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 5, 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 May 5, 2022, the Company issued a press release announcing its financial results for its fiscal quarter ended March 31, 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 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On November 5, 2021, we received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on The Nasdaq Global Market. We were provided an initial period of 180 calendar days, or until May 4, 2022, to regain compliance. On May 5, 2022 we received a letter from Nasdaq informing us that our shares have failed to comply with the $1.00 minimum bid price required for continued listing on The Nasdaq Global Market and, as a result, our shares are subject to delisting. We filed an appeal and hearing request with Nasdaq, which has stayed the delisting of our common stock from The Nasdaq Global Market pending a Nasdaq listing qualifications hearings panel's (the "Panel") decision. The hearing date has been set for June 2, 2022. There can be no assurance that the Panel will grant our request for continued listing; however, we intend to present a plan to regain compliance to the Panel that includes a discussion of the events that we believes will enable us regain compliance in this timeframe and a commitment to effect a reverse stock split, if necessary.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued May 5, 2022
99.2	Transcript of conference call held on May 5, 2022
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: May 11, 2022

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

T2 Biosystems Announces First Quarter 2022 Financial Results

Results driven by strong sepsis-focused instrument placements in the United States

LEXINGTON, Mass., May 5, 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 first quarter ended March 31, 2022.

Recent Highlights

- Achieved first quarter total revenue of $7.2 million, including product revenue of $3.8 million and research contribution revenue of $3.4 million.
- Executed contracts for 15 T2Dx® Instruments during the first quarter, including 11 in the U.S. and 4 outside the U.S.
- Expanded international commercialization by entering into exclusive distributor agreements in Norway, Finland, and Türkiye.
- Completed development milestones under Option 2A of the multiple year product development contract with BARDA.
- Received Option 2B of the contract with BARDA, valued at $4.4 million, to advance the U.S. clinical trials for the T2Biothreat® Panel and T2Resistance® Panel and continue development of the Company's next-generation diagnostics for the detection of bloodstream infections and antimicrobial resistance.
- Submitted applications for Breakthrough Device Designation with the U.S. Food and Drug Administration for the Company's T2Biothreat™ Panel and T2Lyme™ Panel.
- Completed the negative arm of the U.S. clinical trial for T2Biothreat Panel.
- Announced the formation of the Company's Scientific Advisory Board, consisting of leaders in the areas of infectious disease, laboratory medicine, and pharmacy, to provide strategic guidance on the Company's product pipeline, clinical data generation, and clinical utilization.

"Our first quarter results reflect continued progress across our three corporate priorities: accelerating our sales, enhancing our operations, and advancing our pipeline. We are very pleased with the strong T2Dx Instrument placements in the U.S. and successful advances in new product development and U.S. clinical trials under the BARDA contract," stated John Sperzel, Chairman and CEO of the Company. "We are confident that near-term catalysts can create value and drive long-term growth, including significant growth in T2Dx Instrument placements and sepsis test revenues compared to 2021, improving product gross margins, and completing the U.S. clinical trials for the T2Biothreat Panel and T2Resistance Panel."

First Quarter 2022 Financial Results

Total revenue for the first quarter of 2022 was $7.2 million, an increase of 4% compared to the prior year period driven by increased BARDA contract activities and offset by decreased COVID-19 test panel sales. Product revenue for the first quarter of 2022 was $3.8 million, a decrease of 17% compared to the prior year period, resulting primarily from decreased COVID-19 test sales. Contribution revenue for the first quarter of 2022 was $3.4 million, an increase of 47% compared to the prior year period.

Operating expenses (reseach and development and selling, general and administrative expenses) for the first quarter of 2022 were $15.9 million, an increase of $5.0 million compared to the prior year period, driven by increased commercial and medical affairs headcount and increased BARDA contract activity.

Net loss for the first quarter of 2022 was $16.5 million, $0.10 per share, compared to a net loss of $10.7 million, $0.07 per share, in the prior year period.

