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 23, 2023

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 23, 2023, the Company issued a press release announcing its financial results for its fiscal quarter ended March 31, 2023, 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 May 23, 2023
99.2	Transcript of conference call held on May 23, 2023
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 25, 2023

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

T2 Biosystems Announces First Quarter 2023 Financial Results

Filed FDA submission for T2Biothreat Panel, implemented a restructuring program and announced exploration of strategic alternatives

LEXINGTON, Mass., May 23, 2023 (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, 2023.

Recent Financial and Operational Highlights

- Achieved first quarter total revenue of $2.1 million, including sepsis and related product revenue of $1.7 million and research contribution revenue of $0.4 million.
- Increased sepsis panel revenue by 11% year over year, driven by increased T2Bacteria® Panel sales of 109% in the U.S. and 55% globally.
- Executed contracts for 5 T2Dx® Instruments during the first quarter.
- Secured multi-year pricing agreements with two large U.S. health systems, representing a total of 69 Hospitals, for T2Dx Instruments, T2Bacteria Panels and T2Candida® Panels.
- Announced exploration of strategic alternatives and implemented a restructuring program completed this past week including an incremental workforce reduction of nearly 30%.

Recent Pipeline and Clinical Highlights

- Filed FDA submission for T2Biothreat™ Panel, a direct-from-blood test that runs on the FDA-cleared T2Dx Instrument and detects six biothreat pathogens identified as threats by the CDC.
- Applied for FDA Breakthrough Device Designation for *Candida auris*, a multidrug-resistant fungal pathogen that has been labeled as a serious global health threat with mortality rate up to 60%.
- Completed assay development for T2Lyme™ Panel and established preliminary level of detection (LOD) of 2 CFU/mL.
- Advanced U.S. clinical trial for T2Resistance® Panel, completing nearly 90% of patient enrollment.

"In an effort to maximize value, we have engaged an advisory firm to explore all potential strategic alternatives. In addition, to preserve capital, decrease quarterly cash usage and position the Company to explore strategic alternatives, we have simultaneously implemented a restructuring program," stated John Sperzel, Chairman and CEO of T2 Biosystems. "In the first half of the year, we have made very important advances in our product pipeline, including FDA 510(k) submission for the T2Biothreat Panel, FDA Breakthrough Device Designation application for *Candida auris*, completion of assay development for the T2Lyme Panel, and completed nearly 90% of patient enrollment in the T2Resistance Panel U.S. clinical trial, which position us to expand our addressable markets in the future."

First Quarter 2023 Financial Results

Total revenue for the first quarter of 2023 was $2.1 million, a 71% decrease compared to the prior year period, driven by a decline in COVID-19 test sales and reduced BARDA activities. Product revenue was $1.7 million, a decrease of 57% compared to the prior year period, driven by the expected 98% decline in COVID-19 test sales and partially offset by increased sepsis test sales. Research contribution revenues were $0.4 million, an 88% decrease compared to the prior year period, driven by the level of BARDA contract activities.

Cost of product revenue for the first quarter of 2023 was $4.0 million, a 35% decrease compared to the prior year period, driven by decreased COVID-19 test sales. Research and development expenses were $4.5 million, a 33% decrease compared to the prior year period, driven by decreased BARDA contract activities. Selling, general and administrative expenses were $7.3 million, a 21% decrease compared to the prior year period driven by decreased Medical Affairs spending.

Net loss for the first quarter of 2023 was $18.0 million, $1.32 per share, compared to a net loss of $16.5 million, $4.86 per share, in the prior year period.

Cash and cash equivalents totaled $10.1 million as of March 31, 2023. The Company raised $1.0 million in net proceeds through ATM sales in the first quarter of 2023 and in February 2023, raised $11.0 million, net through a common stock and warrants sale. The impact of the incremental 30% workforce reduction is expected to significantly decrease cash usage in the subsequent quarters.

2023 Financial Outlook

The Company reiterates its full year 2023 financial outlook and continues to expect total sepsis and related product revenue of $11.0 million to $13.0 million, representing growth of 31% to 55%, compared to $8.4 million in 2022. Given the focus on product revenue, the Company is not providing guidance on research and contribution revenue.

