2Lyme™ Panel and submitted for funding through the LymeX Initiative.
- Advanced product pipeline under Option 2B of BARDA contract, including the U.S. clinical trials for T2Resistance® Panel and T2Biothreat™ Panel, and development of next-generation products.
- Formed a Scientific Advisory Board, comprised of leading clinicians and researchers in the areas of infectious disease, laboratory medicine, and pharmacy, to provide strategic guidance.
- Implemented cost of goods improvement initiative for the T2Bacteria® Panel and the T2Candida® Panel, resulting in a reduction in the manufacturing costs of those products in future quarters.
- Implemented expense reductions on June 1, reducing the workforce and decreasing operating expenses by approximately 20%.
- Strengthened our balance sheet by raising $27.4 million of net proceeds through ATM facility, including $4.5 million in the second quarter and $22.9 subsequent to the end of the second quarter.

"Our second quarter results demonstrate continued execution across our three corporate priorities: accelerating our sales, enhancing our operations, and advancing our pipeline," stated John Sperzel, Chairman and CEO of T2 Biosystems. "While we have seen an expected decline in sales of COVID-19 tests, we are pleased with our continued progress driving adoption of our T2Dx Instrument and sepsis test panels, while improving operating efficiency and advancing the U.S. clinical trials for the T2Resistance Panel and the T2Biothreat Panel. We strengthened our balance sheet during and subsequent to the end of the second quarter, allowing us to achieve our near-term milestones and keeping us well positioned to drive sustainable, long-term growth."

Second Quarter 2022 Financial Results

Total revenue for the second quarter of 2022 was $5.9 million, a decrease of 12% compared to the prior year period. Product revenue for the second quarter of 2022 was $2.6 million, a decrease of 30% compared to the prior year period. Contribution revenue for the second quarter of 2022 was $3.4 million, an increase of 11% compared to the prior year period.

Research and development and selling, general and administrative expenses were $15.8 million for the second quarter of 2022, an increase of $3.2 million compared to the prior year period, driven by increased BARDA contract activity.

Net loss for the second quarter of 2022 was $18.0 million, $0.10 per share, compared to a net loss of $12.5 million, $0.08 per share, in the prior year period.

Cash, cash equivalents and restricted cash were $14.3 million as of June 30, 2022.

2022 Financial Outlook

The Company continues to expect full year 2022 total revenue of $28.0 to $31.0 million, including product revenue of $16.0 to $17.0 million and research contribution revenue of $12.0 to $14.0 million. The Company continues to expect to close 60 to 70 T2Dx Instrument contracts in 2022 and COVID-19 revenue to decrease from $9.5 to $3.5 million.

Webcast and Conference Call Information

The Company's management team will host a conference call today, August 15, 2022, beginning at 4:30 pm ET. Investors interested in listening to the call may do so by dialing 844-825-9789 for domestic callers or 412-317-5180 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 and antibiotic resistance genes, 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, the T2Bacteria® Panel, the T2Candida® 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 T2Biothreat™ Panel, the T2Cauris™ Panel, and T2Lyme™ Panel, as well as next-generation products for the detection of bacterial and fungal pathogens and associated antimicrobial resistance markers.

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, instrument contracts, timing of filing of an FDA submission, impact of operating expense reductions, plans to develop a diagnostic test for monkeypox, anticipated strategic priorities, product demand, commitments or opportunities, and growth expectations or targets, as well as statements that include the words "expect," "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, 2021, filed with the U.S. Securities and Exchange Commission, or SEC, on March 23, 2022, and other filings the Company makes with the SEC from time to time, including our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. 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.
Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 13,212	$ 22,245
Marketable securities	—	9,996
Accounts receivable	2,721	5,134
Inventories	5,673	3,909
Prepaid expenses and other current assets	3,096	3,110
Total current assets	24,702	44,394
Property and equipment, net	4,447	4,675
Operating lease right-of-use assets	9,169	9,766
Restricted cash	1,131	1,551
Other assets	156	153
Total assets	$ 39,605	$ 60,539
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 5,231	$ 2,832
Accrued expenses and other current liabilities	7,819	8,338
Deferred revenue	142	518
Total current liabilities	13,192	11,688
Notes payable, net of current portion	48,712	47,790
Operating lease liabilities, net of current portion	8,748	9,359
Deferred revenue, net of current portion	88	28
Derivative liability	1,675	—
Other liabilities	4,709	4,577
Commitments and contingencies		
Stockholders' deficit		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; 198,451,428 and 166,400,892 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	198	166
Additional paid-in capital	469,028	459,151
Accumulated other comprehensive loss	—	(4)
Accumulated deficit	(506,745)	(472,216)
Total stockholders' deficit	(37,519)	(12,903)
Total liabilities and stockholders' deficit	$ 39,605	$ 60,539

