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 10, 2022

T2 BIOSYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36571**	**20-4827488**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

101 Hartwell Avenue, Lexington, Massachusetts 02421
(Address of principal executive offices, including Zip Code)

(781) 761-4646
(Registrant's telephone number, including area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	**TTOO**	**The Nasdaq Stock Market LLC (Nasdaq Global Market)**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On November 10, 2022, the Company issued a press release announcing its financial results for its fiscal quarter ended September 30, 2022, and held a conference call to discuss those results. A copy of the Company's press release and a copy of the transcript of the conference call are furnished with this report as Exhibits 99.1 and 99.2, respectively.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 and Exhibits 99.1 and 99.2 of this Current Report on Form 8-K are being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. Furthermore, such information, including Exhibits 99.1 and 99.2 attached hereto, shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly stated by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued November 10, 2022
99.2	Transcript of conference call held on November 10, 2022

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: November 10, 2022

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

T2 Biosystems Announces Third Quarter 2022 Financial Results

Achieves record quarterly sepsis and related revenue and advances product pipeline

LEXINGTON, Mass., November 10, 2022 (GLOBE NEWSWIRE)—T2 Biosystems, Inc. (NASDAQ:TTOO) (the "Company"), a leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes, today announced financial results for the third quarter ended September 30, 2022.

Recent Commercial and Financial Highlights

- Achieved third quarter total revenue of $3.7 million, including product revenue of $2.6 million.
- Achieved sepsis and related revenue (non-COVID product revenue) of $2.4 million, representing a record number for a single quarter and an increase of 24% compared to the prior year period.
- Executed contracts for 11 T2Dx® Instruments during the third quarter, including 3 in the U.S. and 8 outside the U.S., increasing the totals through the first nine months of 2022, to 20 in the U.S. and 18 internationally.
- Amended term loan agreement with CRG, extending both the interest-only period and the maturity date to December 30, 2024

Recent Pipeline and Clinical Highlights

- Completed all milestones for Option 2B of the multiple-year product development contract with BARDA and received Option 3 of the contract, valued at $3.7 million, to finalize U.S. clinical trials and complete FDA submission for the T2Biothreat™ Panel and the T2Resistance® Panel.
- Announced plans to complete the development of and commercialize the T2Lyme Panel, recently awarded FDA Breakthrough Device Designation, with the goal to initiate marketing and sales in the U.S. as a Laboratory Developed Test in 2023.
- Received Phase 1 LymeX Diagnostics prize from U.S. Department of Health and Human Services (HHS) and Steven & Alexandra Cohen Foundation to advance the T2Lyme Panel.
- Initiated studies to expand the T2Bacteria® Panel to include detection of *Acinetobacter baumannii*, the tenth most common pathogen that has a crude ICU mortality rate of 34.0% to 43.4%.
- Announced publication of three peer review studies conducted in Europe in the *Journal of Clinical Microbiology, Microbiology Spectrum and the Journal of Fungi* demonstrating the clinical value of T2's Biosystems' sepsis products for improved rapid detection.

"During the third quarter, the T2 Biosystems team generated a quarterly record of $2.4 million of sepsis and related product revenue. We are very excited by the progress with our near-term product pipeline, including the T2Biothreat, T2Resistance, T2Lyme, and expanded T2Bacteria panels. Each new product represents a differentiated solution to rapidly identify harmful pathogens and allow clinicians to achieve faster targeted therapy," stated John Sperzel, Chairman and CEO of T2 Biosystems. "To close the year, we will remain focused on our three corporate priorities, accelerating our sales, enhancing our operations, and advancing our pipeline to support long term growth and sustained value creation."

Third Quarter 2022 Financial Results

Total revenue for the third quarter of 2022 was $3.7 million, including product revenue of $2.6 million, representing decreases of 50% and 39% respectively, compared to the prior year period, primarily driven by an 88% decline in sales of COVID-19 tests from $2.4 million and reduced BARDA revenue offset by increased sepsis test sales. Research contribution revenue for the third quarter of 2022 was $1.0 million, a decrease of 67% compared to the prior year period primarily due to extensions required to increase enrollment in the T2Resistance trial.