Webcast and Conference Call Information

The Company's management team will host a conference call today, May 23, 2023, beginning at 8:30 am ET. Investors interested in listening to the call may do so by dialing 877-545-0523 for domestic callers or 973-528-0016 for International callers and using conference ID 717782 approximately five minutes prior to the start time. 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. For more information, please visit www.t2biosystems.com.

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 completing clinical trials and filing of an FDA submission, impact of operating expense reductions, 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, 2022, filed with the U.S. Securities and Exchange Commission, or SEC, on March 31, 2023, 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.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 10,117	$ 10,329
Accounts receivable	1,323	2,163
Inventories	4,936	4,285
Prepaid expenses and other current assets	2,549	2,582
Total current assets	18,925	19,359
Property and equipment, net	4,801	4,533
Operating lease right-of-use assets	8,420	8,741
Restricted cash	551	1,551
Other assets	35	143
Total assets	$ 32,732	$ 34,327
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 3,131	$ 1,296
Accrued expenses and other current liabilities	5,162	7,269
Operating lease liability	1,415	1,352
Warrant liabilities	7,972	39
Deferred revenue	149	172
Total current liabilities	17,829	10,128
Notes payable	50,108	49,651
Operating lease liabilities, net of current portion	7,832	8,214
Deferred revenue, net of current portion	74	52
Derivative liability related to Term Loan	1,858	1,088
Accrued interest on term loan	4,917	4,849
Total liabilities	82,618	73,982
Commitments and contingencies		
Stockholders' deficit		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; 20,368,463 and 7,716,519 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	21	8
Additional paid-in capital	502,277	494,556
Accumulated deficit	(552,184)	(534,219)
Total stockholders' deficit	(49,886)	(39,655)
Total liabilities and stockholders' deficit	$ 32,732	$ 34,327

T2 BIOSYSTEMS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2023	2022
Revenue:		
Product revenue	$ 1,655	$ 3,844
Contribution revenue	423	3,390
Total revenue	2,078	7,234
Costs and expenses:		
Cost of product revenue	3,995	6,205
Research and development	4,471	6,656
Selling, general and administrative	7,299	9,230
Total costs and expenses	15,765	22,091
Loss from operations	(13,687)	(14,857)
Other income (expense):		
Interest income	2	3
Interest expense	(1,522)	(1,650)
Change in fair value of derivative related to Term Loan	(770)	—
Change in fair value of warrant liabilities	(1,304)	—
Other income	—	11
Other expense	(682)	—
Other losses	(2)	(2)
Total other expense	(4,278)	(1,638)
Net loss and comprehensive loss	$ (17,965)	$ (16,495)
Net loss per share — basic and diluted	$ (1.32)	$ (4.86)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	13,633,352	3,397,103

Trip Taylor, IR

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, 2023, 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, CEO

Thank you all for joining our first quarter 2023 earnings and business update call. Today, I will start by addressing two press releases that we issued earlier this morning, then discuss our performance during the first quarter, including the progress we have made across our three corporate priorities as outlined in our first quarter earnings press release. I will then turn the call over to John Sprague, our Chief Financial Officer, who will review our first quarter financial results and our outlook for 2023, before I provide closing remarks and we open the call for questions and answers.

This morning, we issued a press release announcing an FDA 510(k) submission for the T2Biothreat™ Panel, a product that we developed in collaboration with the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA).

The FDA submission marks an important milestone in our commitment to protect Americans from the threat of deliberate or naturally occurring outbreaks of biothreat pathogens, and follows the recently completed U.S. clinical evaluation that demonstrated very high sensitivity and specificity, and included 350 contrived positive samples and over 470 negative blood samples from both healthy and febrile subjects.

The T2Biothreat Panel is a fully-automated, direct-from-blood test designed to run on the FDA-cleared T2Dx® Instrument and simultaneously detects six biothreat pathogens identified as threats by the U.S. Centers for Disease Control and Prevention, or CDC, including the organisms that cause anthrax, tularemia, glanders, plague and typhus.

If not treated promptly, infections with these biothreat pathogens can result in mortality rates of 40-90%. The T2Biothreat Panel is able to detect these biothreat pathogens within four hours, directly-from-blood, and rapidly provide clinicians with the needed information to appropriately treat infected patients.