T2 Biosystems, Inc.
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,	
	2022	2021	2022	2021
Revenue:				
Product revenue	$ 2,559	$ 3,678	$ 6,403	$ 8,328
Contribution revenue	3,352	3,016	6,742	5,322
Total revenue	5,911	6,694	13,145	13,650
Costs and expenses:				
Cost of product revenue	5,081	4,831	11,286	10,621
Research and development	8,025	5,399	14,681	10,064
Selling, general and administrative	7,824	7,244	17,054	13,447
Total costs and expenses	20,930	17,474	43,021	34,132
Loss from operations	(15,019)	(10,780)	(29,876)	(20,482)
Other income (expense):				
Interest income	2	6	5	12
Interest expense	(3,021)	(1,700)	(4,671)	(2,713)
Other income, net	4	(1)	13	48
Total other expense	(3,015)	(1,695)	(4,653)	(2,653)
Net loss	$ (18,034)	$ (12,475)	$ (34,529)	$ (23,135)
Net loss per share — basic and diluted	$ (0.10)	$ (0.08)	$ (0.20)	$ (0.15)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	176,788,170	154,885,039	173,340,822	151,576,606
Other comprehensive loss:				
Net loss	$ (18,034)	$ (12,475)	$ (34,529)	$ (23,135)
Net unrealized gain (loss) on marketable securities arising during the period	9	—	2	9
Less: net realized (gain) loss on marketable securities included in net loss	2	(12)	2	(14)
Total other comprehensive (loss) income, net of taxes	11	(12)	4	(5)
Comprehensive loss	$ (18,023)	$ (12,487)	$ (34,525)	$ (23,140)

Emma Poalillo

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 23, 2022, 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 all for joining our second quarter 2022 earnings call. I will start with an overview of our performance during the second quarter and provide an update on our commercial, operational, and new product pipeline progress. I will then turn the call over to our Chief Financial Officer, John Sprague, to review our second quarter financial results, before I provide closing remarks and we open the call for questions and answers.

First, I would like to comment briefly on today's filings, including our press release and Form 10-Q to disclose the results of our business operations during the second quarter of 2022, and our preliminary proxy to disclose the proposals to be voted on at the annual stockholder meeting to be held on October 11, 2022. We planned the filing of these documents to coincide with today's call, to facilitate open and transparent communication with our stockholders. We will address each of these during our prepared remarks.

During the second quarter, we took actions to improve our cost structure and our balance sheet. On June 1st, we implemented workforce and expense reductions that we expect to yield operating expense reductions of approximately 20%, and should favorably impact the second half of 2022. It's important to note that we did not reduce positions in sales or in manufacturing. We have also recently strengthened our balance sheet by utilizing the ATM facility to raise $27.4 million of net proceeds, including $4.5 million during the second quarter and $22.9 million after the end of the second quarter. Together, these actions are intended to reduce our cash burn, increase our cash runway, and shorten our path to profitability.

We continue to focus on three corporate priorities: 1) accelerating our sales, 2) enhancing our operations, and 3) advancing our pipeline. During the second quarter, our commercial team continued to expand the installed base of T2Dx Instruments to increase sepsis test sales, our operations team implemented changes to increase product gross margins, and our R&D team met key development milestones to advance our new product pipeline.

Before I provide an update on our corporate priorities, I would like to remind you of the importance behind our mission *to fundamentally change the way medicine is practiced through transformative culture-independent diagnostics to improve the lives of patients around the world*. Sepsis presents one of the greatest challenges to healthcare systems worldwide, claiming approximately 11 million lives each year; that's more than all cancers combined. In the U.S., sepsis is the #1 cause of death in hospitals, claiming the lives of approximately 270,000 Americans each year. Sepsis is the #1 cost of U.S. hospitalization, costing our healthcare system nearly $62 billion annually. Finally, sepsis is the #1 cause of 30-day U.S. hospital readmissions, requiring nearly 20% of sepsis survivors to be re-hospitalized within 30 days and approximately 40% to be re-hospitalized within 90 days.

