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): July 29, 2024

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 July 29, 2024, the Company issued a press release announcing its financial results for its fiscal quarter ended June 30, 2024, 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 8.01 Other Events

On July 29, 2024, the Company reported the following financial, operational and clinical updates for the quarter ended June 30, 2024:

- Achieved second quarter 2024 total revenue of $2.0 million, flat compared to the prior year period.
- Achieved record quarterly and first half sepsis test revenue, representing growth of 27% and 25% respectively compared to the prior year periods, led by T2Bacteria® and T2Resistance® panel sales.
- Loss from operations was $9.6 million in the second quarter of 2024, a 27% improvement compared to $13.1 million in the second quarter of 2023.
- Net loss for the second quarter of 2024 was $9.2 million, $0.66 per share, compared to a net loss of $6.3 million, or $7.84 per share, in the prior year period
- Cash and cash equivalents totaled $4.2 million as of June 30, 2024, compared to $6.2 million as of March 31, 2024.
- Executed contracts for 2 T2Dx® Instruments during the second quarter, both from outside the U.S. and have executed contracts for 6 additional instruments in July 2024.
- Signed multiple international distribution agreements in the Middle East and Asia, including Qatar, Hong Kong, Malaysia, Indonesia, and Macau.

- Converted $30.0 million of term loan debt with CRG Servicing LLC (“CRG”) in exchange for T2 Biosystems equity, reducing both total debt and quarterly interest payments to CRG by approximately 80% percent from May 2023 amounts.
- Completed clinical studies required to launch the T2Lyme Panel as a laboratory developed test (LDT) in the third quarter of 2024.
- Submitted a 510(k) premarket notification to the U.S. FDA to expand the use of the T2Candida® Panel to include pediatric testing.
- Advanced the T2Resistance Panel toward U.S. FDA 510(k) submission, now expected to occur during the fourth quarter of 2024.
- Presented new data at the American Society for Microbiology (ASM) Microbe 2024 conference demonstrates the clinical benefits of the culture-independent T2Candida Panel.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report on Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding our growth opportunities as a result of the receipt of FDA 510(k) clearance for the T2Candida® Panel to include pediatric testing and development for the T2Resistance Panel, financial results and cash balance, financial outlook, instrument contracts, timing of completing clinical trials and filing of an FDA submission, 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. The [preliminary], estimated financial results contained in this current report on Form 8-K have not been compiled or examined by our independent auditors and they are subject to revision as we prepare our financial statements as of and for the quarter ended June 30, 2024, including all disclosures required by U.S. generally accepted accounting principles. While we believe that such information and estimates are based on reasonable assumptions, actual results may vary, and such variations may be material. You should not place undue reliance on such preliminary information and estimates because they may prove to be materially inaccurate. 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, 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 Current Report on Form 8-K. Any such forward-looking statements represent management’s estimates as of the date of this Current Report on Form 8-K. 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 Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued July 29, 2024
99.2	Transcript of conference call held on July 29, 2024
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.

T2 BIOSYSTEMS, INC.

Date: July 29, 2024

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

Exhibit 99.1

T2 Biosystems Announces Second Quarter 2024 Financial Results

Achieved record quarterly and first half sepsis test revenue, representing growth of 27% and 25% respectively compared to the prior year periods

LEXINGTON, Mass., July 29, 2024 (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 and operational results for the second quarter ended June 30, 2024.

Recent Financial and Operational Highlights

- Achieved second quarter 2024 total revenue of $2.0 million, all from sepsis product sales.
- Achieved record quarterly and first half sepsis test revenue, representing growth of 27% and 25% respectively compared to the prior year periods, led by T2Bacteria® and T2Resistance® panel sales.
- Executed contracts for 2 T2Dx® Instruments during the second quarter, both from outside the U.S., and have executed contracts for 6 additional instruments in July 2024 and have executed contracts for 6 additional instruments in July 2024.
- Signed multiple international distribution agreements in the Middle East and Asia, including Qatar, Hong Kong, Malaysia, Indonesia, and Macau.
- Strengthened balance sheet by converting $30.0 million of term loan debt with CRG Servicing LLC ("CRG") in exchange for T2 Biosystems equity, reducing both total debt and quarterly interest payments to CRG by approximately 80% percent from May 2023 amounts.
- Raised $8.0 million in gross proceeds through a private placement stock sale executed in May 2024.
- $9.6 million loss from operations in the second quarter of 2024, a 27% improvement compared to $13.1 million in the second quarter of 2023.