Research and development expenses were $6.4 million, flat compared to the prior year period. Selling, general and administrative expenses were $7.0 million, a decrease of $1.5 million compared to the prior year period driven by reduced medical affairs expenses.

Net loss for the third quarter of 2022 was $17.4 million, $2.95 per share, compared to a net loss of $14.0 million, $4.21 per share, in the prior year period.

Cash, cash equivalents and restricted cash were $21.5 million as of September 30, 2022 and cash provided by the ATM was $22.9 million.

2022 Financial Outlook

The Company expects full year 2022 total revenue of $22.0 to $23.0 million, including product revenue of $11.5 to $12.0 million and research contribution revenue of $10.5 to $11.0 million. The Company expects to close 50 to 55 T2Dx Instrument contracts in 2022.

Webcast and Conference Call Information

The Company's management team will host a conference call today, November 10, 2022, beginning at 4:30 pm ET. Investors interested in listening to the call may do so by dialing 888-272-8703 for domestic callers or 832-553-1663 for International callers. A live and recorded webcast of the call will be available on the "Investors" section of the Company's website at www.t2biosystems.com.

About T2 Biosystems

T2 Biosystems, a leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes, is dedicated to improving patient care and reducing the cost of care by helping clinicians effectively treat patients faster than ever before. T2 Biosystems' products include the T2Dx® Instrument, the T2Bacteria® Panel, the T2Candida® Panel, the T2Resistance® Panel, and the T2SARS-CoV-2™ Panel and are powered by the proprietary T2 Magnetic Resonance (T2MR®) technology. T2 Biosystems has an active pipeline of future products, including the T2Biothreat™ Panel, the T2Cauris™ Panel, and T2Lyme™ Panel, as well as next-generation products for the detection of bacterial and fungal pathogens and associated antimicrobial resistance markers. For more information, please visit www.t2biosystems.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding our revenue results and cash balance, financial outlook, instrument contracts, timing of filing of an FDA submission, impact of operating expense reductions, plans to develop a diagnostic test for monkeypox, anticipated strategic priorities, product demand, commitments or opportunities, and growth expectations or targets, as well as statements that include the words "expect," "may," "should," "anticipate," and similar statements of a future or forward looking nature. These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, (i) any inability to (a) realize anticipated benefits from commitments, contracts or products; (b) successfully execute strategic priorities; (c) bring products to market; (d) expand product usage or adoption; (e) obtain customer testimonials; (f) accurately predict

growth assumptions; (g) realize anticipated revenues; (h) incur expected levels of operating expenses; or (i) increase the number of high-risk patients at customer facilities; (ii) failure of early data to predict eventual outcomes; (iii) failure to make or obtain anticipated FDA filings or clearances within expected time frames or at all; or (iv) the factors discussed under Item 1A. “Risk Factors” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021, filed with the U.S. Securities and Exchange Commission, or SEC, on March 23, 2022, and other filings the Company makes with the SEC from time to time, including our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management’s estimates as of the date of this press release. While the Company may elect to update such forward-looking statements at some point in the future, unless required by law, it disclaims any obligation to do so, even if subsequent events cause its views to change. Thus, no one should assume that the Company’s silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. These forward-looking statements should not be relied upon as representing the Company’s views as of any date subsequent to the date of this press release.

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T2 BIOSYSTEMS, INC.

