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): November 14, 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 November 14, 2024, the Company issued a press release announcing its financial results for its fiscal quarter ended September 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 November 14, 2024, the Company reported the following financial, operational and clinical updates for the quarter ended September 30, 2024:

- Achieved third quarter total revenue of $2.0 million, representing an increase of 34% compared to the prior year period.
- Achieved sepsis test panel revenue of $1.4 million, representing an increase of 34% compared to the prior year period, driven by increased U.S. T2Bacteria® Panel revenue.
- Executed contracts for 11 T2Dx® Instruments during the third quarter, including 1 in the U.S. and 10 internationally.

- Initiated exclusive U.S. distribution agreement with Cardinal Health for the commercialization of the T2Biosystems Sepsis product portfolio, expanding access to the U.S. hospital market.
- Launched co-marketing collaboration with Prxcision, Inc., for rapid direct-from-blood diagnostics and AI-powered decision support platform to provide hospitals with a solution that is designed to deliver rapid identification of pathogens directly from blood in hours, not days, paired with real-time insights and information to help guide the best possible treatment decisions.
- Received clearance from the U.S. Food and Drug Administration (FDA) to market the T2Candida® Panel for pediatric patients.
- Advanced the T2Resistance® Panel toward U.S. FDA 510(k) submission which is expected to occur during the first quarter of 2025.
- Defended successfully against an opposition of a key patent for the Company's innovative direct-from-blood pathogen detection method filed with the European Patent Office by bioMerieux.
- The article "Changing the Culture of Blood Culture" recently published in The Lancet, a world-leading medical journal, highlighted the weaknesses of blood culture, and the more ideal characteristics of culture-independent diagnostics consistent with the features and benefits provided by the T2Bacteria Panel, the T2Candida Panel, and the T2Resistance 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 distribution agreement with Cardinal Health, 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 November 14, 2024
99.2	Transcript of conference call held on November 14, 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: November 15, 2024

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

Exhibit 99.1

T2 Biosystems Announces Third Quarter 2024 Financial Results

Achieved 34% quarterly revenue growth compared to the prior year period

LEXINGTON, Mass., November 14, 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 third quarter ended September 30, 2024.

Recent Financial and Commercial Highlights

- Achieved third quarter total revenue of $2.0 million, representing an increase of 34% compared to the prior year period.
- Achieved sepsis test panel revenue of $1.4 million, representing an increase of 34% compared to the prior year period, driven by increased U.S. T2Bacteria® Panel revenue.
- Executed contracts for 11 T2Dx® Instruments during the third quarter, including 1 in the U.S. and 10 internationally.
- Initiated exclusive U.S. distribution agreement with Cardinal Health for the commercialization of the T2Biosystems Sepsis product portfolio, expanding access to the U.S. hospital market
- Launched co-marketing collaboration with Prxcision, Inc., for rapid direct-from-blood diagnostics and AI-powered decision support platform to provide hospitals with a solution that is designed to deliver rapid identification of pathogens directly from blood in hours, not days, paired with real-time insights and information to help guide the best possible treatment decisions

Recent Pipeline and Clinical Highlights

- Received clearance from the U.S. Food and Drug Administration (FDA) to market the T2Candida® Panel for pediatric patients.
- Advanced the T2Resistance® Panel toward U.S. FDA 510(k) submission which is expected to occur during the first quarter of 2025.
- Defended successfully against an opposition of a key patent for the Company's innovative direct-from-blood pathogen detection method filed with the European Patent Office by bioMerieux.
- The article "Changing the Culture of Blood Culture" recently published in The Lancet, a world-leading medical journal, highlighted the weaknesses of blood culture, and the more ideal characteristics of culture-independent diagnostics consistent with the features and benefits provided by the T2Bacteria Panel, the T2Candida Panel, and the T2Resistance Panel.

"In the third quarter T2Biosystems generated strong revenue growth driven by 173% sales growth from the T2Bacteria Panel in the U.S. and 78% growth in international instrument sales," stated John Sperzel, Chairman and CEO of T2 Biosystems. "We expect to continue achieving stronger growth following several recent commercial, operational and pipeline advancements. The U.S. commercial distribution agreement with Cardinal, collaboration with Prxcision, and FDA clearance for the T2Candida Panel for pediatrics represent immediate opportunities to provide our clinically differentiated, culture-independent, diagnostics to more patients and hospitals."