Recent Pipeline and Clinical Highlights

- Completed clinical studies required to launch the T2Lyme Panel as a laboratory developed test (LDT) in the third quarter of 2024.
- Submitted a 510(k) premarket notification to the U.S. FDA to expand the use of the T2Candida® Panel to include pediatric testing.
- Advanced the T2Resistance Panel toward U.S. FDA 510(k) submission, now expected to occur during the fourth quarter of 2024.
- Presented new data at the American Society for Microbiology (ASM) Microbe 2024 conference demonstrates the clinical benefits of the culture-independent T2Candida Panel.

"We are highly encouraged by the record second quarter and record first half of 2024 sepsis test revenue, driven by increased sales of the T2Bacteria Panel, which can be attributed to effective commercial execution," stated John Sperzel, Chairman and CEO of T2 Biosystems. "Moving forward, we expect incremental sepsis revenue growth as a result of the recently FDA-cleared expanded T2Bacteria Panel, to include the detection of *Acinetobacter baumannii*, potential U.S. distribution partnership with a multibillion dollar healthcare company, and recently signed international distribution agreements in five new countries. We believe the launch of the T2Lyme Panel as a Laboratory Developed Test (LDT), planned for the third quarter of 2024, represents a significant growth opportunity. Finally, we continue to prioritize enhancing our operations and implementing cost reduction measures to improve cash flow."

Second Quarter 2024 Financial Results

Total revenue for the second quarter of 2024 was $2.0 million, flat compared to the prior year period. Sepsis test revenue grew 27% compared to the prior year period, led by T2Bacteria® and T2Resistance® panel sales. The increased in sepsis test revenue was offset by declines in international instrument sales.

Cost of product revenue for the second quarter of 2024 was $2.7 million, a 45% decrease compared to the prior year period driven by increased test sales and lower instrument sales. Research and development expenses were $3.4 million, a 13% decrease compared to the prior year period, driven by decreased clinical trial activities. Selling, general and administrative expenses were $5.5 million, a 13% decrease compared to the prior year period driven by decreased headcount spending.

Loss from operations was $9.6 million in the second quarter of 2024, a 27% improvement compared to a $13.1 million loss from operations in the second quarter of 2023.

Net loss for the second quarter of 2024 was $9.2 million, $0.66 per share, compared to a net loss of $6.3 million, or $7.84 per share, in the prior year period.

Cash and cash equivalents totaled $4.2 million as of June 30, 2024, compared to $6.2 million as of March 31, 2024. The Company raised $8.0 million in gross proceeds through a private placement stock sale executed in the second quarter of 2024.

Reiterated 2024 Financial Outlook

The Company continues to expect full year 2024 total sepsis product revenue of $10.0 million to $11.0 million, representing growth of 49% to 64%, compared to $6.7 million in 2023. The Company's 2024 revenue guidance consists entirely of sepsis product revenue and does not include potential sales of the T2Biothreat Panel or the T2Lyme Panel.

Webcast and Conference Call Information

The Company's management team will host a conference call today, July 29, 2024, 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 109834 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 T2Biothreat™ Panel, and are powered by the proprietary T2 Magnetic Resonance (T2MR®) technology. T2 Biosystems has an active pipeline of future products, including the U.S. T2Resistance Panel, the Candida auris test, and the T2Lyme™ Panel. 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 about global commercial expansion and international strategy, and the potential for strong

growth in the region, as well as statements that include the words “expect,” “may,” “should,” “anticipate,” and similar statements of a future or forward-looking nature. The financial information included herein have not been compiled or examined by our independent auditors and they are subject to revision as we prepare our financial statements as of and for the quarter ended June 30, 2024, including all disclosures required by U.S. generally accepted accounting principles. While we believe that such information and estimates are based on reasonable assumptions, actual results may vary, and such variations may be material. 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) continue to operate as a going concern and raise additional debt or equity financing necessary to fund working capital, make capital expenditures and service our debt, (b) realize anticipated benefits from commitments, contracts or products; (c) successfully execute strategic priorities; (d) bring products to market; (e) expand product usage or adoption; (f) obtain customer testimonials; (g) accurately predict growth assumptions; (h) realize anticipated revenues; (i) incur expected levels of operating expenses; or (j) 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, 2023, filed with the U.S. Securities and Exchange Commission, or SEC, on April 1, 2024, 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
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415-937-5406

