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 4, 2021

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 4, 2021, T2 Biosystems, Inc. (the "Company") issued a press release announcing its financial results for its third quarter ended September 30, 2021 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 4, 2021
99.2	Transcript of conference call held on November 4, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 5, 2021

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

T2 Biosystems Announces Third Quarter 2021 Financial Results

LEXINGTON, Mass., November 4, 2021 (GLOBE NEWSWIRE)—T2 Biosystems, Inc. (NASDAQ:TTOO), a leader in the rapid detection of sepsis-causing pathogens, today announced financial results for the three months ended September 30, 2021.

Recent Highlights

- Achieved third quarter revenue of $7.4 million, including product revenue of $4.3 million, representing growth of 42% and 15%, respectively, compared to the prior year period
- Generated third quarter U.S. sepsis test panel utilization annualized run rate of $115,000 per legacy sepsis instrument, representing growth of 55% compared to the prior year period
- Sold 8 T2Dx® Instruments during the third quarter
- Expanded commercialization into the Asia-Pacific region signing distribution agreements in Korea and Singapore, resulting in two T2Dx Instruments sold during the third quarter and have received contracts for four T2Dx Instruments to be sold during the fourth quarter
- Received Option 2A of the multiple year product development contract with BARDA valued at $6.4 million, following successful completion of Option 1 development milestones
- Unveiled new clinical data at industry conferences with presentation of poster session and abstract data showcasing the effectiveness of T2 Biosystems' culture-independent rapid diagnostic technologies
- Appointed industry veteran Brett Giffin as Chief Commercial Officer and appointed industry expert Laura Adams to the Board of Directors

"Our third quarter results demonstrate meaningful progress across our corporate priorities, accelerating our sales, enhancing our operations, and advancing our pipeline," stated John Sperzel, Chairman and CEO of T2 Biosystems. "We believe our commercial and medical affairs investments will enable greater adoption and utilization of our current sepsis products, and our pipeline of new products will lead to even greater growth opportunities."

Third Quarter 2021 Financial Results

Total revenue for the third quarter of 2021 was $7.4 million, an increase of 42% compared to the prior year period. Product revenue for the third quarter of 2021 was $4.3 million, an increase of 15% compared to the prior year period, driven by increased test panel sales. Research and contribution revenue for the third quarter of 2021 was $3.1 million, an increase of 110% compared to the prior year period, driven by increased BARDA contract activity.

Operating expenses for the third quarter of 2021 were $14.9 million, an increase of $5.9 million compared to the prior year period, driven by increased BARDA contract research and development activity, increased commercial headcount and tradeshow activity and an ERP system implementation.

Net loss for the third quarter of 2021 was $14.0 million, $0.08 per share, compared to a net loss of $11.3 million, $0.08 per share, in the prior year period.

Cash, equivalents, marketable securities, and restricted cash were $43.6 million as of September 30, 2021.

2021 Financial Outlook

The Company is raising its revenue expectations to reflect its third quarter results and now expects revenue for the full year 2021 to be between $25.0 million and $27.0 million. Product revenue is now expected to be between $15.0 million and $16.0 million. Research and contribution revenue is expected to be between $10.0 million and $11.0 million unchanged from the prior guidance. The Company continues to expect to enter into at least 30 T2Dx Instrument contracts in 2021.

Webcast and Conference Call Information

T2's management team will host a conference call today, November 4, 2021, beginning at 4:30pm ET. Investors interested in listening to the call may do so by dialing 1-844-825-9789 for domestic callers or 1-412-317-5180 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, 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, T2Candida® Panel, the T2Bacteria® 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 T2Cauris™ Panel, and T2Lyme™ Panel, as well as additional products for the detection of bacterial and fungal pathogens and associated antimicrobial resistance markers, and biothreat pathogens.

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, anticipated strategic priorities, product demand, commitments or opportunities, and growth expectations or targets, , as well as statements that include the words "expect," "intend," "plan", "believe", "project", "forecast", "estimate," "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, 2020, filed with the U.S. Securities and Exchange Commission, or SEC, on March 31, 2021, and other filings the company makes with the SEC from time to time. 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.