We believe the T2Biothreat Panel demonstrates very high sensitivity and specificity for a direct-from-blood multi-target biothreat product, and is the only such product developed by a U.S. owned company, which we think will be an important factor in the discussions with U.S. Government entities regarding procurement of the T2Biothreat Panel.

This morning, we also issued a press release announcing the exploration of a range of strategic alternatives focused on maximizing value, and the implementation of a restructuring program.

After careful consideration, the Company has engaged an advisory firm to explore all potential strategic alternatives to maximize value, including an acquisition, merger, reverse merger, other business combination, sale of assets, licensing, and other strategic transactions. No updates on the process are expected to be provided during the evaluation period unless and until the Board of Directors has concluded that disclosure is appropriate or required.

A strategic restructuring program is being implemented to preserve capital and better position the Company to explore all strategic alternatives, while continuing to support its customers, pursue new commercial opportunities and advance pipeline development. The restructuring program is designed to reduce annual operating costs and includes, among other things, an incremental reduction of the Company's workforce by nearly 30%, which was completed last week. I will discuss further strategic changes in the context of our three corporate priorities.

Turning to our recent business progress, the T2 Biosystems team has recently achieved a number of key milestones that position the company for success and support our mission to fundamentally change the way medicine is practiced through transformative culture-independent diagnostics that improve the lives of patients around the world. These accomplishments support our three corporate priorities: 1) accelerating our sales, 2) enhancing our operations, and 3) advancing our pipeline.

Starting with our first priority – accelerating our sales:
Our commercial strategy is focused on increasing the adoption of our products, with emphasis on increasing sales of our FDA-cleared sepsis test panels and expanding the installed base of our FDA-cleared T2Dx Instruments. As we stated during our March 2023 earnings call, our top commercial priority will be increasing the use of our sepsis test panels with existing hospital customers. To drive increased sepsis test revenue we made two important changes to our sales strategy.

The first change consists of expanding our sales targets to include larger hospitals and those that have a higher likelihood of achieving our annualized sepsis test panel utilization target of $200,000. Larger hospitals have shown greater potential for increased use of our T2Bacteria and T2Candida panels, given their increased patient volume and the number of patients that require complex treatments. At the same time, we acknowledge that larger hospitals have longer sales cycles, but believe balancing our sales funnel with a number of large hospitals to compliment the smaller and critical access hospitals provides a greater opportunity for long-term, sustained growth.

The second change consists of shifting our sales team's incentive compensation plan to weigh more heavily on sepsis test revenue, as compared to instruments. Ultimately, this is intended to encourage more time spent with legacy accounts as well as to accelerate the time from when an instrument contract is signed to when the hospital goes "live" with patient testing. Our commercial, medical affairs, and support teams are now more closely integrated to ensure we can provide customers with the training and education required to ramp their utilization and realize the clinical and economic benefits offered by our sepsis products.

During the first quarter, we achieved sepsis and related product revenue of $1.7 million, compared to $2.0 million in the prior year period, driven by lower instrument revenue. We also ended the first quarter with a sepsis test panel backorder of $230,000. We generated sepsis test panel revenue of $1.2 million, representing an increase of 11%, compared to the prior year period, despite ending the quarter with the $230,000 backorder. Had we been able to clear the backorder as of March 31st, the sepsis test panel increase would have been 34% compared to the prior year period. Importantly, we increased sales of the T2Bacteria Panel by 55% globally, including a 109% increase in the U.S. market, compared to the prior year period.

We entered into contracts for five T2Dx Instruments during the first quarter, all of which were sold outside of the U.S. market. We believe these results are representative of the change in our commercial strategy to focus more on increasing sepsis test panel utilization in legacy accounts and on large hospitals with longer sales cycles.

A strong validation of our new commercial strategy is that our U.S. T2Bacteria Panel revenues more than doubled in the first quarter of 2023, compared to the prior year period. This was supported by the addition of four new hospital accounts ordering the T2Bacteria Panel for the first time, and bringing our fourth quarter 2022 instrument closes online on

a faster timeline. We are pleased with the adoption rates of the T2Bacteria Panel as more hospitals are realizing the value of the product, as evidenced by the increased demand in our legacy accounts. We also have approximately 40 T2Dx Instruments in U.S. hospital labs that were initially sold for COVID-19 testing, and which we are targeting for conversion to our sepsis test panels. I am pleased to inform you that another instrument was converted to our sepsis test panels during the first quarter of 2023, and we expect additional conversions from COVID-19 to sepsis in the coming months.