Cash, cash equivalents, marketable securities and restricted cash were $20.5 million as of March 31, 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, May 5, 2022, beginning at 4:30 pm ET. Investors interested in listening to the call may do so by dialing 877-545-0320 for domestic callers or 973-528-0002 for International callers, using passcode: 927471. 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

The Company, 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. The Company's products, which are powered by the Company's proprietary T2 Magnetic Resonance (T2MR®) technology, include the T2Dx® Instrument, the T2Candida® Panel, the T2Bacteria® Panel, the T2Resistance® Panel, and the T2SARS-CoV-2™ Panel. The Company has an active pipeline of future products, including the T2Biothreat Panel, the T2Cauris™ Panel, the 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, timing of filing of an FDA submission, 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)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 9,397	$ 22,245
Marketable securities	9,989	9,996
Accounts receivable	4,361	5,134
Inventories	5,172	3,909
Prepaid expenses and other current assets	4,584	3,110
Total current assets	33,503	44,394
Property and equipment, net	4,778	4,675
Operating lease right-of-use assets	9,472	9,766
Restricted cash	1,131	1,551
Other assets	155	153
Total assets	$ 49,039	$ 60,539
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 3,385	$ 2,832
Accrued expenses and other current liabilities	8,950	8,338
Deferred revenue	338	518
Total current liabilities	12,673	11,688
Notes payable	48,257	47,790
Operating lease liabilities, net of current portion	9,060	9,359
Deferred revenue, net of current portion	47	28
Other liabilities	4,653	4,577
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; 171,412,940 and 166,400,892 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	171	166
Additional paid-in capital	462,900	459,151
Accumulated other comprehensive income	(11)	(4)
Accumulated deficit	(488,711)	(472,216)
Total stockholders' (deficit) equity	(25,651)	(12,903)
Total liabilities and stockholders' (deficit) equity	$ 49,039	$ 60,539

T2 Biosystems, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2022	**2021**
Revenue:		
Product revenue	$ 3,844	$ 4,650
Contribution revenue	3,390	2,306
Total revenue	7,234	6,956
Costs and expenses:		
Cost of product revenue	6,205	5,790
Research and development	6,656	4,665
Selling, general and administrative	9,230	6,203
Total costs and expenses	22,091	16,658
Loss from operations	(14,857)	(9,702)
Other income (expense):		
Interest income	3	6
Interest expense	(1,650)	(1,013)
Other income, net	9	49
Total other expense	(1,638)	(958)
Net loss	$ (16,495)	$ (10,660)
Net loss per share — basic and diluted	$ (0.10)	$ (0.07)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	169,855,170	148,231,412
Other comprehensive loss:		
Net loss	$ (16,495)	$ (10,660)
Net unrealized gain (loss) on marketable securities arising during the period	(7)	9
Less: net realized gain on marketable securities included in net loss	—	(2)
Total other comprehensive loss, net of taxes	(7)	7
Comprehensive loss	$ (16,502)	$ (10,653)

Malcolm MacLeod

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 first quarter 2022 earnings conference call. Today, I will review the company's performance in the first quarter and provide details on the progress we are making on our three corporate priorities. I will then turn the call over to our Chief Financial Officer, John Sprague, who will review our first quarter financial results, before I make some closing remarks and we open the call for questions and answers.

First, I would like to address today's announcement related to our Nasdaq listing. Today, we received a letter from The Nasdaq Stock Market informing the Company that its shares of common stock have failed to comply with the $1.00 minimum bid price required for continued listing on The Nasdaq Global Market under Nasdaq Listing Rule 5450(a) (1), and, as a result, the Company's shares are subject to delisting. The letter further stated that the Company may appeal the Nasdaq Staff delisting determination to a Nasdaq listing qualifications hearings panel.

The Company has filed an appeal and hearing request to the Nasdaq Staff's determination which will stay the delisting of the Company's shares of common stock from The Nasdaq Global Market pending the Panel's decision. The Nasdaq Staff has informed the Company that the delisting action has been stayed, pending a final written decision by the Panel, and the hearing date has been set for June 2, 2022. While there can be no assurance that the Panel will grant the Company's request for continued listing, the Company intends to present a plan to regain compliance to the Panel that includes a discussion of the events that it believes will enable it to regain compliance in this timeframe and a commitment to effect a reverse stock split, if necessary.

During the first quarter, the T2 Biosystems team generated total revenue of $7.2 million, including product revenue of $3.8 million and R&D revenue of $3.4 million. We entered into contracts for 15 T2Dx Instruments during the first quarter, including 11 in the U.S. and 4 internationally, all of which will be used for sepsis.