Media Contact:
Gina Kent, Vault Communications
gkent@vaultcommunications.com
610-455-2763

Investor Contact:
Philip Trip Taylor, Gilmartin Group
philip@gilmartinIR.com
415-937-5406

T2 BIOSYSTEMS, INC.

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 22,047	$ 16,793
Marketable securities	20,042	25,396
Accounts receivable	4,222	5,099
Inventories	4,822	3,636
Prepaid expenses and other current assets	3,327	2,660
Total current assets	54,460	53,584
Property and equipment, net	3,813	3,771
Operating lease right-of-use assets	10,052	11,034
Restricted cash	1,551	551
Marketable securities	—	10,002
Other assets	161	136
Total assets	$ 70,037	$ 79,078
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 2,616	$ 2,058
Accrued expenses and other current liabilities	8,169	7,512
Deferred revenue	613	230
Total current liabilities	11,398	9,800
Notes payable	47,132	45,235
Operating lease liabilities, net of current portion	9,665	10,533
Deferred revenue, net of current portion	50	424
Derivative liability	—	1,010
Other liabilities	4,255	3,350
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; 165,967,924 and 148,078,974 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	165	148
Additional paid-in capital	457,440	431,544
Accumulated other comprehensive income	4	9
Accumulated deficit	(460,072)	(422,975)
Total stockholders' (deficit) equity	(2,463)	8,726
Total liabilities and stockholders' (deficit) equity	$ 70,037	$ 79,078

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,	
	2021	2020	2021	2020
Revenue:				
Product revenue	$ 4,306	$ 3,757	$ 12,634	$ 5,843
Research revenue	—	—	—	11
Contribution revenue	3,122	1,488	8,444	4,488
Total revenue	7,428	5,245	21,078	10,342
Costs and expenses:				
Cost of product revenue	4,720	6,833	15,341	13,804
Research and development	6,384	3,782	16,448	12,348
Selling, general and administrative	8,536	5,266	21,983	17,226
Total costs and expenses	19,640	15,881	53,772	43,378
Loss from operations	(12,212)	(10,636)	(32,694)	(33,036)
Other income (expense):				
Interest income	6	1	18	2
Interest expense	(1,919)	(647)	(4,632)	(3,908)
Other income, net	163	27	211	53
Total other expense	(1,750)	(619)	(4,403)	(3,853)
Net loss	$ (13,962)	$ (11,255)	$ (37,097)	$ (36,889)
Net loss per share — basic and diluted	$ (0.08)	$ (0.08)	$ (0.24)	$ (0.33)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	165,882,334	147,793,891	156,397,584	112,371,006
Other comprehensive loss:				
Net loss	$ (13,962)	$ (11,255)	$ (37,097)	$ (36,889)
Net unrealized gain on marketable securities arising during the period	—	—	9	—
Less: net realized gain on marketable securities included in net loss	—	—	(14)	—
Total other comprehensive loss, net of taxes	—	—	(5)	—
Comprehensive loss	$ (13,962)	$ (11,255)	$ (37,102)	$ (36,889)

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 31, 2021, 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 for joining our third quarter 2021 earnings conference call. Today, I will review the company's third quarter performance and provide updates and developments across our three corporate priorities. I will then turn the call over to John Sprague, who will review our third quarter financial results, before I make some closing remarks and we open the call for questions and answers.

During the third quarter of 2021, the T2 Biosystems team generated total revenue of $7.4 million, an increase of 42% compared to the prior year period. Product revenue during the third quarter was $4.3 million, an increase of 15% compared to the prior year period.
Importantly, our U.S. sepsis test panel revenue increased 55% compared to the prior year period, and 18% sequentially compared to last quarter. We are very pleased with the total product sales growth compared to the prior year period, which included a record-high number of T2Dx Instruments and the launch of our COVID-19 molecular diagnostic test.