Third Quarter 2024 Financial Results

Total revenue for the third quarter of 2024 was $2.0 million, an increase of 34% compared to the prior year period. Sepsis test revenue grew 34% compared to the prior year period, led by T2Bacteria®.

Cost of product revenue for the third quarter of 2024 was $4.1 million, a 4% increase compared to the prior year period driven by increased international instrument and sepsis test sales. Research and development expenses were $2.7 million, which is comparable to the prior year period. Selling, general and administrative expenses were $5.4 million, a 10% decrease compared to the prior year period driven by decreased headcount, offset by increased legal expense.

Net loss for the third quarter of 2024 was $10.1 million, $(0.57) per share, compared to the prior year third quarter net loss of $15.4 million, or $(3.45) per share.

Cash and cash equivalents totaled $2.1 million as of September 30, 2024. The Company raised $4.3 million in net proceeds with our ATM during the quarter and $3.2 million since September 30, 2024.

2024 Financial Outlook

The Company expects fourth quarter 2024 total sepsis product revenue of $2.5 million to $3.5 million. This target 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, November 14, 2024, beginning at 4:30 pm ET. Investors interested in listening to the call may do so by dialing 877-545-0320 for domestic callers or 973-528-0002 for International callers and using conference ID 903508 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 September 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:

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415-937-5406

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

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 2,083	$ 15,689
Accounts receivable, net	2,033	1,420
Inventories	3,825	4,819
Prepaid expenses and other current assets	1,845	3,261
Total current assets	9,786	25,189
Property and equipment, net	1,477	1,658
Operating lease right-of-use assets	6,268	7,395
Restricted cash	551	551
Other assets	—	4
Total assets	$ 18,082	$ 34,797
Liabilities and stockholders' deficit		
Current liabilities:		
Notes payable to related party	$ 11,922	$ 41,284
Accounts payable	4,210	1,527
Accrued expenses and other current liabilities	4,627	4,905
Accrued final payment fee on Term Loan with related party	1,306	4,807
Operating lease liability	1,724	1,616
Derivative liability related to Term Loan with related party	347	1,554
Warrant liabilities	66	235
Deferred revenue	233	224
Total current liabilities	24,435	56,152
Operating lease liabilities, net of current portion	5,298	6,598
Deferred revenue, net of current portion	59	83
Total liabilities	29,792	62,833
Commitments and contingencies		
Stockholders' deficit		
Preferred stock, $0.001 par value; 10,000,000 shares authorized: Series B Convertible Preferred Stock, 0 shares designated on September 30, 2024, 0 and 93,297 shares issued and outstanding to related party on September 30, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; 18,760,092 and 4,058,381 shares issued and outstanding on September 30, 2024 and December 31, 2023, respectively	18	4
Additional paid-in capital	605,182	556,256
Accumulated deficit	(619,910)	(584,296)
Total stockholders' deficit	(11,710)	(28,036)
Total liabilities and stockholders' deficit	$ 18,082	$ 34,797

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue:				
Product revenue	$ 1,985	$ 1,472	$ 5,998	$ 5,091
Contribution revenue	—	—	—	423
Total revenue	1,985	1,472	5,998	5,514
Costs and expenses:				
Cost of product revenue	4,101	3,925	10,996	12,789
Research and development	2,667	2,663	9,749	10,984
Selling, general and administrative	5,378	5,980	17,589	19,575
Impairment of property and equipment	—	2,511	—	2,511
Total costs and expenses	12,146	15,079	38,334	45,859
Loss from operations	(10,161)	(13,607)	(32,336)	(40,345)
Other income (expense):				
Interest expense to related party	(370)	(1,119)	(2,027)	(4,182)
Change in fair value of derivative related to Term Loan with related party	77	184	1,207	436
Change in fair value of warrant liabilities	321	(930)	169	4,958
Other, net	16	47	373	(604)
Total other income (expense)	44	(1,818)	(278)	608
Net loss	$ (10,117)	$ (15,425)	$ (32,614)	$ (39,737)
Net loss per share — basic and diluted	$ (0.57)	$ (3.45)	$ (2.63)	$ (21.79)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	17,892,606	4,477,321	12,381,110	1,823,485

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 third quarter 2024 results call. I will start by discussing our recent highlights and providing an update on the progress of 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 before opening the call for questions and answers.

