# 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 7, 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 Capital 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 7, 2023, the Company issued a press release announcing its financial results for its fiscal quarter ended June 30, 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 August 7, 2023 |
| 99.2 | Transcript of conference call held on August 7, 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: August 11, 2023

**T2 BIOSYSTEMS, INC.**

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

**Exhibit 99.1**

**T2 Biosystems Announces Second Quarter 2023 Financial Results**

*Received FDA Breakthrough Device Designation for Candida auris test, achieved record quarterly sepsis test panel orders and received second largest sepsis driven T2Dx® Instrument order*

LEXINGTON, Mass., August 7, 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 second quarter ended June 30, 2023.

**Recent Financial and Operational Highlights**

- Achieved second quarter total revenue of $2.0 million, a decrease of 67% compared to the prior year period primarily due to a $3.4 million reduction in BARDA research contribution revenues.
- Achieved sepsis test panel revenue of $1.3 million, representing an increase of 7% compared to the prior year period, despite ending the quarter with a $350 thousand sepsis test backorder.
- Executed contracts for 11 T2Dx Instruments during the second quarter, including 4 in the U.S. and 7 internationally.
- Secured multi-year contract with a European distributor for 7 T2Dx Instruments and sepsis test panels for Poland – including T2Bacteria® Panel, T2Candida® Panel, and T2Resistance® Panel.
- Strengthened balance sheet by converting $10.0 million, or approximately 20%, of term loan debt with CRG Servicing LLC ("CRG") in exchange for shares of T2 Biosystems equity.
- Cash and cash equivalents totaled $16.1 million as of June 30, 2023, and the Company raised an additional $10.9 million in net proceeds through ATM sales during the third quarter.
- Received extension to comply with Nasdaq listing requirements through November 20, 2023.

**Recent Pipeline and Clinical Highlights**

- Received FDA Breakthrough Device designation for *Candida auris* direct-from-blood molecular diagnostic test, marking the third T2 Biosystems' product to receive this designation.
- Completed patient enrollment in the U.S. clinical trial for the T2Resistance Panel.
- Filed FDA submission for T2Biothreat™ Panel, a direct-from-blood diagnostic test that runs on the FDA-cleared T2Dx Instrument and detects six biothreat pathogens identified as threats by CDC.
- Established a clinical collaboration with Vanderbilt University Medical Center to implement the T2Bacteria Panel and assess its impact on antibiotic usage and clinical interventions.

"Our second quarter results were highlighted by record quarterly sepsis test panel orders and the second largest sepsis-driven instrument order in company history, demonstrating increasing demand for our life-saving direct-from-whole blood sepsis pathogen detection products," stated John Sperzel, Chairman and CEO of T2 Biosystems. "Progressing each of our corporate priorities, the implementation of our strategic restructuring program, which has led to a reduction in operating costs and the strengthening of the balance sheet, positions T2 Biosystems to continue the exploration of strategic alternatives and execute on our product development and growth initiatives."

**Second Quarter 2023 Financial Results**

Total revenue for the second quarter of 2023 was $2.0 million, a 67% decrease compared to the prior year period, driven primarily by reduced BARDA contribution revenues and de minimus COVID-19 test sales. Product revenue was $2.0 million, a decrease of 23% compared to the prior year period, driven by the decline in COVID-19 test sales and partially offset by increased sepsis test sales.

Cost of product revenue for the second quarter of 2023 was $4.9 million, a 4% decrease compared to the prior year period, driven by decreased COVID-19 test sales. Research and development expenses were $3.9 million, a 52% decrease compared to the prior year period, driven by decreased BARDA contract activities. Selling, general and administrative expenses were $6.3 million, a 20% decrease compared to the prior year period driven by decreased Medical Affairs spending.

Net loss for the second quarter of 2023 was $6.3 million, $0.08 per share, compared to a net loss of $18.0 million, $5.10 per share, in the prior year period.

Cash and cash equivalents totaled $16.1 million as of June 30, 2023. The Company raised $18.5 million in net proceeds through ATM sales in the second quarter of 2023 and on July 6, 2023, converted $10 million, or approximately 20%, of its term loan into equity.