Our mission at T2 Biosystems is *to fundamentally change the way medicine is practiced through transformative diagnostics that improve the lives of patients around the world*. To achieve our mission, we are focused on driving adoption and increasing the utilization of our culture-independent rapid diagnostic tests for the detection of sepsis-causing pathogens and resistance genes. Our T2Bacteria, T2Candida, and T2Resistance Panels can improve patient outcomes by reducing the time to detect sepsis-causing pathogens and accelerating time to achieve targeted therapy, thus reducing the burden of sepsis.

Sepsis is the body's overwhelming and life-threatening response to an infection. It is one of the greatest challenges to healthcare systems globally, and exacts an enormous economic and human toll each year. I want to share three staggering facts about sepsis:

1. Sepsis is the leading cost of U.S. hospitalization. According to the U.S. Department of Health and Human Services, sepsis costs our healthcare system approximately $62 billion annually.
2. Sepsis is the leading cause of death in U.S. hospitals. According to the U.S. Centers for Disease Control and Prevention, sepsis claims the lives of approximately 270,000 Americans each year.
3. Sepsis is the leading cause of 30-day hospital readmissions. According to data from the National Center for Biotechnology Information, approximately 20% of sepsis survivors are re-hospitalized within 30 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 the cases. The current standard of care also relies on a positive blood culture to identify the presence of a blood stream infection, despite the fact that blood culture can yield false negative results due to poor sensitivity, and can take 1-5 days to achieve the growth needed for pathogen identification. Finally, traditional microbiology or molecular diagnostic tests, which rely on a positive blood culture, may

then be required to determine species ID and susceptibility. The challenge in managing patients at risk of or suspected of sepsis is that it is a race against time. Each hour of delayed treatment can increase mortality risk by up to 8%; therefore, early identification of sepsis-causing pathogens is critical to improving patient outcomes.

Our aim at T2 Biosystems is to change the standard of care by enabling targeted therapy, faster. Our T2Bacteria and T2Candida Panels are the first and only FDA cleared products able to detect sepsis-causing pathogens directly from whole blood, within 3-5 hours, without the need to wait days for a positive blood culture. Strategically, we are focusing our efforts around three corporate priorities to create and provide value: accelerating our sales, enhancing our operations, and advancing our pipeline.

Starting with our first priority – accelerating our sales

Our sales strategy consists of three elements: 1) increase sepsis test utilization among our installed base of T2Dx Instruments, 2) expand our T2Dx Instrument installed base by selling or placing new instruments, and 3) transition the U.S. COVID-driven instruments sold during 2020 from our T2SARS-CoV-2 Panel to our sepsis panels.

During the third quarter, we achieved annualized sepsis test utilization of $115,000 per legacy T2Dx Instrument within our U.S. hospital customers, a 55% increase compared to the prior year period. Long-term, we continue to believe that routine use implementation of our sepsis panels will reach $200,000 per instrument.

In line with expectations, we entered into contracts for 8 T2Dx Instruments during the third quarter, including 1 in the U.S. and 7 internationally. In addition, we have already entered into 5 T2Dx Instrument contracts during the fourth quarter, and we continue to believe we will enter into at least 30 T2Dx Instrument contracts for the full year 2021.

As a reminder, we sold 47 T2Dx Instruments to U.S. hospitals during 2020 for COVID-19 testing, and plan to transition these customers to sepsis testing over time. We prequalified these customers based on their commitment to evaluate our sepsis panels following the

pandemic and we continue to believe these customers will convert to our sepsis panels. While we have converted some accounts, the widespread conversion has been delayed as these customers continue to use our COVID-19 test and currently lack capacity to evaluate our sepsis products due to the continued demands of the pandemic.

With the evolution of the SARS-CoV-2 virus mutating into different variants, we have been diligent in our efforts to ensure that our test is capable of detecting the new variants. To date, based on sequence and *in silico* analysis, our T2SARS-CoV-2 Panel can detect all variants of interest as noted by the CDC, including the alpha, beta, gamma, delta, lambda, mu, and iota variants. The recent increases in COVID-19 infection rates have led to continued customer demand for our T2SARS-CoV-2 Panel, which we expect will continue through the remainder of the year.