T2 Biosystems, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 4,246	$ 15,689
Accounts receivable, net	1,297	1,420
Inventories	5,169	4,819
Prepaid expenses and other current assets	2,283	3,261
Total current assets	12,995	25,189
Property and equipment, net	1,517	1,658
Operating lease right-of-use assets	6,656	7,395
Restricted cash	551	551
Other assets	1	4
Total assets	$ 21,720	$ 34,797
Liabilities and stockholders' deficit		
Current liabilities:		
Notes payable to related party	$ 11,787	$ 41,284
Accounts payable	1,686	1,527
Accrued expenses and other current liabilities	4,276	4,905
Accrued final payment fee on Term Loan with related party	1,315	4,807
Operating lease liability	1,687	1,616
Derivative liability related to Term Loan with related party	424	1,554
Derivative liabilities with placement agent	894	—
Warrant liabilities	1,091	235
Deferred revenue	237	224
Total current liabilities	23,397	56,152
Operating lease liabilities, net of current portion	5,746	6,598
Deferred revenue, net of current portion	74	83
Total liabilities	29,217	62,833
Commitments and contingencies		
Stockholders' deficit		
Common stock, $0.001 par value; 400,000,000 shares authorized; 17,394,249 and 4,058,381 shares issued and outstanding on June 30, 2024 and December 31, 2023, respectively	17	4
Additional paid-in capital	599,559	556,256
Accumulated deficit	(607,073)	(584,296)
Total stockholders' deficit	(7,497)	(28,036)
Total liabilities and stockholders' deficit	$ 21,720	$ 34,797

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue:				
Product revenue	$ 1,952	$ 1,964	$ 4,013	$ 3,619
Contribution revenue	—	—	—	423
Total revenue	1,952	1,964	4,013	4,042
Costs and expenses:				
Cost of product revenue	2,693	4,869	6,895	8,864
Research and development	3,361	3,850	7,082	8,321
Selling, general and administrative	5,473	6,296	12,211	13,595
Total costs and expenses	11,527	15,015	26,188	30,780
Loss from operations	(9,575)	(13,051)	(22,175)	(26,738)
Other income (expense):				
Interest expense to related party	(478)	(1,541)	(1,657)	(3,063)
Change in fair value of derivative related to Term Loan with related party	1,238	1,022	1,130	252
Change in fair value of derivatives with placement agent	(322)	—	(322)	—
Change in fair value of warrant liabilities	(138)	7,192	(110)	5,888
Other, net	32	31	357	(651)
Total other income (expense)	332	6,704	(602)	2,426
Net loss	$ (9,243)	$ (6,347)	$ (22,777)	$ (24,312)
Net loss per share — basic and diluted	$ (0.66)	$ (7.84)	$ (2.37)	$ (51.23)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	14,095,348	809,168	9,595,079	474,609
Other comprehensive loss:				
Net loss	$ (9,243)	$ (6,347)	$ (22,777)	$ (24,312)
Total other comprehensive income, net of taxes	—	—	—	—
Comprehensive loss	$ (9,243)	$ (6,347)	$ (22,777)	$ (24,312)

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 April 1, 2024, 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 2024 results call. Today, I will start by discussing the July 2024 health alerts issued by multiple U.S. Government agencies informing healthcare providers that Becton Dickinson, or BD, is unable to supply sufficient quantities of blood culture media bottles, which has the potential to favorably impact our sepsis revenue. I will then provide a brief update on our three corporate priorities, before turning the call over to John Sprague, our Chief Financial Officer, who will review our financial results. I will then provide closing remarks and open the call for questions and answers.