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 20,366	$ 22,245
Marketable securities	—	9,996
Accounts receivable	1,578	5,134
Inventories	4,242	3,909
Prepaid expenses and other current assets	2,690	3,110
Total current assets	28,876	44,394
Property and equipment, net	4,734	4,675
Operating lease right-of-use assets	9,058	9,766
Restricted cash	1,131	1,551
Other assets	153	153
Total assets	$ 43,952	$ 60,539
Liabilities, Series A convertible redeemable preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 2,063	$ 2,832
Accrued expenses and other current liabilities	8,531	8,338
Derivative warrant liability	186	—
Deferred revenue	163	518
Total current liabilities	10,943	11,688
Notes payable	49,188	47,790
Operating lease liabilities, net of current portion	8,569	9,359
Deferred revenue, net of current portion	8	28
Derivative liability	1,792	—
Other liabilities	4,791	4,577
Commitments and contingencies		
Series A convertible redeemable preferred stock; $0.001 par value; 3,000 shares designated; 3,000 shares issued and outstanding at September 30, 2022; liquidation value of $330,000; 0 shares issued and outstanding at December 31, 2021	330330	—
Stockholders' deficit		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; 7,050,854 and 3,328,017 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	7	3
Additional paid-in capital	492,444	459,314
Accumulated other comprehensive loss	—	(4)
Accumulated deficit	(524,120)	(472,216)
Total stockholders' deficit	(31,669)	(12,903)
Total liabilities, Series A convertible redeemable preferred stock and stockholders' deficit	$ 43,952	$ 60,539

T2 BIOSYSTEMS, INC.

CONDENSED 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,	
	2022	2021	2022	2021
Revenue:				
Product revenue	$ 2,641	$ 4,306	$ 9,044	$ 12,634
Contribution revenue	1,036	3,122	7,778	8,444
Total revenue	3,677	7,428	16,822	21,078
Costs and expenses:				
Cost of product revenue	6,085	4,720	17,371	15,341
Research and development	6,375	6,384	21,056	16,448
Selling, general and administrative	7,017	8,536	24,071	21,983
Total costs and expenses	19,477	19,640	62,498	53,772
Loss from operations	(15,800)	(12,212)	(45,676)	(32,694)
Other income (expense):				
Interest income	1	6	6	18
Interest expense	(1,560)	(1,919)	(4,556)	(5,642)
Change in fair value of derivative instrument	(117)	—	(1,792)	1,010
Change in fair value of derivative warrant liability	179	—	179	—
Other income, net	(78)	163	(65)	211
Total other expense	(1,575)	(1,750)	(6,228)	(4,403)
Net loss	$ (17,375)	$ (13,962)	$ (51,904)	$ (37,097)
Deemed dividend on Series A redeemable convertible preferred stock	$ (330)	$ —	$ (330)	$ —
Net loss attributable to common stockholders	$ (17,705)	$ (13,962)	$ (52,234)	$ (37,097)
Net loss per share — basic and diluted	$ (2.95)	$ (4.21)	$ (12.08)	$ (11.86)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	6,008,819	3,317,646	4,323,452	3,127,951
Other comprehensive loss:				
Net loss	$ (17,375)	$ (13,962)	$ (51,904)	$ (37,097)
Net unrealized gain on marketable securities arising during the period	—	—	2	9
Net realized (gain) loss on marketable securities included in net loss	—	—	2	(14)
Total other comprehensive (loss) income, net of taxes	—	—	4	(5)
Comprehensive loss	$ (17,375)	$ (13,962)	$ (51,900)	$ (37,102)

Philip Taylor

Thank you, operator. I would like to remind everyone that comments made by management today and answers to questions will include forward-looking statements. Those include statements related to T2 Biosystems' future financial and operating results and plans for developing and marketing new products.

Forward-looking statements are based on estimates and assumptions as of today and are subject to risks and uncertainties that may cause actual results to differ materially from those expressed or implied by these statements, including the risks and uncertainties described in T2 Biosystems' annual report on Form 10-K filed with the SEC on March 23, 2022, and other filings the company makes with the SEC from time to time. The company undertakes no obligation to publicly update or revise any forward-looking statements, except as required by law.

With that, I would like to turn the call over to Chairman and CEO, John Sperzel. John?