T2 Biosystems is focused primarily on sepsis, and I will remind everyone that sepsis continues to take 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 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 blood culture-based diagnostics, which are the current standard of care for the management of patients suspected of sepsis. Relying on blood culture as a clinical specimen for patients at risk of sepsis presents several challenges, including poor sensitivity – which can lead to false negative results or missed infections – and slow time to results (typically 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 in this space, 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 BD BACTEC blood culture supply interruption, which led to customer letters from the U.S. Food and Drug Administration (FDA) and the U.S. Centers for Disease Control and Prevention (CDC), and resulted in blood culture media bottles being added to the Medical Devices Shortage List, 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 bacterial and fungal pathogens and antibiotic resistance genes directly-from-blood, independent of blood culture, and we are actively lobbying for such changes.

In response to this critical supply situation, a manuscript titled "Changing the Culture of Blood Culture" was recently published in The Lancet, a world-leading medical journal. It highlights the potential for culture-independent diagnostics like our T2Bacteria® Panel, the T2Candida® Panel, and the T2Resistance® Panel to compliment and improve the existing protocols for patients suspected of sepsis.

T2 Biosystems has developed and is commercializing a technology that is designed to address the challenges associated with the other diagnostics used to detect sepsis-causing pathogens and antibiotic resistance. We provide 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.

Now turning to review the significant progress we have made 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.

In the U.S. market, our commercial team continues to prioritize increasing sales of our sepsis test panels. The T2 Biosystems team generated third quarter revenue of $2.0 million representing 34% growth compared to the prior year period. Growth was driven by $1.4 million of sepsis test panel revenue that included a 173% increase in sales of the T2Bacteria Panel in the U.S. market. During the third quarter, we executed contracts for 11 T2Dx instruments, including 1 in the U.S. and 10 internationally. The international contracts helped drive a more than a 78% increase in sales of the T2Dx Instrument compared to the third quarter of 2023.

To strengthen our U.S. commercialization efforts with our sepsis products and capitalize on what we believe is a significant opportunity to improve the standard of care, we are extremely pleased to have entered into an exclusive commercial distribution agreement with Cardinal Health.

Cardinal Health is a distributor of pharmaceuticals, a global manufacturer and distributor of medical and laboratory products, and a provider of performance and data solutions for healthcare facilities. Cardinal Health trades on the New York Stock Exchange under the symbol CAH, has annual revenue of more than $200 billion, has operations in more than 30 countries, and has approximately 48,000 employees.

Our agreement grants Cardinal Health exclusive rights to the only FDA-cleared direct-from-blood pathogen detection products. In addition to the economic benefits, having access to T2 Biosystems' direct-from-blood diagnostics strengthens Cardinal Health's product offering to microbiology laboratories. We believe our agreement with Cardinal Health will be transformative, with the objectives of accelerated revenue growth and a faster path to profitability by expanding our access to the more than 6,000 U.S. hospitals. We expect the exclusive nature of the agreement to align interests and motivate the Cardinal commercial team and give Cardinal with a competitive advantage vis-à-vis their competitors.

Cardinal Health is one of the largest healthcare companies in the U.S. and sells to 90% of U.S. hospitals through its extensive commercial organization and holds contracts with a large number of U.S. Group Purchasing Organizations, or GPOs. Cardinal Health's reach includes the 200-plus Children's hospitals in the U.S., which we are now targeting following the recent T2Candida Panel FDA clearance for use in pediatric patients.

We expect this collaboration to greatly expand our access to the U.S. hospital market as Cardinal Health has an extensive commercial and distribution infrastructure, including capital equipment specialists who will sell the T2Dx Instrument. At this point we have trained the team at Cardinal to fully understand the science behind our technology, its

features and benefits, and the clinical and economic value it offers. Our products are now established in the Cardinal Health ecosystem, they are in the process of launching the initial sales campaigns, and our teams have begun working together in the field.