On July 10, 2024, the U.S. Food and Drug Administration, or FDA, issued an alert to inform health care providers of interruptions in the supply of BD BACTEC blood culture media bottles because of recent supplier issues and added blood culture media bottles to the Medical Device Shortages List. According to the FDA alert, “the disruption in supply of this device is expected to impact patient diagnosis, follow up patient management, and antimicrobial stewardship efforts.”

On July 23, 2024, the U.S. Centers for Disease Control and Prevention, or CDC, issued a Health Alert Network to inform health care providers, laboratory professionals, health care facility administrators, and state, tribal, local, and territorial health departments of a critical shortage of BD BACTEC™ blood culture media bottles. The CDC alert included a link informing that the BD BACTEC blood culture media bottles had an estimated shortage duration through Q4 2024.

This is very important, as the current guidelines for treating patients with a bloodstream infection or sepsis, referred to as the SEP-1 bundle, specify a collection of blood cultures before the initiation of empirical treatment with broad-spectrum antibiotics or antifungals. As such, blood culture is one of the most widely used diagnostic tests in U.S. hospitals with an estimated 58 million tests run each year. According to the CDC, most blood cultures in the United States are performed using continuous-monitoring blood culture systems, and the BD continuous-monitoring blood culture system is used in about half of all U.S. laboratories and is only compatible with BD BACTEC™ blood culture media bottles.

T2 Biosystems is focused on sepsis, and I will remind everyone that sepsis continues to exact an enormous human and economic toll. Sepsis is the leading cause of death in U.S. hospitals and claims the lives of approximately 350,000 Americans annually. Sepsis also represents the leading cost of hospitalization in the U.S., costing our healthcare system an estimated $62 billion annually. Lastly, sepsis is the leading cause of 30-day hospital readmission in the U.S., with 19% of sepsis survivors re-hospitalized within 30 days and 40% within 90 days.

On previous earnings calls, I have described the limitations of relying on blood culture as a clinical specimen for patients at risk of sepsis, including poor sensitivity (i.e., false negative results or missed infections) and slow time to results (i.e., 1-5 days). Despite these shortcomings, blood culture remains as the standard of care for patients at risk of sepsis and, except for T2 Biosystems' sepsis products, all other FDA-cleared products authorized for pathogen detection or antibiotic resistance [testing] require a positive blood culture as the clinical specimen. These blood culture-dependent diagnostic products – which include virtually all our competitors provide little to no clinical value if blood culture yields a false negative result due to poor sensitivity, or if blood culture is not available due to supplier issues.

The blood culture supply interruption underscores the risk of creating guidelines based on a single diagnostic technology (i.e., blood culture). We believe this is the perfect time to lobby for changes to the guidelines to include diagnostic products that are able to detect sepsis-causing pathogens and antibiotic resistance genes directly-from-blood and independent of blood culture.

As a reminder, T2 Biosystems developed, and is commercializing, the only FDA-cleared diagnostics able to detect sepsis-causing pathogens directly from whole blood, without the need to wait days for a positive blood culture. The combination of our FDA-cleared T2Dx® Instrument, T2Bacteria® Panel, and T2Candida® Panel can detect sepsis-causing bacterial and fungal pathogens in 3-5 hours directly-from-blood. No other company in the world can make that claim. It is important to note that our expanded T2Bacteria Panel, which now includes the detection of *Acinetobacter baumannii*, covers approximately 75% of all sepsis-causing bacterial pathogens commonly found in bloodstream infections. Likewise, our T2Candida Panel covers approximately 90% of candida species commonly found in bloodstream infections.

As part of the communication, both the FDA and CDC have recommended that health care providers develop strategies to minimize the use of blood culture media bottles. Our products can be effectively used to minimize the use of blood culture bottles, especially during this critical shortage, and can also provide results for the most common pathogens much faster than blood culture, which can lead to faster targeted antimicrobial treatment.

Now turning to review the significant progress we made in second quarter of 2024 across our three corporate priorities: 1) accelerating our sales, 2) enhancing our operations, and 3) advancing our pipeline.

Starting with our first corporate priority — accelerating our sales.

The T2 Biosystems team achieved record quarterly and first half sepsis test revenue, representing growth of 27% and 25% respectively, compared to the prior year periods. This double-digit sales growth was driven by sales of our T2Bacteria Panel and our T2Resistance Panel. During the second quarter, we executed contracts for 2 T2Dx Instruments in international markets and ended the quarter with a number of opportunities deep in our sales funnel. As expected, we have already executed contracts for an additional 6 T2Dx Instruments valued at approximately $400,000 in July of 2024.