John Sperzel

Thank you all for joining our third quarter 2022 earnings call. Today, I will review the Company's performance during the third quarter, highlighting a number of recent accomplishments, and discuss the progress we are making across our three corporate priorities. I will then turn the call over to John Sprague, our Chief Financial Officer, who will review our third quarter financial results, before I provide some closing remarks and we open the call for questions and answers.

During the third quarter, the T2 Biosystems team achieved total revenue of $3.7 million, including product revenue of $2.6 million and R&D revenue of $1.1 million. Importantly, our product sales included $2.4 million of sepsis and related product revenue, which excludes COVID-19 product sales, representing a 24% increase compared to the prior year period. We entered into contracts for 11 T2Dx® Instruments during the third quarter, including 3 in the U.S. and 8 internationally, bringing our year-to-date totals, through the first nine months of 2022, to 20 instruments in the U.S. and 18 internationally.

Our team has realized a number of important accomplishments in recent months. During the third quarter, we achieved the highest quarterly sales of our sepsis and related products in Company history, and we have continued to increase our installed base of T2Dx Instruments. We have continued to expand our international commercial strategy, and we have entered into a territory exclusive distribution agreement in the Baltic region. We have advanced our near-term product pipeline by meeting milestones in the ongoing U.S. clinical trials for the T2Resistance® Panel and the T2Biothreat™ Panel. We also attained multiple milestones related to the T2Lyme™ Panel, including the receipt of Breakthrough Device designation from the FDA, and receipt of the LymeX award from the U.S. Department of Health and Human Services and the Cohen Foundation. Finally, we recently regained compliance with the NASDAQ minimum bid price listing requirement.

These accomplishments support our mission *to fundamentally change the way medicine is practiced through transformative culture-independent diagnostics to improve the lives of patients around the world*. Given the recent developments with our T2Lyme Panel, we are now expanding our target markets to include Lyme disease, along with sepsis. Both of which represent significant opportunities within the infectious disease field, where the current standard of care is leading to poor patient outcomes.

Sepsis presents one of the greatest challenges to healthcare systems worldwide, and claims approximately 11 million lives each year. In the United States, sepsis is the #1 cost of hospitalization, costing our healthcare system approximately $62 billion annually; the #1 cause of death in hospitals, claiming approximately 270,000 American lives annually; and the #1 cause of 30-day hospital readmissions, requiring nearly 20% of sepsis survivors to be readmitted within 30 days and nearly 40% to be readmitted within 90 days.

The current standard of care for patients at risk of sepsis relies on broad, empiric protocols to administer antimicrobial therapy, despite the fact that such protocols are only optimal in approximately one-half of cases and can contribute to the growing problem of antimicrobial resistance. The current standard of care also continues to rely on a positive blood culture to identify the presence of a bloodstream infection, which can take anywhere from 1-5 days to turn positive, and is widely understood to have poor sensitivity. Rapid detection of sepsis-causing pathogens and antibiotic resistance genes is critical for treatment decisions and improving patient outcomes, as each hour of delayed targeted antimicrobial treatment can lead to increased mortality risk of up to 8%.

Lyme disease is a bacterial infection caused by the bacteria *Borrelia*, and is considered the most common vector borne illness in the United States. *Borrelia burgdorferi* is transmitted to humans through the bite of infected ticks: by deer ticks in the northeastern, mid-Atlantic and north-central regions of the U.S.; and by western blacklegged ticks on the Pacific Coast. According to the U.S. Centers for Disease Control and Prevention, or CDC, approximately 476,000 Americans may get Lyme disease each year in the United States. Typical symptoms include fever, headache, fatigue, and skin rash. If left untreated, infection can spread to joints, the heart, and the nervous system.