Separately, we are excited that we recently entered into multi-year pricing agreements with two large U.S. health systems, covering a total of sixty-nine U.S. hospitals. The key hospitals in each of these two health systems are multi-year users of T2 Biosystems' sepsis test panels. In those hospitals, our sepsis panels are integrated in the sepsis management protocols and they are experiencing improved clinical results and positive economic benefits. The new agreements provide these sixty-nine U.S. hospitals with contracted pricing for the T2Bacteria Panel and the T2 Candida Panel for an initial three-year period, as well as options to procure T2Dx Instruments. We are certainly excited about the opportunity to expand the use of our sepsis products within these two large health systems. Increasing sepsis test utilization within existing hospitals and expanding broadly across health systems are core tenets of our growth strategy and represent top commercial priorities.

Internationally, there continues to be a significant commercial opportunity for our T2Dx Instruments and sepsis panels. This is reflected by continued sales of instruments and sepsis test panels to our distribution partners. We continue to see strong demand in Europe and the Middle East, and expect to continue to expand distribution across the Asia Pacific region in the coming months.

Our efforts to increase awareness of the benefits of our sepsis test panels extend beyond the activities of our commercial team, medical affairs team, key opinion leaders and scientific advisory board. In April, we presented clinical data at the European Society of Clinical Microbiology and infectious Disease, ECCMID. Three presentations were delivered by clinicians highlighting their real-world experience, including the speed, accuracy, and clinical benefits delivered by the T2Dx Instrument and sepsis test panels.

Driving awareness of the benefits of the T2 technology combined with our optimized commercial approach gives us confidence in our ability to accelerate sales in the coming quarters.

Moving to our second priority – enhancing our operations:
We recognize that efficient operations are critical to our long-term success. To drive greater efficiency, we have taken measures to reduce expenses across the company. T2 Biosystems is now operating as a leaner organization with 110 employees compared to 204 employees in May of 2022. We expect the net result of our workforce reduction and cost control measures to significantly reduce our quarterly cash burn throughout 2023.

Driving increased leverage is a constant focus for our organization. We can achieve significant gross margin expansion as our customers continue to increase sepsis test panel utilization. Test panels carry a higher contribution margin and, as we increase test unit volumes, our overhead will be allocated across greater volume, which can lead to improved product gross margins. To support the growing demand for our sepsis test panels, our operations and manufacturing teams are hard at work managing the supply chain and continually improving our manufacturing process to drive greater efficiency. Over the last several months, we have strengthened our operations team by hiring a new VP of Operations, and subsequently hired new manufacturing and supply chain leadership.

On our March 2023 call, we discussed a raw material issue that we identified during our routine internal quality inspection that was limiting our ability to manufacture sufficient volume of sepsis test panels to meet consumer demand. Considering we identified this issue during our in-process inspection, product that was shipped to customers or distributors was not affected. We are pleased to report we have cleared the $230,000 backorders for the T2Candida Panel and T2 Bacteria Panel, since the end of the first quarter, and we are returning to more normalized shipment patterns for these products. We are still working through the materials issue for the T2Resistance Panel and we expect to have it resolved before the end of the second quarter.

Finally, in the first quarter, we strengthened our balance sheet by raising $12 million in gross proceeds. In the coming quarters, and consistent with the workforce reduction that we implemented last week, we will continue to be disciplined with our operating expenses to increase our operating leverage and extend our cash runway.

Moving to our third priority – advancing our pipeline:
T2 Biosystems' novel technology platform and scientific expertise position the company to expand our addressable markets in the future. Our new product pipeline is focused on two goals; 1) developing new tests to expand the test menu on the T2Dx Instrument and, 2) developing a next-generation instrument and comprehensive sepsis test panel.