In the U.S. market, our commercial team continues to prioritize increasing sales of our sepsis test panels. We believe the BD blood culture media bottle shortage represents an opportunity for T2 Biosystems to increase adoption of our direct-from-blood, or blood culture-independent diagnostics, and our team is implementing a plan to proactively contact hospital microbiology departments.

Over the last twelve months, we have been exploring a range of strategic alternatives, including U.S. commercial partnerships to accelerate the growth of our business. I am pleased to inform you that we are in negotiations with a multibillion-dollar healthcare company regarding a potential U.S. commercial partnership for the distribution of our products.

In international markets, we continue to execute on our plan to expand our commercial footprint by entering into territory-exclusive distribution agreements to market and sell the T2Dx® Instrument, the T2Bacteria® Panel, the T2Candida® Panel, and the T2Resistance® Panel. During the second quarter, we entered into new territory exclusive distribution agreements covering Qatar, Hong Kong, and Macau. Earlier today, we announced a new territory exclusive distribution agreement covering Malaysia and Indonesia.

The execution of these distribution agreements further expands our commercial footprint in the Asia Pacific and Middle East regions, which we believe represents strong growth potential for our culture-independent rapid diagnostics. The introduction of the T2Dx Instrument and sepsis panels into Hong Kong, Macau, Malaysia, Indonesia and Qatar will allow rapid detection of certain sepsis-causing pathogens and antibiotic resistance genes, in hours instead of days, enabling clinicians to potentially achieve targeted therapy, faster. We look forward to building lasting relationships with our newly appointed distributors.

Our sepsis products continue to generate data further validating the value we can deliver to hospital microbiology labs to improve patient care. In May, T2 customers presented new clinical data to support the T2Candida Panel at American Society for Microbiology ASM Microbe 2024 conference in Atlanta.

The first presentation at ASM demonstrated how the use of the T2Candida Panel led to improved patient care for patients suspected of Candidemia at Henry Ford Hospital. The findings highlighted the T2Candida Panel results being available over 38 hours faster than beta-D-glucan tests and the detection of over three times as many infections as blood culture. The evidence further supports the improved clinical outcomes that can be achieved with the T2Candida Panel in the diagnosis and management of Candidemia at a large, urban academic center.

The second presentation was at ASM demonstrated clinical outcome data for patients admitted to an ICU at Henry Ford Hospital that utilized the T2Candida Panel compared to a control hospital using only the blood culture standard of care. Analysis revealed that more patients diagnosed with the T2Candida Panel were alive without any events and had a 58.6% probability of achieving a better outcome compared to conventional blood culture testing. There was also less incidence of treatment failures, persistent candidemia

and infectious complications in patients who were diagnosed via the T2Candida Panel compared to conventional testing. Overall, the presentation highlighted that use of the T2Candida Panel within an antifungal stewardship policy was associated with an overall better clinical outcome compared to diagnosis with blood culture.

Beyond sepsis, we are also applying our technology to two additional areas: bioterrorism and Lyme disease. We believe these additional applications have the potential to be significant growth catalysts for the company.

On the T2Biothreat Panel, we have entered into an agreement with Dr. Robin Robinson to serve as a strategic advisor. He is currently fielding interest and identifying strong potential government targets to procure the T2Biothreat Panel. We believe the panel represents a strong market opportunity and has the important ability to protect our nation from the consequences of deliberate or accidental exposure to biothreats.

We plan to launch our T2Lyme Panel as a Laboratory Developed Test, or LDT, during the third quarter of 2024 through a strategic partnership with ECO Laboratory. We believe there are numerous advantages of launching the T2Lyme Panel in this format, including: 1) faster time to market, 2) higher test throughput, and 3) stronger product contribution margins, as the LDT format does not require the use of the T2Dx Instrument, or the costs associated with a cartridge. Internal market research confirms that reference laboratories often charge greater than $250 for two-tiered antibody Lyme tests, and greater than $250 for PCR Lyme tests.