Because our products and technology are at the forefront of solving one of the most complex healthcare problems, several functional groups at each hospital are involved in the purchase decision. Accordingly, we are building a team and commercial process to address the priorities for clinicians, laboratorians, pharmacists, and administrators.

As we announced today, Brett Giffin will join T2 Biosystems as Chief Commercial Officer, effective Monday, November 8th, replacing Tony Pare who recently accepted a CEO role with another firm. Brett will lead our commercial growth initiatives with direct responsibility for global sales, marketing, service, and customer support. He brings significant industry experience and commercial leadership, having served as Chief Executive Officer for two early stage medical technology companies, as Chief Commercial Officer at Accriva Diagnostics (formerly ITC Medical, where Brett and I worked together), and in several sales and marketing leadership roles at Datascope, Covidien, Boston Scientific, and Johnson & Johnson. Brett began his career as a U.S. Army officer, serving in Panama and Central America.

As we have previously described, we are expanding our U.S. commercial team to increase T2Dx Instrument sales, and drive adoption and increased utilization of our sepsis

tests. During the second quarter, we expanded from 2 to 11 Regional Account Managers, and we spent significant time training our new team during the second and third quarter. Our plan is to expand to 20 Regional Account Managers by January 2022. The Regional Account Managers are working closely with our Medical Affairs Team to support the needs of our customers and provide customer centric solutions.

To further expand our business, we have initiated commercialization in the Asia Pacific region through distribution agreements in Singapore and South Korea. Under terms of the distribution agreements, we will sell our sepsis products – including T2Dx Instruments, and T2Bacteria, T2Candida and T2Resistance Panels – to our new distribution partners in Singapore and South Korea. The Asia Pacific region, home to 4.6 billion people, represents a meaningful growth opportunity for T2 Biosystems and we view Singapore and South Korea as ideal locations to establish a commercial foothold and build long-term relationships with distributors and customers. According to estimates by the Asia Pacific Sepsis Alliance, national sepsis incidence in the region ranges from 120 to 1,600 per 100,000 people, with mortality rates related to sepsis up to 35%. I am pleased to report that we have initiated shipments to these new geographies as part of initial instrument purchase orders, with two T2Dx Instruments shipped to Singapore during the third quarter and four T2Dx Instruments to be shipped to South Korea during the fourth quarter.

Simultaneous with our commercial expansion, we have been rebuilding our Clinical and Medical Affairs teams to raise awareness and enhance the messaging on the clinical value of our products. Our new team is comprised of laboratory professionals, pathologists, clinical microbiologists, infectious disease MDs, and PharmDs and is actively engaged with Key Opinion Leaders to generate and share real world data via scientific journal publications, at medical conferences, and at industry trade shows.

Our ability to demonstrate and message the improvements in clinical outcomes and cost reductions are key elements of our value proposition. We are committed to the generation of clinical and health economic outcome data to support the adoption and utilization of

our rapid diagnostic technology, especially when it comes to bloodstream infections and sepsis. Accordingly, we are increasing our clinical data library and our presence at key medical conferences.

Earlier this year, a meta-analysis of 14 controlled studies was published in Expert Review of Medical Devices, a peer-reviewed medical journal, comparing our sepsis products to the blood culture standard of care. The use of T2's products showed significant clinical improvements and efficiencies, including: faster time to species identification (by 77 hours), faster time to administer targeted antimicrobial therapy (by 42 hours), faster time to de-escalation of empiric therapy (by 7 hours), and decreased length of patients' stay in the ICU (by 5 days).

During the third quarter, we unveiled new data with the medical community at several conferences including the Sepsis Alliance Summit, the American Association for Clinical Chemistry's Annual Scientific Meeting and Clinical Lab Expo, the College of American Pathologists' Annual Meeting, and IDWeek. This data allows our team to continue essential discussions on the important role of culture-independent rapid diagnostic tests in the timely and accurate detection of sepsis-causing pathogens, as well as positive patient and healthcare outcomes.