The current CDC recommended serological testing for Lyme disease relies on the presence of antibodies and can only be used accurately four to six weeks after infection. We believe there is a significant unmet need for a sensitive diagnostic test to detect early Lyme disease, and the initial performance data on our T2Lyme Panel is very encouraging. We believe the T2Lyme Panel will allow clinicians to detect active infections and ensure patients receive appropriate therapy faster, and prevent the negative impact of a delay in delivery of treatment and the overuse of antibiotics.

To advance our mission and create value for our stakeholders, we are focused on three corporate priorities: 1) accelerating our sales, 2) enhancing our operations, and 3) advancing our pipeline. I will now provide an update on our recent progress as it relates to each of these corporate priorities.

Starting with our first priority – accelerating our sales:

Our commercial strategy is focused on driving adoption of our T2Dx technology by expanding our instrument installed base globally, and increasing utilization of our sepsis test panels. As I mentioned earlier, third quarter sepsis and related revenue was $2.4 million, representing a record number for a single quarter and an increase of 24% compared to the prior year period. We entered into contracts for 11 T2Dx Instruments for sepsis testing, increasing our installed base of instruments to 170, including 101 in the U.S. and 69 internationally, including clinical trial instruments.

We generated sepsis test panel revenue of $1.5 million, representing growth of 25% from prior year period. From an instrument pull-through perspective, in the U.S., we achieved annualized sepsis test utilization of $104,000 per legacy instrument. We continue to believe that annualized U.S. sepsis test utilization will reach $200,000 per instrument, and we have a number of customers that have already surpassed that target.

The record quarterly sepsis and related revenue was driven by our growing installed base of T2Dx Instruments and our ability to bring new accounts online faster than we have in the past. As a reminder, it has historically has taken four to six months from contract close to “go live” testing at hospital labs. Through improvements integrating our sales and field operations teams, and streamlining our processes, we are seeing improvements and we are targeting three months from contract close to “go live” testing. This should translate to new customers consuming tests earlier, and contributing to our sepsis test revenue faster.

The second driver of sepsis revenue in the quarter was growth in sales of the T2Bacteria® Panel in the U.S., and internationally. It is encouraging to see customers realize the value of the T2Bacteria Panel and increase their utilization. We have typically seen customers adopt the T2Candida® Panel first, followed by the adoption of the T2Bacteria Panel. We are beginning to see some customers start with T2Bacteria because of its unique ability to detect the most critical sepsis causing pathogens. We believe we are benefitting from our work to increase awareness of the benefits of this panel. Following the field force realignment, our medical affairs personnel are making progress improving customer engagement and leveraging the increasing library of peer reviewed clinical data that demonstrates the value of the T2Bacteria Panel.

The core market opportunity for our sepsis products targets hospital microbiology labs, which we believe represents a market opportunity exceeding $2 billion. We are in the early innings of commercialization and are encouraged by the potential that lies ahead. Our ability to place instruments across all types of hospitals, ranging from large academic hospitals to critical access hospitals, gives us confidence we can continue to expand our installed base of instruments and accelerate growth of our sepsis test panels.

We recently sold a second T2Dx Instrument to one of the leading U.S. laboratory service providers, to be deployed for sepsis testing in one of that provider's managed-hospital laboratories. We believe there is potential to further expand our business in the laboratory service providers, in their quest to expand their managed-hospital laboratory business. We now have multiple end-user customers that have added a second T2Dx Instrument, to expand their testing capacity, or to add an additional testing site within their system.

Outside of the U.S., there is also a significant market opportunity for our products. Our international go-to-market strategy includes a network of exclusive distributors that sell and support our products in specific countries or regions, and we are focused on continuing to expand our international presence. We recently executed a territory exclusive distribution agreement covering the Baltic region – including Lithuania, Latvia, and Estonia – where we believe our products offer a solution to drive meaningful improvement in the management of sepsis patients. In fact, studies have shown that the Baltic region has a higher average incidence of sepsis per population than Western Europe and guidelines have been issued in the region to improve sepsis management. We expect further international expansion in 2022 and 2023.