While the terms of our agreement with Cardinal Health are confidential, in general, the economics and logistics are similar to those we have with our international distributors. For example, T2 Biosystems will sell our FDA-cleared products to Cardinal Health — including the T2Dx Instrument, the T2Bacteria Panel, and the T2Candida Panel – and Cardinal Health will sell the products to U.S. hospitals.

In the U.S., we recently announced a co-marketing collaboration with PrXcision, Inc., aimed at pioneering a new frontier in antibiotic stewardship to combat the growing threat of antimicrobial resistance. Antibiotic resistance is one of the greatest threats facing modern medicine, with millions of lives at risk. Over 1.27 million deaths are reported annually due to antimicrobial resistance (AMR), which threatens to render essential antibiotics useless. The stakes are high, and time is critical—each hour of delayed targeted treatment can increase the risk of death by up to 8% for sepsis patients.

PrXcision is a NY-based private company that is leveraging two decades of expertise in antibiotic development to create a real-time, AI-powered decision support platform. The product, also called pRxcision, is integrated with electronic health records (e.g., EPIC and Cerner), and provides clinicians with ranked, evidence-based antibiotic regimens tailored to each patient's needs. This approach can potentially stop antibiotic misuse, break the cycle of resistance, reduce healthcare costs, and ultimately save lives.

We believe that Artificial Intelligence (AI) will have an important and increasing role in healthcare delivery, and specifically in the management of patients at risk of sepsis. AI can be used to diagnose diseases, develop personalized treatment plans, and assist clinicians with decision-making. We have been searching for an AI-powered decision support platform to combine with our rapid direct-from-blood diagnostics.

The pRxcision platform is designed to leverage data from diagnostics, such as our T2Dx Instrument and test panels, to provide another level of precision—using advanced pharmacokinetic models, pathogen profiles, and real-time patient data to enable clinicians to prescribe the right drug, dose, and duration as the patient's condition evolves. The platform adapts continuously to changing clinical information, providing ranked, evidence-based treatment regimens that help clinicians optimize care and improve outcomes.

By combining our direct-from-blood diagnostics with the AI-driven pRxcision platform, we believe we can empower clinicians with the information to stop infections in their tracks—faster than ever before. Beyond improving patient care, this collaboration is intended to drive product adoption and create exciting opportunities for growth in a rapidly evolving market. With speed and accuracy at its core, we believe the combined solution can provide hospitals with a powerful tool to improve outcomes and reduce costs.

We are really excited about our new initiatives with Cardinal and Prxcision and believe each will contribute meaningfully to revenue in 2025 and beyond.

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 our products, including the T2Dx Instrument, the T2Bacteria Panel, the T2Candida Panel, and the T2Resistance Panel. During the third quarter, we entered into new distribution agreements covering Malaysia and Indonesia. As indicated by our executed international instrument contracts this expansion is already proving valuable.

Outside of sepsis we are making progress toward commercialization of our T2Biothreat Panel and T2Lyme panels. We are identifying strong potential government targets and fielding interest to procure the T2Biothreat Panel. We have presented to multiple U.S. government agencies, organized by the Administration for Strategic Preparedness and Response, or ASPR, and have ongoing discussions with leading biothreat response laboratories in the U.S. regarding their interest in the T2Biothreat Panel. We believe the unique attributes of the T2Biothreat Panel, coupled with it being the only FDA-cleared multi-target biothreat panel developed and manufactured in the U.S., will be of interest under the new administration.

Finally, we maintain our plan to launch the T2Lyme Panel as a Laboratory Developed Test (LDT), and we anticipate initiating commercialization by the start of the 2025 tick season.

Moving to our second corporate priority — enhancing our operations.

Operationally, we have converted approximately 80% of our debt to common stock over the past 12-18 months, which strengthens our balance sheet and significantly reduces our quarterly interest payments. We are currently focused on strengthening our cash position and making further improvements to our cost structure.

As you will see in our 10-Q filing, we have used our At-The-Market (ATM) facility, intermittently, to raise capital during the third quarter and early fourth quarter of 2024. We are continuing to explore other sources of capital, and we are actively engaged with potential strategic investors or partners.