It is important to note that sales of the T2Biothreat Panel and T2Lyme Panel are not in our current 2024 revenue guidance, so potential sales during 2024 represent upside to that guidance.

Moving to our second corporate priority — enhancing our operations.

We continue to take important steps to transform our balance sheet and improve our cost structure. Over the past twelve months, we have reduced our debt by approximately 80% by converting $40 million of our term loan with entities affiliated with CRG Servicing LLC, or CRG, to common stock. This has significantly strengthened our balance sheet and reduced our annual interest payments by approximately $3.2 million.

During the second half of 2024, we plan to further consolidate our real estate space, by exiting our facility at 4 Hartwell Ave in Lexington, MA and consolidating those operations into our headquarters at 101 Hartwell Ave. in Lexington, MA. We expect this move to reduce our annual facilities costs by approximately $1.0 million annually.

Effective August 1, 2024, we are partnering with ADP TotalSource, as our Professional Employer Organization, or PEO, to provide comprehensive and cost-effective HR benefits including, healthcare benefits, workers' compensation, payroll and tax support, and HR guidance. We estimate this change will result in annualized savings of approximately $0.4 million.

Since early 2023, we have reduced our headcount by approximately 30% to 113 people. At the same time, we have reduced employee-related operating expenses.

Finally, during the second quarter, we expanded the use of our Oracle ERP system to improve inventory planning and material management. We believe the Oracle ERP expansion will favorably impact inventory levels, cost of goods sold, and ultimately improve cashflow.

Moving to our third corporate priority — advancing our pipeline.

We have three tests in our pipeline – including the U.S. T2Resistance Panel, the T2Lyme Panel, and the expanded T2Candida Panel to include detection of *Candida auris*. These three tests, or test panels, have each received FDA Breakthrough Device designation, and each share a critical requirement for rapid detection of the causative pathogen and targeted antimicrobial treatment.

The U.S. T2Resistance Panel is a direct-from-blood molecular diagnostic test that runs on the FDA-cleared T2Dx Instrument and simultaneously detects 13 antibiotic resistance genes, in just 3-5 hours, without the need to wait days for a positive blood culture. We believe the T2Resistance Panel will be a significant catalyst to drive broader adoption of our T2Dx Instrument and our T2Bacteria Panel.

In March, we issued a press release to announce the results of a new prospective study that was published in the *Journal of Clinical Microbiology*, highlighting the performance and clinical benefits of the T2Resistance Panel compared to blood culture and standard microbiology methods, including high accuracy (i.e., 94.7% sensitivity, 94.7% specificity), rapid turnaround time (i.e., results available is 4.4 hours 58.3 hours), and clinical impact (i.e., clinical interventions in 41% of patients in the study; 24 of 59 patients).

We believe this performance data demonstrates the enormous potential of this unique and highly differentiated product — to reduce cost, improve patient outcomes, and reduce the threat of antibiotic resistance. We expect this to be a catalyst for greater adoption of the T2Resistance Panel in countries where we currently market under CE mark. We also believe the international experience with the direct-from-blood detection of antibiotic resistance genes is an important precursor to our launch in the U.S. market.

Due to our priority to provide products for our existing customers, our internal verification and validation studies were delayed. As a result, we now plan to submit a 510(k) premarket notification to the U.S. Food and Drug Administration, or FDA, during the fourth quarter of 2024, and we expect to receive a prioritized FDA review due to its Breakthrough Device designation.

The T2Lyme Panel is a direct-from-blood molecular diagnostic test designed for the early detection of *Borrelia burgdorferi*, the bacterium that causes Lyme disease in the U.S.

Lyme disease is the leading vector-borne disease in America, with an estimated 3.4 million tests performed each year. The current diagnostic process is a two-tiered antibody test algorithm that relies on the presence of antibodies and can only be used accurately four to eight weeks after infection. If left untreated, the bacteria may spread throughout the body and become much harder to eradicate and treat effectively. Although early symptoms of Lyme disease are similar to the flu, *Borellia burgdorferi* infections can lead to chronic, debilitating disease.