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. This is of particular concern given the recent report

issued by the Centers for Disease Control and Prevention, or CDC, showing an alarming increase in antimicrobial resistance in the United States as a result of the widespread use of antibiotics during the COVID-19 pandemic. The current standard of care also continues to rely on a positive blood culture to identify the presence of a bloodstream infection, which can take anywhere from 1-5 days to turn positive and is widely understood to have poor sensitivity. This presents a serious health challenge, as each hour of delayed targeted antimicrobial treatment can increase mortality risk by up to 8%, demonstrating that early detection of sepsis-causing pathogens and antibiotic resistance genes is crucial for optimal treatment decisions and improving patient outcomes.

Our aim at T2 Biosystems is to advance patient care by enabling faster, more accurate detection of sepsis-causing pathogens and antibiotic resistance genes. We are commercializing the first and only FDA-cleared products able to detect sepsis-causing pathogens directly from whole blood, within 3-5 hours, eliminating the need to wait days for a positive blood culture. Our products empower clinicians to deliver faster, targeted antimicrobial therapy, by rapidly identifying sepsis-causing pathogens and antibiotic resistant genes.

During the second quarter, the T2 Biosystems team generated total revenue of $5.9 million, including product revenue of $2.6 million and R&D revenue of $3.4 million. We entered into contracts for 12 T2Dx Instruments during the second quarter, including 6 in the U.S. and 6 internationally. I will now turn to an update on our corporate priorities.

Starting with our first priority – accelerating our sales:

We continue to pursue a commercial strategy focused on two objectives: 1) expanding our global T2Dx Instrument installed base, and 2) significantly increasing our sepsis test revenue by driving adoption and increasing utilization among new and existing customers. During the second quarter, we expanded our installed base by adding 12 new instruments, which brings our total instrument installed base to 155, including 94 in the United States and 61 internationally. We continue to sell or place instruments across all types of hospitals, including large teaching hospitals, large hospital systems, and smaller

community hospitals. Importantly, and consistent with the previous two quarters, all of our instrument sales and placements during the second quarter were for sepsis testing. Our teams – including sales, medical affairs, service and support – are closely aligned to execute our implementation strategy.

We generated sepsis test panel revenue of $1.2 million, consistent with the prior year period. I am pleased to announce that in July, we received a $600,000 order, the largest sepsis order in company history, which included 4 T2Dx Instruments that are expected to ship in the second half of 2022, and sepsis test panels. From an instrument pull-through perspective, in the U.S., we achieved annualized sepsis test utilization of $106,000 per legacy instrument. We continue to believe that annualized U.S. sepsis test utilization will reach $200,000 per instrument, and we have a number of customers that have already surpassed that target.

We believe there is a significant market opportunity for our products and we are excited to expand our presence in new and existing customers. During the second quarter, two U.S. hospital customers ordered their second T2Dx Instruments to support their growing sepsis testing needs. These customers continue to increase their utilization of our sepsis test panels and have expanded the use cases across their sepsis management protocols. We view this as an important validation of our technology.

The first hospital, a large academic center in the Midwest, has adopted both the T2Bacteria Panel and the T2Candida Panel. In this account, we are closely engaged with a champion who continues to articulate the benefits of our products throughout the hospital. The second hospital, part of a large health system in New Jersey, is a long time user of the T2Candida Panel and has implemented its routine use based on their experience with the test and determination of its clinical benefits. Both hospitals serve as reference accounts supporting our ongoing commercial efforts.

Early in 2022, we set expectations regarding a potential decline in sales of our COVID-19 molecular diagnostic test, the T2SARS-CoV-2 Panel, which we experienced during the second quarter. We view this development as a positive because it allows us to convert COVID-driven instruments to sepsis testing. As a reminder, we sold 47 T2Dx Instruments to hospital microbiology labs during 2020, initially for COVID-19 testing, with the expectation that approximately 80% would convert to our sepsis test panels over time. Nearly one-half of the COVID-driven instruments reside within two large hospital systems, so we have the potential to convert a sizeable number of these instruments through a centralized decision-making process, and we are in active discussion regarding their conversion to our sepsis test panels.