**Updated 2023 Financial Outlook**

The Company now expects full year total sepsis and related product revenue of $9.5 million to $10.5 million, representing growth of 13% to 25%, compared to 2022.

**Webcast and Conference Call Information**

The Company's management team will host a conference call today, August 7, 2023, beginning at 4:30 pm ET. Investors interested in listening to the call may do so by dialing 888-506-0062 for domestic callers or 973-528-0011 for International callers and using conference ID 420267 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 Candida auris test, 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; (iv) failure to regain and maintain compliance with Nasdaq listing requirements and receipt of shareholder approval at our upcoming annual meeting of a reverse stock split; or (v) 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.

**Investor Contact:**

Philip Trip Taylor, Gilmartin Group
ir@T2Biosystems.com
415-937-5406

T2 BIOSYSTEMS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

| | June 30, 2023 | December 31, 2022 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 16,084 | $ 10,329 |
| Accounts receivable | 1,349 | 2,163 |
| Inventories | 4,337 | 4,285 |
| Prepaid expenses and other current assets | 2,100 | 2,582 |
| Total current assets | 23,870 | 19,359 |
| Property and equipment, net | 4,572 | 4,533 |
| Operating lease right-of-use assets | 8,088 | 8,741 |
| Restricted cash | 551 | 1,551 |
| Other assets | 49 | 143 |
| Total assets | $ 37,130 | $ 34,327 |
| **Liabilities and stockholders' deficit** | | |
| Current liabilities: | | |
| Notes payable | $ 50,571 | $ 49,651 |
| Accounts payable | 2,234 | 1,296 |
| Accrued expenses and other current liabilities | 10,400 | 7,269 |
| Operating lease liability | 1,480 | 1,352 |
| Derivative liability related to Term Loan | 836 | — |
| Warrant liabilities | 270 | 39 |
| Deferred revenue | 265 | 172 |
| Total current liabilities | 66,056 | 59,779 |
| Operating lease liabilities, net of current portion | 7,433 | 8,214 |
| Deferred revenue, net of current portion | 64 | 52 |
| Derivative liability related to Term Loan, net of current portion | — | 1,088 |
| Accrued interest on term loan | — | 4,849 |
| Total liabilities | 73,553 | 73,982 |
| Commitments and contingencies (see Note 13) | | |
| 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; 241,849,922 and 7,716,519 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively | 242 | 8 |
| Additional paid-in capital | 521,866 | 494,556 |
| Accumulated deficit | (558,531) | (534,219) |
| Total stockholders' deficit | (36,423) | (39,655) |
| Total liabilities and stockholders' deficit | $ 37,130 | $ 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Revenue: | | | | |
| Product revenue | $ 1,964 | $ 2,559 | $ 3,619 | $ 6,403 |
| Contribution revenue | — | 3,352 | 423 | 6,742 |
| Total revenue | 1,964 | 5,911 | 4,042 | 13,145 |
| Costs and expenses: | | | | |
| Cost of product revenue | 4,869 | 5,081 | 8,864 | 11,286 |
| Research and development | 3,850 | 8,025 | 8,321 | 14,681 |
| Selling, general and administrative | 6,296 | 7,824 | 13,595 | 17,054 |
| Total costs and expenses | 15,015 | 20,930 | 30,780 | 43,021 |
| Loss from operations | (13,051) | (15,019) | (26,738) | (29,876) |
| Other income (expense): | | | | |
| Interest income | 2 | 2 | 4 | 5 |
| Interest expense | (1,541) | (1,346) | (3,063) | (2,996) |
| Change in fair value of derivative related to Term Loan | 1,022 | (1,675) | 252 | (1,675) |
| Change in fair value of warrant liabilities | 7,192 | — | 5,888 | — |
| Other income | 37 | 4 | 37 | 13 |
| Other expense | — | — | (682) | — |
| Other losses | (8) | — | (10) | — |
| Total other income (expense) | 6,704 | (3,015) | 2,426 | (4,653) |
| Net loss | $ (6,347) | $ (18,034) | $ (24,312) | $ (34,529) |
| Net loss per share — basic and diluted | $ (0.08) | $ (5.10) | $ (0.51) | $ (9.96) |
| Weighted-average number of common shares used in computing net loss per share — basic and diluted | 80,916,888 | 3,535,763 | 47,460,986 | 3,466,816 |
| **Other comprehensive loss:** | | | | |
| Net loss | $ (6,347) | $ (18,034) | $ (24,312) | $ (34,529) |
| Net unrealized gain on marketable securities arising during the period | — | 9 | — | 2 |
| Net realized loss on marketable securities included in net loss | — | 2 | — | 2 |
| Total other comprehensive income, net of taxes | — | 11 | — | 4 |
| Comprehensive loss | $ (6,347) | $ (18,023) | $ (24,312) | $ (34,525) |