We are currently developing five new tests that focus on expanding the test menu on our FDA-cleared T2Dx Instrument. By leveraging our existing instrument technology we are able to efficiently increase the capabilities of our sepsis test panels and add new tests to the platform. We believe additional testing menu will increase instrument adoption and test utilization. Each test represents a differentiated solution to rapidly identify harmful pathogens and potentially allow clinicians to achieve faster, targeted therapy. As we have discussed the T2Biothreat Panel earlier, I will focus my comments on the four remaining menu expansion programs:

1. The T2Resistance Panel is a direct-from-blood molecular diagnostic test designed to simultaneously detect 13 antibiotic resistance genes known to cause antibiotic resistant infections, in just 3-5 hours, without the need to wait days for a positive blood culture. The T2Resistance Panel, which is marketed and sold in Europe under CE mark, detects resistance genes that may confer resistance to common antimicrobials such as carbapenems, methicillin, and vancomycin. We have advanced the U.S. clinical trial and completed nearly 90% of the patient enrollment, and plan to file our submission to the FDA upon completion of the study. As a reminder, the T2Resistance Panel was granted Breakthrough Device Designation by the FDA, which provides for a prioritized review process upon submission, and has received funding under our contract with BARDA.

2. The T2Lyme™ Panel is a direct-from-blood molecular diagnostic test designed to detect Borrelia burgdorferi, the bacteria that is the major cause of Lyme disease in the U.S. The T2Lyme Panel is intended to test individuals with signs and symptoms of Lyme disease, and aid in the diagnosis of early Lyme disease, and we believe it will provide a significant advantage over the currently recommended serological testing that requires the presence of antibodies, which can take the body four to six weeks to create, post infection.

In 2022, our T2Lyme Panel was named a winner in the Lyme Innovation accelerator, or LymeX, a partnership between the U.S. Department of Health and Human Services and the Steven & Alexandra Cohen Foundation, the largest public-private partnership for Lyme disease that plans to award up to a total of $9 million to future award winners. We previously received a patent from the U.S. Patent and Trademark Office covering the T2Lyme Panel, and the FDA granted Breakthrough Device Designation for the T2Lyme Panel in 2022, allowing for a prioritized review process upon submission to the FDA.

We have completed the early assay development for the T2Lyme Panel and we established a preliminary level of detection (LOD) of 2 CFU/mL. We plan to initiate commercialization of the T2Lyme Panel as a Laboratory Developed Test and subsequently commence a U.S. clinical trial to support submission for FDA clearance.

3. We plan to add *Candida auris* to our T2Candida Panel, a direct-from-blood molecular diagnostic test that detects over 90% of Candida blood stream infections. *Candida auris* is a multidrug-resistant pathogen recognized by the CDC as a serious global health threat with a mortality rate up to 60%. According to CDC, *Candida auris* is difficult to identify with standard laboratory methods, which can lead to inappropriate treatment, and some strains are resistant to all three available classes of antifungals. The CDC estimates the costs associated with U.S. fungal diseases, in general, are as high as $48 billion annually, and has called on public health professionals to help lower the burden of fungal disease by continuing to raise awareness of the life-saving benefits of early detection and proper treatment.

We believe adding *Candida auris* to our existing T2Candida Panel will provide a significant time advantage compared to other blood culture-based methods and strengthen the value proposition of the test panel, making it even more attractive to our hospital customers. We have recently completed feasibility and early development of a diagnostic test to detect the *Candida auris* pathogen, and I am pleased to report we recently applied for FDA Breakthrough Device Designation for this test.

4. We plan to add Acinetobacter *baumannii* to the T2Bacteria Panel, a direct-from-blood molecular diagnostic test, to expand the number of pathogens detected on the test panel. Acinetobacter *baumannii* can cause bloodstream infections, especially in critically ill patients, which can range from benign transient bacteremia to septic shock, and has been reported to have a crude ICU mortality rate of 34% to 43%. Acinetobacter infections rarely occur outside of health care settings in the United States and can disproportionately impact those with weakened immune systems, chronic lung disease or diabetes. Acinetobacter can be resistant to many antibiotics, including carbapenems, highlighting the importance of rapid detection and targeted antimicrobial treatment.

Looking ahead at longer-term projects, we are focusing on developing next-generation sepsis products, including a new instrument and a comprehensive sepsis test panel. The next-generation instrument is designed to increased number of detections from a single, whole blood sample. The comprehensive sepsis test panel is a direct-from-blood test designed to detect >95% of all bloodstream infections caused by bacterial and *Candida* species, and antibiotic resistance genes identified as threats by the CDC, in a single test with a time to result of approximately three hours. The next-generation instrument and comprehensive sepsis test panel have been funded under our contract with BARDA.