Throughout the pandemic, our commercial and medical affairs teams have faced hospital access restrictions that limited in-person engagement that has been a headwind to the adoption of our sepsis products. We had previously expected a more favorable environment during the second half of the year, as hospitals loosened restrictions and granted increased access. We have seen improvements and we anticipate that our sales and medical affairs teams will have continued access to U.S. hospitals during the fourth quarter, and that hospital personnel will have increased bandwidth to engage in discussions regarding sepsis protocols and innovative diagnostic technology for sepsis management.

We are raising our revenue expectations to reflect our third quarter results and now expect total revenue for the full year 2021 of $25.0 million to $27.0 million, consisting of increased product revenue of $15.0 million to $16.0 million and research contribution revenue of $10.0 to $11.0 million which remains unchanged. We continue to expect to enter into at least 30 T2Dx Instrument contracts in 2021.

Moving to our second priority – enhancing our operations

At the beginning of 2021, we set the goal of enhancing our business operations with an emphasis on product gross margins, operating cost structure, and efficiency. We reviewed all business and manufacturing processes, as well as our business tools. During this review, each cost line item was carefully scrutinized to ensure that expenses and investments were aligned with our 2021 priorities, including our growth objectives.

Throughout 2021, we have focused on scaling our manufacturing capabilities and strengthening our supply chain. Over the last year, we have scaled our manufacturing from being able to produce 2,000 tests a week to over 7,000 test a day. To achieve this level of production, we scrutinized every aspect of the manufacturing process, eliminating waste and adding efficiencies. As a result of these initiatives and increased volumes, we are seeing significant improvement in our product gross margins.

Not only did we make efforts to streamline our manufacturing process, but we also explored new tools to help us better manage our growth. We assessed multiple tools and determined that one of best ways to improve our efficiency is by implementing a new Oracle ERP system, which we implemented in the third quarter. This new system will help us gain efficiencies and scale across operations including supply chain and accounting.

During the third quarter, we finalized a lease that will consolidate our existing operations into a 70,000 square foot state-of-the-art life sciences facility in Billerica, Massachusetts to accommodate current and future growth. The new facility will include R&D labs and manufacturing space designed specifically to advance the development of current and new products, while reducing operating costs, highlighted by a 60% reduction in rent. We expect the move to occur in during the second half of 2022, at which time we will exit our current facilities.

Lastly, moving to our third priority – advancing our pipeline

We are continuing to advance the programs outlined in our product development contract awarded by the Biomedical Advanced Research Development Authority, or BARDA, that is valued at up to $69 million based upon the achievement of certain milestones within defined contract phases.

During the third quarter, our scientific team successfully completed the milestones under Option 1 of the contract, which led to BARDA's decision to exercise Option 2A. Option 2A is planned for the period between October 2021 and March 2022 and valued at $6.4 million. As a reminder, we are developing four products under the BARDA contract: the T2Resistance Panel, the T2Biothreat Panel, the comprehensive sepsis panel, and the next-generation instrument.

The T2Resistance Panel is a direct-from-blood test panel designed to detect thirteen antibiotic resistance genes from gram-positive and gram-negative pathogens in 3-5 hours, and runs on our FDA cleared T2Dx Instrument. We are currently marketing and selling the T2Resistance Panel in Europe, under CE mark, and we are on a pathway to apply U.S. FDA 510(k) clearance prior to commercialization in the U.S. market. The T2Resistance Panel has previously received "breakthrough device" designation from the FDA and we have engaged in conversations with the FDA on the clinical trial requirements required for 510(k) submission. We plan to initiate a multi-site clinical trial during the first quarter of 2022, which is anticipated to involve 10 sites and will recruit up to 1,500 subjects.