As we have discussed, we have taken steps to expand and realign our commercial team. We are confident the sales, medical affairs, service and support teams are aligned to execute our strategy, including spending appropriate time pursuing new instrument sales and working with existing customers to increase sepsis test utilization. At the beginning of 2022, we communicated our belief that sales of our COVID-19 molecular diagnostic test, the T2SARS-CoV-2 Panel, would decrease during the year and provide an opportunity to convert COVID-driven instruments to sepsis testing. While the conversion process has taken longer than we anticipated, we continue to believe this represents a potentially meaningful growth opportunity to increase sepsis test utilization.

Moving to our second priority – enhancing our operations:

In the current macroeconomic environment, we recognize that operating efficiently is a critical success factor. As such, we have prioritized improving our product gross margins and reducing our operating expenses, and we have taken steps to address both priorities.

The product gross margin improvement initiative includes the T2Bacteria and T2Candida panels and has resulted in a reduction in the manufacturing costs of those two products. In June, we made changes to improve our overall cost structure, including reducing our workforce and operating expenses by approximately 20%. We expect both improvements to become more apparent in the coming quarters, as we continue to increase volume and fully absorb our overhead and one-time costs related to the organizational changes.

Finally, our operations team has worked to ensure that there is an uninterrupted supply of products to our customers, and we are effectively managing longer lead times and inflationary pressures. While supply chain challenges continue to exist across the industry, our team remains confident in our ability to continue supplying our customers without interruption.

Moving to our third priority – advancing our pipeline:

We are advancing the development of multiple new products that leverage both our technology platform and our scientific expertise. Our product pipeline is supported in part by a milestone-based product development contract awarded by BARDA, the U.S. Biomedical Advanced Research Development Authority, which is valued at up to $62 million if all options are exercised. We recently completed Option 2B of the contract,

following our team's successful completion of all the milestones for advancing the U.S. clinical trials for the T2Resistance Panel and the T2Biothreat Panel, and advancing the development of the next-generation instrument and the comprehensive sepsis panel. We were awarded Option 3 valued at $3.7 million, to finalize U.S. clinical trials and complete FDA submission for the T2Biothreat Panel and the T2Resistance Panel.

Several products are being developed with the goal of expanding the test menu on our FDA-cleared T2Dx Instrument, including four products that I will highlight on today's call, the T2Biothreat Panel, T2Resistance Panel, T2Lyme Panel, and T2Bacteria Panel enhancements. We believe these new products could potentially be commercially launched in 2023, subject to regulatory approvals. Each of these new products represents a differentiated solution to rapidly identify harmful pathogens and potentially allow clinicians to achieve faster, targeted therapy.

The T2Biothreat Panel is a direct-from-blood test panel designed to run on the T2Dx Instrument and simultaneously detect six biothreat pathogens identified as threats by the U.S. Government, in just 3-5 hours. This program is funded under our BARDA contract and we believe the target customer for this panel would be the U.S. Government. We initiated a clinical evaluation for the T2Biothreat Panel in December 2021, which is very near completion, and we remain on track to file an FDA submission in 2022.

The T2Resistance Panel is a direct-from-blood test panel designed to run on the T2Dx Instrument and simultaneously detect thirteen antibiotic resistance genes known to cause antibiotic-resistant infections, in just 3-5 hours. This program is funded under our BARDA contract. As a reminder, we are currently marketing and selling the T2Resistance Panel in Europe, under CE mark, and we are on a pathway to apply for FDA clearance prior to U.S. commercialization. We initiated a U.S. clinical trial for the T2Resistance Panel in December 2021 and we are currently enrolling patients at eight hospitals, and we are adding two additional hospitals to increase patient enrollment. We anticipate completion of the trial in early 2023 and plan to subsequently file with the FDA. As a reminder, the T2Resistance Panel was previously granted "breakthrough device" designation from the FDA, which provides for a prioritized FDA review process.