We have been operating in Option 3 of the BARDA contract, after successfully meeting all development milestones under the Base Phase, Option 1, Option 2A, and Option 2B. We have filed a no-cost extension with BARDA, under Option 3, to allow additional time to complete the U.S. clinical trial for the T2Resistance Panel. Further funding from BARDA may resume following the completion of Option 3 and BARDA's potential exercise of Option 4 of the contract. Considering timing and funding is still uncertain, we are not providing guidance on BARDA revenue at this time.

With that, I will now turn the call over to John Sprague to provide a detailed update of our first quarter financial results and our financial outlook for 2023.

John Sprague

Thank you, John.

Total revenue for the first quarter of 2023 was $2.1 million, a 71% decrease compared to the prior year period, driven by a decline in COVID-19 test sales and reduced BARDA revenue. Product revenue was $1.7 million, a decrease of 57% compared to the prior year period, driven by a 98% decline in COVID-19 test sales partially offset by increased sepsis test sales. Research contribution revenues were $400 thousand, an 88% decrease compared to the prior year period, driven by decreased BARDA contract activities.

Cost of product revenue for the first quarter of 2023 was $4.0 million, a 35% decrease compared to the prior year period, driven by decreased COVID-19 test sales. Research and development expenses were $4.5 million, a 33% decrease compared to the prior year period, driven by decreased BARDA contract activities. Selling, general and administrative expenses were $7.3 million, a 21% decrease compared to the prior year period driven by decreased Medical Affairs spending.

Net loss for the first quarter of 2023 was $18.0 million, $1.32 per share, compared to a net loss of $16.5 million, $4.86 per share, in the prior year period.

Cash and cash equivalents were $10.1 million at March 31, 2023. In the first quarter of 2023 we raised $1.0 million from ATM sales and $11.0 million from a public offering. The 30% workforce reduction will decrease our burn. We remain in compliance with our loan covenants.

We reiterate guidance and expect 2023 total sepsis and related product revenue of $11.0 million to $13.0 million.

Thank you and back to John Sperzel for closing remarks.

John Sperzel

Thank you, John.

Before I conclude, I would like to address our Nasdaq listing compliance. On November 22, 2022, we received a letter from Nasdaq indicating that, for the last thirty consecutive business days, the Market Value of Listed Securities had been below the $35 million minimum requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). We were provided an initial period of 180 calendar days, or until May 22, 2023, to regain compliance. We expect to receive a letter from Nasdaq informing us that our shares have failed to comply with the MVLS required for continued listing on The Nasdaq Capital Market and, as a result, our shares are subject to delisting. We will file an appeal and hearing request with Nasdaq, which Nasdaq must grant, which will stay the delisting of our common stock from The Nasdaq Capital Market pending a Nasdaq listing qualifications hearings panel’s decision. 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 believe will enable us regain compliance in this timeframe.

As a reminder, sepsis presents one of the greatest challenges to healthcare systems worldwide, claiming approximately 11 million lives each year. In the U.S., sepsis is the #1 cost of hospitalization, costing our healthcare system approximately $62 billion annually; the #1 cause of death in hospitals, claiming the lives of approximately 270,000 Americans annually, and another 80,000 deaths in hospice each year; and the #1 cause of 30-day hospital readmissions, requiring nearly 20% of sepsis survivors to be readmitted within 30 days and nearly 40% to be readmitted within 90 days.

We are making progress to enhance the current standard of care for patients at risk of sepsis with our advanced diagnostic technology and we continue to be uniquely positioned to as the only company with FDA cleared diagnostics to detect sepsis causing pathogens directly from whole blood samples. Our sepsis and related product revenue continues to grow, including sepsis test panels and instruments, and we expect full year 2023 growth of 31% to 55%. The demand for our products is strong and our sales funnel continues to grow domestically and internationally. In an effort to maximize value, we also have taken important actions to reduce our operating expenses, including the restructuring program that was implemented last week, and we have engaged an advisory firm to explore all potential strategic alternatives. Finally, we are making excellent progress advancing our product pipeline, including several near-term programs focused on expanding the test menu on the FDA-cleared T2Dx Instrument, and that have the potential to add revenue as early as 2023.

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