Outside the U.S., we continue to see a significant opportunity for our products, as hospitals around the world face similar challenges when caring for patients suspected of sepsis. Our international go-to-market strategy includes working with distributors to sell and support our products. Our team of international business managers is focused on supporting our existing distributors as well as expanding our international distribution network into more countries. We are pleased with the initial groundwork in Norway, Finland, and Türkiye after expanding our distribution to these countries earlier this year. We maintain a strong pipeline of geographic expansion opportunities and expect further expansion throughout 2022.

Finally, I'd like to highlight a recent publication from the CDC on antimicrobial resistance and its global impact that reinforces the importance of our products. The publication demonstrates the need to invest in proven prevention-focused health actions, such as accurate laboratory detection and rapid response and control, in order to address current and future antimicrobial-resistant threats. Antimicrobial resistance is a leading cause of death globally. As the COVID-19 pandemic weighed on healthcare facilities, resistant hospital-onset infections and deaths both increased at least 15% during the first year of the pandemic. We are proud to offer a solution that helps address antimicrobial resistance by enabling clinicians to make more informed and timely decisions.

Moving to our second priority – enhancing our operations:

To build a solid foundation for sustainable growth, we continue to take actions to create a more efficient business model. We have a number of ongoing initiatives to increase efficiencies across the business, and we have taken recent actions that we expect to favorably impact future financial results.

In May, we implemented an important cost of goods improvement initiative for T2Bacteria and T2Candida test panels, resulting in a reduction in the manufacturing costs of those two products in future quarters. This further expands test panel gross margins, helps us achieve a faster return on deployed instruments, and provides an overall benefit for our razor, razor blade business model.

In June, we made changes to improve our overall cost structure, including reducing our workforce and operating expenses by approximately 20%. We expect these changes to favorably impact our financials during the second half of 2022.

Finally, our operations team has worked diligently to insure uninterrupted supply of products to our customers. While supply chain challenges exist across the industry, our team remains confident in our ability to continue supplying our customers without interruption during the second half of 2022.

Moving to our third priority – advancing our pipeline:

We continue to make substantial progress with the programs under our milestone-based product development contract awarded by the U.S. Biomedical Advanced Research Development Authority, or BARDA, which is valued at up to $69 million. As a reminder, in the first quarter, BARDA chose to exercise Option 2B of the contract, following our team's successful completion of the milestones described under Option 2A. We are nearing completion of the milestones required under Option 2B, which is valued at $4.4 million, and we anticipate the award of Option 3 during the third quarter of 2022. We are very excited about the entire portfolio of products in our pipeline, as each one represents a future growth driver.

Under our agreement with BARDA, we are developing four diagnostic products that we believe have the potential to meaningfully advance standards of care and protect our nation from biothreat attacks: 1) the T2Resistance Panel, 2) the T2Biothreat Panel, 3) the comprehensive panel to detect bloodstream infections and antimicrobial resistance, and 4) the next-generation instrument.

The T2Resistance Panel is a direct-from-blood test panel designed to run on the T2Dx Instrument and simultaneously detects thirteen antibiotic resistance genes known to cause antibiotic-resistant infections, in just 3-5 hours. We are selling the T2Resistance Panel in Europe, under CE mark, and we are on a pathway to apply for U.S. FDA 510(k) prior to U.S. commercialization. We initiated a U.S. clinical trial for the T2Resistance Panel in December 2021 and we are currently enrolling patients at five hospitals. We plan to increase patient enrollment by adding three additional hospitals during the third quarter, and we anticipate completion of the trial in 2022, which provides the potential to file with the FDA as early as this year. As a reminder, the T2Resistance Panel previously received "breakthrough device" designation from the FDA, which provides for a prioritized FDA review process.

The T2Biothreat Panel is a direct-from-blood test panel designed to run on the T2Dx Instrument and simultaneously detect six biothreat pathogens identified as threats by the U.S. Government. Like our sepsis test panels, the T2Biothreat Panel is designed to provide results in 3-5 hours, without the need to wait days for a positive blood culture. We initiated a clinical evaluation for the T2Biothreat Panel in December 2021 to support submission to the FDA. We have completed the negative arm of the study and we are currently testing positive samples in a high-containment BSL-3 laboratory. We remain on track to file an FDA submission in 2022.