The T2Lyme Panel is a direct-from-blood test panel designed to run on the T2Dx Instrument and detect active *Borrelia* infections, the bacteria that causes Lyme disease, in just 3-5 hours. We expect it to be used to aid in the diagnosis of early Lyme disease. Earlier this week, we announced that the T2Lyme Panel was selected as 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. While we plan to potentially commence marketing and sales of the T2Lyme Panel as a Lab Developed Test in 2023, we also plan to initiate discussions with the FDA with the purpose of pursuing FDA clearance. The T2Lyme Panel was also granted “Breakthrough Device” designation from the FDA, which provides for a prioritized review process.

Finally, we have initiated studies to expand the number of pathogens detected on our FDA-cleared T2Bacteria Panel to include the detection of *Acinetobacter baumannii*. *Acinetobacter* is a cause of bloodstream infections especially in critically ill patients, which can range from a benign transient bacteremia to septic shock, and has been reported to have a crude ICU mortality rate of 34% to 43%. *Acinetobacter* can be resistant to many antibiotics, including carbapenems, highlighting the importance of rapid detection and targeted antimicrobial treatment. *Acinetobacter* infections rarely occur outside of healthcare settings in the U.S. and can disproportionally impact those with weakened immune systems, chronic lung disease, or diabetes. Adding Acinetobacter detection to the T2Bacteria Panel will provide clinicians with a rapid direct from blood diagnostic that will provide them with actionable data for the appropriate antimicrobial treatment for patients. We plan to submit for FDA clearance in early 2023.

With that, I will now turn the call over to John Sprague to provide a detailed update of our third quarter 2022 financial results and our financial outlook for the remainder of the year.

John Sprague

Thank you, John.

Total revenue for the third quarter of 2023 was $3.7 million, a decrease of 50% compared to the prior year period. Product revenue was $2.6 million, a decrease of 39% compared to the prior year period, primarily due to an 88% decline in sales of COVID-19 tests from $2.4 million, offset by increased sepsis test sales. Research contribution revenue was $1.0 million, a decrease of 67% compared to the prior year period primarily due to the timing of enrollment in the T2Resistance trial.

Product costs for the third quarter of 2022 were $6.1 million, an increase of $1.4 million compared to the prior year period, driven by increased supply chain cost inefficiencies. Research and development expenses were $6.4 million, flat compared to the prior year period. Selling, general and administrative expenses were $7.0 million, a decrease of $1.5 million compared to the prior year period driven by decreased medical affairs spending.

Net loss for the third quarter of 2022 was $17.4 million, $2.95 per share, compared to a net loss of $14.0 million, $4.21 per share for the prior year period.

Cash, marketable securities and restricted cash were $21.5 million as of September 30, 2022. ATM sales were $22.9 million in the third quarter, and we raised approximately $700,000 since September 30, 2022. We redeemed the Series A preferred stock in October 2022, and there are no longer any preferred shares outstanding. We remain in compliance with the CRG loan agreement covenants. Today we announced an amendment of term loan agreement with CRG, extending both the interest-only period and the maturity date to December 30, 2024 which we believe will provide balance sheet flexibility as we advance our growth strategy.

For guidance, we now expect full year 2022 total revenue of $22.0 to $23.0 million, including product revenue of $11.5 to $12.0 million and research contribution revenue of $10.5 to $11.0 million, and we expect to close 50 to 55 T2Dx Instrument contracts in 2022.

Thank you and back to John Sperzel for closing remarks.

John Sperzel

Thank you, John.

During the third quarter, the T2 Biosystems team generated a quarterly record of sepsis and related product revenue, and we remain on track to achieve record sepsis-driven T2Dx Instruments in 2022. We are excited by the progress with our near-term product pipeline, including the T2Biothreat, T2Resistance, T2Lyme, and T2Bacteria expansion. To close the year, we will remain focused on our three corporate priorities, accelerating our sales, enhancing our operations, and advancing our pipeline to support long term growth and sustained value creation.

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