**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 second quarter 2023 earnings and business update call. Today, I will start by discussing our performance, including the key achievements we have made across our three corporate priorities. I will then turn the call over to John Sprague, our Chief Financial Officer, who will review our second quarter financial results and our outlook for 2023, before I provide closing remarks and we open the call for questions and answers.

The T2 Biosystems team has recently achieved a number of key milestones. During the second quarter, we received record quarterly sepsis test panel orders. We received the second largest sepsis-driven T2Dx® Instrument order in company history. We filed an FDA 510(k) submission for the T2Biothreat™ Panel. We applied for FDA Breakthrough Device designation for a *Candida auris* diagnostic test, and we received Breakthrough

Device designation from the FDA last month. We established a clinical collaboration on the T2Bacteria® Panel with Vanderbilt University Medical Center. We strengthened our balance sheet by raising capital and by converting of a portion of the CRG debt to equity. We believe that each of these milestones represents important progress toward driving increased adoption and utilization of our sepsis products, expanding our market opportunity, and providing flexibility to pursue our growth and development initiatives.

Our recent accomplishments contribute toward advancing our mission; to fundamentally change the way medicine is practiced through transformative, culture-independent diagnostics that improve the lives of patients around the world.

When it comes to sepsis, our main area of focus, we believe drastic changes are needed. There are an estimated 11 million sepsis-related deaths worldwide each year, more than all cancers combined. Sepsis is the #1 cost of U.S. hospitalization, costing our healthcare system an estimated $62 billion annually; sepsis the #1 cause of death in U.S. hospitals, causing the death of 270,000 Americans annually (and 80,000 more die each year in hospice); and sepsis is the #1 cause of 30-day re-hospitalization in the U.S., causing 19% of sepsis survivors to be re-hospitalized within 30 days and 40% to be re-hospitalized within 90 days. Current treatment methods are failing patients, payers, and providers.

As a reminder, T2 Biosystems has the only FDA-cleared products able to detect sepsis-causing pathogens directly-from-blood, in just 3-5 hours. We believe our products have a significant competitive time-to-result advantage, as our competitors continue to rely on positive blood culture results that can take 1-5 days, and longer for fungal infections, resulting in delayed targeted antimicrobial therapy. Data shows that the risk of death can increase by up to 8% for each hour of delayed, targeted antimicrobial therapy.

As we advance our mission, we are focused on three corporate priorities, 1) accelerating our sales, 2) enhancing our operations, and 3) advancing our pipeline. We will discuss each of these priorities in more detail.

Starting with our first priority – accelerating our sales

During the second quarter, we achieved total revenue of $2.0 million, comprised entirely of product revenue and notably, we received record quarterly sepsis test panel order volume. Sepsis test panel revenue was $1.3 million, representing an increase of 7% compared to the prior year period, despite ending the quarter with a $350,000 backorder. Had we been able to clear the backorder as of June 30th, sales of our sepsis test panels would have increased by 36% compared to the prior year period.