We continue to make progress on our three corporate priorities: accelerating our sales, enhancing our operations, and advancing our pipeline. Our first quarter results, and our sales funnel, have been positively impacted by our investments in sales, marketing, and medical affairs. We are experiencing sales success in the U.S. market, as well as outside of the U.S., having signed numerous distribution agreements in Europe, Asia Pacific, and Latin America — most recently in Norway, Finland, and Turkey – and we anticipate additional international expansion. We also continue to enhance our operations through manufacturing efficiency and workflow updates along with broad organizational cost controls. On the new product pipeline, we are advancing our two U.S. clinical trials, launched in December of 2021, for the T2Resistance Panel and T2Biothreat Panel.

As we continue to execute on our strategy, we are simultaneously furthering our mission: *to fundamentally change the way medicine is practiced through transformative culture-independent diagnostics that improve the lives of patients around the world.*

To remind you, sepsis is the #1 cause of death in U.S. hospitals, claiming nearly 270,000 lives annually. Sepsis is the #1 cost of hospitalization in the U.S., costing our healthcare system approximately $62 billion annually. Finally, sepsis is the #1 cause of 30-day hospital readmissions, resulting in nearly 20% of survivors to be re-hospitalized in 30 days and approximately 40% in 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. To further complicate matters, the current standard of care continues to rely on a positive blood culture to identify the presence of a bloodstream 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 identification and susceptibility.

Our aim at T2 Biosystems is to advance care by enabling faster times to targeted therapy. We are commercializing the first and only FDA cleared products able to detect sepsis-causing pathogens directly in whole blood, in just 3-5 hours, eliminating the need to wait for a positive blood culture. This is critical as each hour of delayed targeted treatment increases patient mortality rates by up to 8%. Our products enable clinicians to achieve faster targeted antimicrobial therapy, by rapidly identifying sepsis-causing pathogens and antibiotic resistant genes.

At our analyst and investor day in April, the critical nature of this mission, and our progress spearheading the advancement of culture-independent diagnostics, was validated and articulated by influential KOL and T2Dx users, Dr. Thomas Walsh, the Founding Director, Center for Innovative Therapeutics and Diagnostics, and Dr. James Snyder, Director of Microbiology and Infectious Diseases, Molecular Diagnostics at the University of Louisville School of Medicine and Hospital.

To advance our mission and create value for 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 provide an update on our recent progress as it relates to each of these three corporate priorities.

Starting with our first priority – accelerating our sales:

We have focused our sales strategy with respect to two distinct objectives: 1) significantly expanding our T2Dx Instrument installed base, through the sale or placement of new instruments, and 2) doubling our sepsis test panel revenue by driving broad adoption and utilization among new and existing customers.

In the first quarter, we entered into 15 T2Dx Instruments contracts, expanding our installed base of instruments to 91 in the U.S. and 55 internationally. We generated sepsis panel revenue of $1.1 million. In the U.S., we achieved annualized sepsis test utilization of $109,000 per legacy T2Dx Instrument. While disruptions from the COVID-19 case surge in January negatively impacted sepsis test utilization, sepsis test panels were strong in the last weeks of the quarter. We continue to believe that, over time, annualized U.S. sepsis test utilization will reach $200,000 per instrument.

In recent quarters, we have significantly expanded our U.S. commercial team to accelerate sales of our sepsis products market penetration. Under new leadership this team has been organized regionally and has implement an advanced metrics driven sales process. Our new sales management process allows us to generate, qualify, and forecast lead conversions more accurately. We are confident the new structure and analytics can help build and execute a strong funnel of placements and utilization with greater visibility into monthly and annual performance. To that end we are able to tightly manage the salesforce against internal quantitative performance metrics.

We are seeing increased productivity as our expanded commercial team gains traction in the market. The T2Dx Instrument placement model we are now offering is also shortening deal cycle times. Placements are generating higher test panel pricing and establishing volume requirements. Waning COVID-19 demand is creating capacity for new hospitals to evaluate sepsis solutions and also provide the opportunity to convert COVID-driven instrument placements to sepsis testing. We expect these instruments will eventually transition to sepsis testing in the coming quarters.