During the third quarter of 2024, we began 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 expect this change to result in annualized savings of at least $0.4 million.

During the third quarter of 2024, we reduced our inventory by leveraging our new Oracle ERP system to drive better demand planning and material management. We believe the Oracle ERP expansion will continue to favorably impact inventory levels, cost of goods sold, and ultimately improve cash flow.

Finally, in the first quarter of 2025, we plan to further consolidate our real estate space, by exiting our facility at 4 Hartwell Avenue in Lexington, MA and consolidating those operations into our headquarters at 101 Hartwell Avenue in Lexington, MA. We expect this action to reduce our facilities costs by approximately $1.0 million annually.

Moving to our third corporate priority — advancing our pipeline.

Our pipeline initiatives are focused on expanding the test menu for the T2Dx instrument. There are four test expansion programs in our pipeline – including the U.S. T2Resistance Panel, the T2Lyme Panel, the expanded T2Candida Panel to include detection of *Candida auris*, and the expanded T2Bacteria Panel to include a claim for pediatric testing. Three of these programs have already received FDA Breakthrough Device designation — including the T2Resistance Panel, the T2Lyme Panel, and the *Candida auris* test — which should provide for a straightforward path to market and help solve an unmet need for rapid detection of the respective target biomarkers.

The U.S. T2Resistance Panel is a CE-marked diagnostic test able to detect antibiotic resistance genes directly-from-blood, in just 3-5 hours. The T2Resistance Panel simultaneously detects thirteen antibiotic resistance genes from both Gram-positive and Gram-negative bacterial pathogens. The T2Resistance Panel is marketed and sold in Europe under a CE-mark and has received FDA Breakthrough Device designation which provides for a prioritized 510(k) review process. We expect to submit the T2Resistance Panel to the FDA during the first quarter of 2025. The one quarter delay is due to our decision to prioritize manufacturing products for current and new customers ahead of manufacturing T2Resistance Panel cartridges for internal R&D testing.

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.

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.

The expanded T2Bacteria Panel to include a claim for pediatric testing. The T2Candida Panel has recently been granted clearance 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 in 2025.

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.

Third quarter 2024 revenues were $2.0 million, all from sepsis product sales, a 34% increase from the prior year period. International instrument sales increased 78% and sepsis test sales increased 34% compared to the prior year period.

Second quarter 2024 cost of product revenues were $4.1 million, a 4% increase compared to the prior year period driven by increased international instrument and sepsis test sales. Research and development expenses were $2.7 million, which is comparable to the prior year period. Selling, general and administrative expenses were $5.4 million, a 10% decrease compared to the prior year period driven by decreased headcount, offset by increased legal expenses.

The second quarter 2024 net loss was $10.1 million, $(0.57) per share, compared to the prior year third quarter net loss of $15.4 million, $(3.45) per share.

Cash and cash equivalents were $2.1 million as of September 30, 2024. We raised $4.3 million in net proceeds with our ATM during the quarter and $3.2 million since September 30, 2024.

As we announced last week the Company received a notice from NASDAQ on November 7, 2024, indicating that the Company's market value has been trading below listing requirements. We have appealed the notice and expect to put forth a plan of compliance to NASDAQ.

We expect fourth quarter 2024 total sepsis product revenue of $2.5 million to $3.5 million. This target does not include potential sales of the T2Biothreat™ Panel or the T2Lyme™ Panel.

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

John Sperzel

We are very encouraged by our progress made in the third quarter of 2024 compared to the prior year period, including total revenue growth of 34%, sepsis test panel growth of 34%, U.S. T2Bacteria Panel growth of over 173%, and T2Dx Instrument growth of 78% internationally. Moving forward, we are excited by the potential to accelerate the growth of our sepsis business in the U.S. through the exclusive commercial agreement with Cardinal Health, and the co-marketing agreement with PrXcision

Our new product pipeline is 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 first quarter of 2025, the T2Lyme Panel, the expanded T2Candida Panel to include the detection of *Candida auris*, and the expanded T2Bacteria Panel to include a claim for pediatric testing.

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