To address this critical unmet need, we have developed an extremely sensitive diagnostic test for the detection of early Lyme disease, with an analytical sensitivity that is in line with our FDA-cleared sepsis tests. We have recently completed clinical studies required to launch the T2Lyme Panel as a LDT. We believe our test will detect Lyme disease within the first 30 days post infection, compared to antibody tests that can take 30-60 days post infection.

As I mentioned earlier on the call, we plan on launching the T2Lyme Panel as an LDT in the third quarter of 2024, through a strategic partnership with Eco Laboratory. Our ultimate objective is to provide early Lyme disease results to major U.S. reference laboratories. We believe we can utilize their retail networks to collect patient samples, which would potentially allow us to provide testing to Lyme patients across the country. These samples would then be sent to our LDT laboratory partner to perform the T2Lyme Panel in their lab. It is important to note that T2Lyme Panel sales are also not in our current 2024 revenue guidance, so any potential sales during 2024 represent upside to that guidance.

The expanded T2Candida Panel, which will include the detection of *Candida auris,* is a direct-from-blood molecular diagnostic test designed to detect *Candida* species, in just 3-5 hours, without the need to wait days for a positive blood culture. We believe the addition of a *Candida auris* test will strengthen the value proposition of our T2Candida Panel and lead to increased adoption.

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. The CDC estimates the costs associated with U.S. fungal diseases 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.

A 2022 *Journal of Clinical Microbiology* study conducted at the Bambino Gesù hospital in Rome, Italy found that pediatric patients suspected of fungal bloodstream infections that were tested with the T2Candida Panel received species identification results 121.8 hours faster compared to blood culture-based diagnostics.

Finally, we are also pursuing expanded claims for our FDA-cleared T2Candida Panel and T2Bacteria Panel, to include pediatric testing. In December 2023, we submitted a 510(k) premarket notification to the FDA to expand the use of the T2Candida Panel to include pediatric testing, and we expect to submit a 510(k) premarket notification to the FDA to expand the use of the T2Bacteria Panel to include pediatric testing during 2024.

With that, I will now turn the call over to John Sprague to provide a detailed update on our first quarter financial results.

John Sprague

Thank you, John.

Second quarter 2024 revenues were $2.0 million, all from sepsis product sales. Sepsis test panel sales increased 27% compared to the prior year period and increased 12% compared to the first quarter of 2024 led by increase sepsis test sales, offset by lower international instrument sales.

Second quarter 2024 cost of product revenues were $2.7 million, a 45% decrease compared to the prior year period, driven by increased sepsis test sales and lower international instrument sales. Research and development expenses were $3.4 million, a 13% decrease compared to the prior year period, driven by decreased clinical trial activities. Selling, general and administrative expenses were $5.5 million, a 13% decrease compared to the prior year period driven by decreased headcount spending.

The second quarter 2024 net loss was $9.2 million, $(0.66) per share, compared to the prior year second quarter net loss of $6.3 million, $(7.84) per share.

Cash and cash equivalents were $4.2 million as of June 30, 2024, and we raised $7.3 million in net proceeds from a private placement stock sale in the quarter. The CRG debt conversation reduced our debt by almost 80% and interest expense by almost 70% compared to a year ago.

In 2024 we continue to expect total sepsis and related product revenues to grow between 49% and 64% to $10.0 million to $11.0 million over 2023 and this target excludes any potential sales from our T2Biothreat or T2Lyme panels.

Thank you and back to John Sperzel for the closing remarks.

John Sperzel

We are highly encouraged by our progress made in the second quarter of 2024, including record sepsis test sales, significantly improving our balance sheet, materially improving our cost of product revenue, and reducing our operating expenses. Moving forward, we are excited by the potential to accelerate the growth of our sepsis business in the U.S. and internationally.

We are also excited by the potential near-term catalysts, including the opportunity created by the BD blood culture media bottle shortage, the U.S. commercial launch of our T2Lyme Panel for the detection of early Lyme disease planned for the third quarter of 2024, and the potential to establish a U.S. commercial partnership with a multibillion-dollar healthcare company.

Our pipeline is also rich with potential catalysts that have already received FDA Breakthrough Device designation, including the U.S. T2Resistance Panel, which we plan to submit to the FDA for 510(k) clearance during the fourth quarter of 2024, and the expanded T2Candida Panel, to include the detection of *Candida auris*.

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