We have rebuilt and expanded our medical and clinical affairs teams. These teams are actively engaged with Key Opinion Leaders, or KOLs, and working together to generate and disseminate real-world data through scientific journal publications, at medical conferences, and at industry trade shows. Our medical affairs team, which consists of infectious disease MDs, laboratory professionals, and Pharm Ds, is now reporting into Brett Giffin, our Chief Commercial Officer, and this organizational realignment ensures that these resources are best positioned to drive growth in our sepsis business. Our clinical affairs team is now reporting into Roger Smith, our Senior VP of Science R&D, which aligns our product development and clinical validation under common leadership. Aparna Ahuja has resigned as Chief Medical Officer, to pursue other opportunities, and we thank her for her contributions to T2 Biosystems and our customers.

Hospitals around the globe largely face the same challenges when caring for patients suspected of sepsis, and we view this as an opportunity to bring our solutions to additional patients and customers. To capture this opportunity and maximize our distributor relationships we have employed three international business managers. As previously announced, we expanded our distribution networks with agreements in Norway, Finland, and Türkiye during the first quarter. We are having success expanding our international distribution network, enabling commercialization of our products in more countries, and we anticipate further expansion in 2022.

Moving to our second corporate priority – enhancing our operations:

We are continuing to make investments and implement changes to our operations that will enable sustained long-term growth. Scaling our manufacturing capabilities and strengthening our supply chain have been major focuses here in recent quarters. We have made strategic investments in tooling, automation, and efficiency projects to further scale our manufacturing capabilities and continue to improve our costs of goods. The workflow updates that we implemented have resulted in lower scrap rates and higher efficiency with reagent materials. As a result, we expect to see gross margin improvement throughout the year. We are experiencing supply chain challenges and our team has been effectively managing these dynamics by building inventory through pre-purchases and continuously evaluating alternate material suppliers, where possible.

Moving to our third priority – advancing our pipeline:

Our new product development priorities continue to be 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. We highlighted the four products that we are developing under our contract with BARDA, the T2Resistance Panel, the T2Biothreat Panel, the comprehensive sepsis panel, and the next-generation instrument at our recent analyst and investor day. This pipeline represents a portfolio of differentiated diagnostics that have the potential to meaningfully advance standards of care and protect our nation from biothreat attacks.

We are pleased that our scientific and engineering teams successfully completed the milestones described under Option 2A of the BARDA contract during the first quarter. BARDA subsequently chose to exercise Option 2B of the contract, which is valued at $4.4 million and planned for the period between April 2022 and July 2022. Upon the successful completion of Option 2B, we are optimistic that BARDA will choose to exercise Option 3 to continue to support the development of these important products.

As a reminder, in December 2021, we initiated the U.S. clinical trials for the T2Resistance Panel and the T2Biothreat Panel, both ahead of our previously announced schedule. We designed these clinical trials to evaluate the performance of the T2Resistance and T2Biothreat Panels. The data will be used to support respective regulatory submissions to the U.S. Food and Drug Administration in 2022

The T2Resistance Panel a direct-from-blood test panel designed to run on the T2Dx Instrument and simultaneously detect thirteen antibiotic resistance genes from both Gram-positive and Gram-negative bacterial pathogens, which are known to cause antibiotic-resistant infections, in 3-5 hours. We are currently marketing and selling the T2Resistance Panel in Europe, under CE mark, and we are on a pathway to apply for U.S. FDA 510(k) clearance prior to commercialization in the U.S. market. The T2Resistance Panel was granted “breakthrough device” designation from the FDA, which provides for a prioritized FDA review process. The clinical trial will include up to 1,500 patients from multiple sites across the U.S. We expect the trial to be completed in 2022, opening the door for the filing of an FDA submission as early as this year.

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, including: *Bacillus anthracis, Francisella tularensis, Burkholderia mallei, Burkholderia pseudomallei, Yersinia pestis, and Rickettsia prowazekii*. Similar to our sepsis products, the T2Biothreat Panel is designed to provide results in 3-5 hours, without the need to wait days for a positive blood culture. The U.S. clinical trial includes negative samples being analyzed at a single site, which has been completed, and positive samples being prepared and analyzed at a high-containment Biosafety Level 3 laboratory, which is expected to be completed in 2022, potentially enabling the filing of an FDA submission in 2022.