The comprehensive panel to detect bloodstream infections and antimicrobial resistance is a direct-from-blood test panel designed to run on our next generation instrument and detect greater than 95% of all bloodstream infections caused by bacterial and *Candida* pathogens, as well as antibiotic resistance markers identified as threats by the CDC, in a

single test with a time to result of approximately 3 hours. Think of it as combining our existing T2Bacteria, T2Candida, and T2Resistance panels into a single test, significantly expanding the pathogen detection capabilities, and accelerating the time to result. We believe the comprehensive panel will establish a new standard of care for the detection of sepsis causing pathogens and antibiotic resistance genes.

The next-generation instrument is being developed in parallel with our comprehensive panel. The instrument is designed to be fully-automated, on-demand, and random access, similar to our T2Dx Instrument, but incorporates faster turnaround times and the ability to detect an increased number of pathogens and resistance genes from a single, whole blood sample. We have built multiple development units, and are now in the process of conducting qualification testing prior to merging the comprehensive test panel with the instrument to initiate full scale system wet testing. We believe that our next-generation instrument and comprehensive panel have the potential to replace many blood cultures for patients at risk of sepsis.

Let's shift to Lyme disease. Lyme is a debilitating disease caused by the bacteria *Borrelia burgdorferi* and is transmitted to humans through the bite of infected ticks. Typical symptoms include fever, headache, fatigue, and skin rash. If left untreated, infection can spread to joints, the heart and the nervous system. According to the CDC, an estimated 476,000 people are treated for Lyme disease each year in the United States.

New York-based FAIR Health, recently published results using its database of over 36 billion privately billed U.S. healthcare claims to carry out an analysis of Lyme disease. The analysis found diagnoses of Lyme disease rose 357 percent in rural areas in the United States between 2007 and 2021, prompting FAIR to conclude that Lyme disease has become an "illness of increasing national concern."

Currently, there are no FDA-cleared diagnostic tests for the sensitive detection of early Lyme disease. Laboratory diagnosis of Lyme disease has traditionally used a two-tier process for detecting the presence of antibodies in a patient's blood. In the case of Lyme disease, antibodies can take several weeks to develop, so patients may test negative using current FDA-cleared diagnostics if a patient has been recently infected.

We have developed the T2Lyme™ Panel, a molecular diagnostic test designed to run on our FDA-cleared T2Dx® Instrument and simultaneously detect the bacteria that cause Lyme disease directly from whole blood. We expect it to be used to aid in the diagnosis of early Lyme disease.

In June, the U.S. Patent and Trademark Office issued a patent covering the T2Lyme Panel, "NMR Methods and Systems for the Rapid Detection of Tick-Borne Pathogens." In July, the FDA granted Breakthrough Device Designation for our T2Lyme Panel, which is intended to expedite development, assessment and review of a potential submission for market clearance. In August, we submitted for additional funding through the LymeX Initiative, and we are also pursuing other sources of non-dilutive funding for the T2Lyme Panel.

As we announced last week, we are exploring the potential to develop a rapid molecular diagnostic test for detection of the monkeypox virus, including technical and commercial feasibility. Monkeypox is a rare disease caused by infection with the monkeypox virus that is part of the orthopoxvirus family of viruses, which also contains smallpox. The main symptom of monkeypox is a rash, but individuals may also present with flu like symptoms. A rapid and accurate diagnosis of monkeypox is essential to expedite treatment and to limit exposure and spread of the disease. We believe it is possible to develop a molecular diagnostic test on our platform and we also believe non-dilutive funding may be available to assist in such development efforts.

Finally, we formed a Scientific Advisory Board during the second quarter of 2022, comprised of leading clinicians and researchers in the areas of infectious disease, laboratory medicine, and pharmacy. The Scientific Advisory Board is chaired by Roger Smith, Senior Vice President of Science Research & Development at T2 Biosystems, and will provide insights on clinical utilization, product pipeline, preclinical development, clinical research, clinical data generation, and strategic guidance to advance the Company's mission.

With that, I will now turn the call over to John Sprague to provide a detailed update of our second quarter 2022 financial results, our preliminary proxy, and our financial outlook for the remainder of the year.

John Sprague

Thank you, John.