In addition to our record quarterly sepsis test panel orders, we executed contracts for 11 T2Dx Instruments during the second quarter, of which 4 were in the U.S. and 7 were outside the U.S. There continues to be a significant commercial opportunity for our products in international markets, reflected by continued sales of our T2Dx Instruments and sepsis test panels to our international distribution partners.

Our second quarter results included our second largest sepsis-driven instrument sale in the company's history, to satisfy a new contract that one of our European distributors won, to supply our sepsis products to hospitals in Poland. The initial term of the contract is for three years and includes 7 T2Dx Instruments as well as orders for our sepsis test panels, including the T2Bacteria Panel, the T2Candida® Panel, and the T2Resistance® Panel. The contract has the potential for 9 additional T2Dx Instruments to be sold and deployed into hospitals in Poland, which may occur during the second half of 2023, and the potential to extend the contract for an additional two years.

Poland has a population of over 40 million people, making it one of the most populous member states in the European Union, and more than 1,200 hospitals. A study of severe sepsis in ICU patients in Poland found mortality rates from 46% to 54%, and the length of stay in the ICU ranging from 8 to 13 days. We believe our products' ability to rapidly detect sepsis-causing pathogens and antibiotic resistant genes can enable clinicians to achieve faster targeted antimicrobial therapy, reduce length of stay in the ICU, and improve patient outcomes. Our discussions with our European distributors affirm our belief that there is a significant opportunity to deploy more of our products into an increasing number of hospitals in Poland, and throughout Europe.

Increased adoption and utilization of our sepsis products are being driven by a number of factors, including our efforts to increase awareness of their clinical and economic value. Our commercial, medical affairs, and service teams are closely aligned, educating current and potential customers on identifying use cases, expanding testing criteria, and implementing testing in hospitals' sepsis protocols.

During the second quarter, we announced a clinical collaboration with Vanderbilt University Medical Center to implement and evaluate our FDA-cleared T2Dx Instrument and T2Bacteria Panel in a clinical setting and to conduct a prospective study. Vanderbilt will assess the capability of the T2Bacteria Panel to improve clinical interventions and antibiotic usage for patients with a bloodstream infection. We believe this collaboration provides an opportunity to generate additional data to further demonstrate the value of the T2Bacteria Panel in one of the top academic medical centers in the U.S.

We anticipate additional findings from the Vanderbilt study will add to the clinical data library and further assist our Medical Affairs team in their education efforts. Data is continually being published and presented by Key Opinion Leaders around the world, as was on display at the recent European Society of Clinical Microbiology and Infectious Diseases (ECCMID) where three new studies were presented. At the American Society of Microbiology conference in June, Laboratory leaders from Butler Hospital, part of the newly formed Independence Health System, shared their experience with the T2Bacteria Panel. Their data demonstrates that the T2Bacteria Panel detects key infections in their patient population within 3-5 hours, as well as broad coverage, having identified positive patients for each of the T2Bacteria Panel targets. The team at Butler has developed a protocol to trigger the use of the T2Bacteria Panel and presented case studies showing that the T2Bacteria Panel allowed for targeted therapy as much as 37 hours faster than blood culture-based methods.

Moving to our second priority – enhancing our operations

We have taken a number of important steps to enhance our operations, including our cost structure, balance sheet, supply chain, and manufacturing. We believe these steps are essential for our long-term success, including our Nasdaq listing.

In May, we implemented a strategic restructuring program, which included a reduction of the company's workforce by nearly thirty percent, which now stands at approximately 100 employees, and has resulted in a significant reduction of our operating costs. As part of the restructuring program, we converted $10 million, or approximately 20%, of our CRG debt into equity, which strengthens our balance sheet. We view the conversion of debt to equity as a show of strong support from CRG. Finally, we announced our intent to explore strategic options, including acquisition, merger, reverse merger, other business combination, sale of assets, or licensing, which we continue to explore despite a significant improvement in our balance sheet since early May.