The comprehensive panel for the detection of 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 Centers for Disease Control and Prevention, in a single test with a time to result of approximately 3 hours. We are developing the comprehensive sepsis panel using our pre-existing proprietary technology.

The next-generation instrument is designed to be fully automated, on-demand, and random access, similar to our T2Dx Instrument, but with faster turnaround times and the ability to detect an increased number of pathogens and resistance genes from a single, whole blood sample. We are pleased to announce that we have successfully completed the build of multiple development units, ahead of schedule, and are in the process of conducting qualification testing on all of them with the goal of merging the assay to initiate full scale system wet testing.

We believe that our next-generation instrument and the comprehensive panel for the detection of bloodstream infections and antimicrobial resistance we will replace most blood cultures for patients at risk of sepsis. The launch is those new products will transition the position T2 from use as an adjunct test, to the primary product to detect sepsis-causing pathogens and antibiotic resistance genes.

Finally, we have submitted two applications with the U.S. Food and Drug Administration for Breakthrough Device Designation: 1) the T2Biothreat Panel, which we announced in April 2022, and 2) the T2Lyme™ Panel, which we included today's first quarter earnings press release. The T2 Lyme Panel is a qualitative, molecular diagnostic assay designed to run on our T2Dx Instrument and to detect the presence of *Borellia* bacteria directly in human whole blood specimens and provide results in 3-5 hours.

As a reminder, the FDA Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. It is available for devices and device-led combination products which are subject to review

under a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request. This program is intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standards for PMA approval, 510(k) clearance, and De Novo marketing authorization, consistent with the FDA's mission to protect and promote public health.

With that, I will now turn the call over to John Sprague to go over the details of our first quarter 2022 financial results, and our financial outlook for 2022. John?

John Sprague

Thank you, John.

Total revenue for the first quarter of 2022 was $7.2 million, an increase of 4% compared to the prior year period driven by increased T2Dx instrument sales and BARDA contract activities offset by decreased COVID-19 test panel sales. Product revenue was $3.8 million, a decrease of 17% compared to the prior year period. Research contribution revenues were $3.4 million, an increase of 47% compared to the prior year period.

Product costs for the first quarter of 2022 were $6.2 million, an increase of $0.4 million compared to the prior year period, driven by increased T2Dx instrument sales and offset by decreased Covid-19 test panel sales. Research and development expenses were $6.7 million, an increase of $2.0 million driven by increased BARDA contract activities. Selling, general and administrative expenses were $9.2 million, an increase of $3.0 million driven by increased commercial and medical affairs headcount.

Net loss for the first quarter of 2022 was $16.5 million, $0.10 per share, compared to a net loss of $10.7 million, $0.07 per share for the prior year period.

Cash, marketable securities and restricted cash were $20.5 million as of March 31, 2022. We have used the ATM facility minimally in 2022, through March 31 we sold 3.5 million shares for net proceeds of $1.4 million. CRG has extended the interest only period and loan maturity to December 31, 2023, and we are in compliance with the remaining loan agreement covenants.

We continue 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 revenues of $12.0 to $14.0 million. 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.

We are pleased with the progress that we across our three of our corporate priorities during the first quarter, and we are encouraged by the financial results we are generating following the expansion of our commercial and medical affairs teams.

Under new commercial leadership, our expanded salesforce is increasing the installed base of T2Dx Instruments, globally, while focusing on increasing adoption and utilization of sepsis products. Our Medical Affairs team will work closely with our sales team to increase awareness of our sepsis products through Key Opinion Leader engagement, as well as the generation of additional clinical and economic evidence to reinforce the value proposition of our products. Expansion of our international distribution network is ongoing to capture the global demand for our culture-independent diagnostics. We have improved our manufacturing efficiency and continue to make investments to scale the business and improve product gross margins. Finally, we continue to successfully complete the milestones associated with the BARDA product development contract. This advances us toward two FDA regulatory submissions we expect to make in 2022 and drives the next generation of culture-independent products to rapidly detect bloodstream infections and antibiotic resistance genes.

Our recent accomplishments have created business momentum in early 2022 and we are extremely excited about the future for T2 Biosystems and confident in our ability to change the standard of care for patients at risk of sepsis.

Now let’s open it up to questions. Operator?