Total revenue for the second quarter of 2022 was $5.9 million, a decrease of 12% compared to the prior year period driven by decreased COVID-19 test panel sales offset by increased T2Dx Instrument sales and BARDA contract activities. Product revenue was $2.6 million, a decrease of 30% compared to the prior year period. Research contribution revenues were $3.4 million, an increase of 11% compared to the prior year period.

Product costs for the second quarter of 2022 were $5.1 million, an increase of $0.3 million compared to the prior year period, driven by increased T2Dx Instrument sales and offset by decreased COVID-19 test sales.

Research and development expenses were $8.0 million, an increase of $2.6 million driven by increased BARDA contract activities. Selling, general and administrative expenses were $7.8 million, an increase of $0.6 million driven by increased commercial headcount.

Net loss for the second quarter of 2022 was $18.0 million, $0.10 per share, compared to a net loss of $12.5 million, $0.08 per share for the prior year period.

Cash, cash equivalents, and restricted cash were $14.3 million as of June 30, 2022. This includes net proceeds of $4.5 million from the sale of 21.6 million shares through the ATM facility during the second quarter. As John mentioned earlier, we also raised $22.9 million through the ATM facility after the end of the second quarter. We remain in compliance with the CRG loan agreement covenants.

Our guidance for the full year 2022 remains unchanged. We expect total revenue of $28.0 to $31.0 million, including product revenue of $16.0 to $17.0 million and research contribution revenues of $12.0 to $14.0 million. Additionally, we continue to expect to close 60 to 70 T2Dx Instrument contracts in 2022 and COVID-19 revenue to decrease from $9.5 to $3.5 million.

Thank you and back to John Sperzel for closing remarks.

John Sperzel

Thank you, John.

I'd like to provide an update on the compliance status with Nasdaq listing requirements. During the quarter, we presented a plan to Nasdaq to regain compliance, which included operating plans to organically drive our share price to compliance, as well as plans to implement a reverse stock split, as may be required. In June, we announced that the Nasdaq Hearing Panel granted our request for an extension until November 1, 2022 to regain compliance with Nasdaq's minimum bid price requirement.

Today, we filed our preliminary proxy statement for our annual stockholder meeting. One of the items to be voted on at the stockholder meeting is a request for stockholder approval to authorize a reverse stock split, in the event we need this by November 1, 2022 to achieve the minimum bid price required by Nasdaq. We urge our stockholders to review the proxy statement and vote their shares of common stock for the reverse split proposal. We believe it is in the best interest of T2 Biosystems and our stockholders to maintain our Nasdaq listing. There are three main reasons listing on Nasdaq is important: 1) it provides share liquidity at an efficient market price, 2) it enables more flexibility to finance the business and 3) it is valuable for attracting and retaining the most skilled talent. Thank you for your consideration and efforts ensuring T2 Biosystems maintains its Nasdaq listing.

In light of the importance of this proposal to our stockholders, and the fact that our shares are largely held by retail holders that traditionally do not vote in large numbers, as well as by brokers that have eliminated discretionary voting, we have taken certain steps to improve the chances of having this proposal approved. These steps include 1) amending our bylaws to reduce the quorum requirement, or the number of shares that need to be present at a meeting for the transaction of business, and 2) issuing shares of preferred stock with limited special voting rights. These preferred shares are only permitted to vote on the proposals related to the reverse split, and they cannot vote against the interests of the common stockholders. The purpose of the preferred shares is to amplify the vote of the common holders by submitting votes in the same exact proportion as the votes submitted by the common stockholders in order to achieve the vote threshold required by Delaware law. The reverse split proposal will only be approved if more common stockholders approve the reverse split than don't approve the split.

In summary, we are pleased with the continued execution across our three corporate priorities, which we believe are key to advancing the standard of care for patients at risk of sepsis. We have worked diligently to reduce expenses and enable a sustainable business model. Our commercial team continued to expand the installed base of T2Dx Instruments globally, which is important to increase sepsis test sales. Our operations team implemented important changes to increase product gross margins. Our R&D team continues to meet key milestones to advance our new product pipeline under our BARDA contract. Our accomplishments during the second quarter reinforce our excitement about the future for T2 Biosystems and commitment to our leadership position for the rapid detection of sepsis-causing pathogens and antibiotic resistance genes.

I'd like to turn the call back over to the operator to open the line for questions. Operator?