On our first quarter earnings call we discussed raw material issues that had limited our ability to produce sufficient volume of sepsis test panels to meet consumer demand. As a reminder, this was identified during routine, internal in-process inspection, so product that was shipped to customers or distributors was not affected. While we cleared the majority of the backorder that existed at the end of the first quarter, we ended the second quarter with a backorder of approximately $350,000. We have made significant changes that we expect to address and resolve the backorder, including the hiring of a new Vice President of Operations, improvements to the controls around our manufacturing capabilities, the advanced purchase of new critical raw materials, and the engagement of a consultant with significant experience manufacturing our products. We continue to have strong demand for our sepsis test panels from hospitals around the globe, and we expect to resolve the backorder to meet current and future customer and distributor demand for our products.

Finally, I would like to provide an update on our Nasdaq compliance plans. The Nasdaq Stock Market has rules that require all companies listed on the Nasdaq Capital Market to maintain a $1.00 minimum bid price and to maintain a minimum value of listed securities of at least $35 million. On July 6, 2023, we participated in an appeal hearing with the Nasdaq in which we presented our plans to regain compliance with both the $1.00 minimum bid price and the $35 million minimum value of listed securities, and requested additional time to regain compliance with those requirements. We are pleased to report that the Nasdaq has provided T2 Biosystems with a formal response approving our appeal and granting an extension to regain compliance until November 20, 2023, and we are executing on the plans that we presented to the Nasdaq.

Moving to our third priority – advancing our pipeline

Our new product development priorities target sepsis, bioterrorism, and Lyme disease, which represent areas of significant unmet medical need in which rapid detection can lead to faster targeted antimicrobial treatment and improved patient outcomes. Near term, we are prioritizing test menu expansion on our FDA-cleared T2Dx Instrument. Longer term, we are developing a next-generation instrument and comprehensive sepsis test panel.

We are developing five new products intended to expand the test menu on our T2Dx Instrument, including: the T2Biothreat Panel, the T2Resistance Panel, the T2Lyme™ Panel, a *Candida auris* test, and the addition of *Acinetobacter baumannii* to our existing FDA-cleared T2Bacteria Panel. Each new test panel, or test, represents a differentiated solution to rapidly identify harmful pathogens and potentially allow clinicians to achieve faster, targeted antimicrobial therapy. We believe expanding the test menu with these five new products will increase both instrument adoption and test utilization.

1. The T2Biothreat Panel is a direct-from blood molecular diagnostic test designed to run on the FDA-cleared T2Dx Instrument and simultaneously detect 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 purchases of the T2Biothreat Panel.

We filed an FDA submission for 510(k) clearance for the T2Biothreat Panel in early May 2023, we are actively engaged with the FDA on the submission, and we anticipate a positive outcome.

2. The T2Resistance Panel is a direct-from-blood molecular diagnostic test designed to run on the FDA-cleared T2Dx Instrument and 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, including completing patient enrollment, and we plan to file an FDA submission for 510(k) clearance after completing additional internal testing, including stability testing.

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.

3. The *Candida auris* test is a direct-from-blood molecular diagnostic test designed to run on the FDA-cleared T2Dx Instrument and detect *Candida auris* species in just 3-5 hours, without the need to wait days for a positive blood culture.

*Candida auris* is a multidrug-resistant fungal pathogen that has a mortality rate of up to 60%, and is recognized as a serious global health threat by the CDC and the World Health Organization. *Candida auris* is difficult to identify with standard laboratory methods, which can lead to inappropriate treatment. 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.

As a reminder, we currently market and sell the T2Candida Panel, the only FDA-cleared diagnostic test able to detect sepsis-causing fungal pathogens directly from blood, in just 3-5 hours, without the need to wait days for a positive blood culture. The T2Candida Panel runs on the FDA-cleared T2Dx Instrument and simultaneously detects five *Candida* species, including *Candida albicans*, *Candida tropicalis*, *Candida parapsilosis*, *Candida krusei*, and *Candida glabrata*. Rapid detection of these pathogens, as well as *Candida auris*, is essential to getting infected patients on targeted antifungal therapy and improving patient outcomes.