The T2Biothreat Panel is a direct-from-blood panel designed to detect six biothreat pathogens, and runs on our FDA cleared T2Dx Instrument. The development of the T2Biothreat Panel has concluded, and we have demonstrated preliminary detection of targeted biothreat pathogens directly in whole blood at clinically relevant concentrations.

Analytical verification studies have been initiated and we plan to initiate the clinical trial for the T2Biothreat Panel during the first quarter of 2022, with positive samples being prepared and analyzed in a high-containment Biosafety Level 3 laboratory.

The comprehensive sepsis panel is a direct-from-blood test panel designed to detect up to 99% of all bloodstream infections caused by bacterial and *Candida* species, as well as all blood-borne antibiotic resistant threats identified as urgent by the Centers for Disease Control and Prevention, in a single test with time to results of approximately three hours. The comprehensive sepsis panel is being developed using our pre-existing and proprietary technology.

The next-generation instrument is being developed in parallel with our comprehensive sepsis panel and is designed to be fully automated, on-demand and random access, similar to our T2Dx Instrument, but with faster turnaround times and the ability to detect an increased number of pathogens and resistance genes from a single, whole blood sample. The industrial design is nearing completion and, based on the current schedule, we plan to have a fully functioning beta unit in mid-2022. Once completed, we will merge the prototypes with the assay and initiate full scale system wet testing.

With that, I will now turn the call over to John Sprague to go over the details of our first quarter financial results.

John Sprague

Thank you, John.

Total revenue for the third quarter of 2021 was $7.4 million, an increase of 42% compared to the prior year period. Product revenue was $4.3 million, an increase of 15% compared to the prior year period driven primarily by increased test panel sales. Research contribution revenue was $3.1 million, an increase of 110% compared to the prior year period driven by increased BARDA contract activity.

Product costs for the third quarter of 2021 were $4.7 million, a decrease of $2.1 million compared to the prior year period, driven by manufacturing cost efficiency initiatives. Research and development expenses were $6.4 million, an increase of $2.6 million driven by increased BARDA contract activity. Selling, general and administrative expenses were $8.5 million, an increase of $3.3 million driven by increased commercial team headcount, increased trade show activity and an ERP system implementation, which went live in October.

Net loss for the third quarter of 2021 was $14.0 million, $0.08 per share, compared to a net loss of $11.3 million, $0.08 per share for the prior year period.

Cash, marketable securities and restricted cash were $43.6 million as of September 30, 2021. We did not use the ATM facility in the third or fourth quarter of 2021 and we are in compliance with the remaining covenants of the CRG loan agreement.

As John mentioned with respect to 2021 guidance, we are raising our revenue expectations to reflect our third quarter results and now expect total revenue for the full year 2021 of $25.0 million to $27.0 million, consisting of increased product revenue of $15.0 million to $16.0 million and research contribution revenue of $10.0 to $11.0 million which remains unchanged. We continue to expect to enter into at least 30 T2Dx Instrument contracts in 2021.

Thank you and back to John Sperzel for closing remarks.

John Sperzel

Thank you, John.

We are building a foundation for sustained growth and we are encouraged by the progress made across our corporate priorities during the third quarter. Our sales have increased considerably compared to the prior year period, and we continue to expand our

commercial and medical affairs teams to raise awareness of our technology, and drive adoption and utilization of our products. Simultaneously, we are advancing new products toward commercialization, including the T2Resistance Panel and T2Biothreat Panel, and taking actions to efficiently scale our manufacturing and prepare to produce future products, like our next generation instrument and comprehensive sepsis panel. I am confident we will continue to make major contributions to the advancement of care for patients at risk of sepsis.

Before concluding, I would like to welcome Laura Adams to our board of directors. She is a healthcare industry thought leader who continues to optimize patient care delivery through data and analytics. We are excited to have her on board and look forward to her valued input and leadership. I would also like to thank Tony Pare for his contributions to the Company and wish him well in his new role, and finally welcome Brett Giffin as our new Chief Commercial Officer.

Now let’s open it up to questions. Operator?