I am pleased to report we recently received FDA Breakthrough Device designation for the *Candida auris* test, which provides greater and more frequent access to the FDA and may accelerate our path to FDA clearance.

4. The *Acinetobacter baumannii* test is direct-from-blood molecular diagnostic test designed to run on the FDA-cleared T2Dx Instrument and detect *Acinetobacter baumannii* in just 3-5 hours, without the need to wait days for a positive blood culture. We plan to add the *Acinetobacter baumannii* test to our FDA-cleared T2Bacteria Panel to expand our pathogen detection capabilities. The addition of *Acinetobacter baumannii* will increase the detection capabilities of the T2Bacteria Panel to approximately 75% of all sepsis-causing bacterial infections commonly found in blood culture.

*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.

We believe that we have sufficient data to file an FDA submission for 510(k) clearance, and we plan to file that during the second half of 2023.

5. The T2Lyme™ Panel is a direct-from-blood molecular diagnostic test designed to run on the FDA-cleared T2Dx Instrument and 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 also received FDA Breakthrough Device designation for the T2Lyme Panel, which allows 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 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 510(k) clearance.

Looking ahead at longer-term products, we are developing a next-generation instrument and a comprehensive sepsis test panel. The next-generation instrument is designed to increase number of detections from a single, whole blood sample. The comprehensive sepsis test panel is a direct-from-blood test panel 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.

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

**John Sprague**

Thank you, John.

Second quarter 2023 revenues were $2.0 million, a 67% decrease compared to the prior year period, driven by a $3.4 million reduction in BARDA research contribution revenues and lower COVID-19 test sales. Sepsis test panel sales were $1.3 million, a 7% increase compared to the second quarter of 2022.

Second quarter 2023 cost of product revenue were $4.9 million, a 4% decrease compared to the prior year period, driven by lower COVID-19 test sales. Research and development expenses were $3.9 million, a 52% decrease compared to the prior year period, driven by decreased BARDA contract activities. Selling, general and administrative expenses were $6.3 million, a 20% decrease compared to the prior year period driven by decreased medical affairs spending. In May 2023, we initiated workforce reduction of nearly 30% across production, research and selling, general and administrative groups that will reduce our future expenses.

The second quarter 2023 net loss was $6.3 million, $0.08 per share, compared to a second quarter 2022 net loss of $18.0 million, $5.10 per share.

Cash and cash equivalents were $16.1 million as of June 30, 2023. In the second quarter we raised $18.5 million, net through the ATM facility, and we have raised an additional $10.9 million, net through ATM facility in the third quarter.

In early July 2023, CRG converted $10 million, approximately 20%, of its outstanding debt to common and preferred stock, strengthening our balance sheet and improving our cash flows. The preferred stock will convert to common stock in the third quarter of 2023, subject to shareholder approval.

We now believe the U.S. launch of the T2Resistance Panel will occur in 2024, and we expect total 2023 sepsis and related product revenue of $9.5 million to $10.5 million, representing growth of 13% to 25%, compared to 2022. We expect second half sepsis and related product revenue to be skewed to the fourth quarter. We anticipate no revenue from BARDA during the second half of 2023.

Thank you and back to John Sperzel for closing remarks.

**John Sperzel**

Thank you, John.

We achieved key milestones across our three corporate priorities during the second quarter of 2023. Commercially, we received record quarterly sepsis test panel orders and received the second largest sepsis-driven T2Dx Instrument order in company history. Operationally, we significantly improved our cost structure and strengthened our balance sheet, implemented a plan to eliminate the product backorder, and we are executing a plan to regain compliance with the Nasdaq listing requirements. Scientifically, we advanced a number of new product development initiatives that have all received FDA

Breakthrough Device designation, including the T2Resistance Panel, the T2Lyme Panel, and the *Candida auris* test. We view this as recognition, from one of the most stringent regulatory agencies in the world, that our products have a unique ability to positively impact healthcare.

We believe that applying our patented technology to three areas – sepsis, bioterrorism, and Lyme disease – which represent multi-billion dollar market opportunities, presents a significant opportunity to create shareholder value.

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