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): February 15, 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 1.01 Entry into a Material Definitive Agreement.

On February 15, 2022, T2 Biosystems, Inc. (the "Company") entered into Amendment No. 7 to Term Loan Agreement (the "Seventh Amendment"), with CRG Servicing LLC as administrative agent and collateral agent (in such capacities, "Administrative Agent") and the lenders listed on the signature pages thereto to modify certain terms of that certain Term Loan Agreement, dated as of December 30, 2016, by and among the Company, the Administrative Agent and the lenders party thereto.

The Seventh Amendment extends the interest-only payment period from December 31, 2022 to December 31, 2023 and extends the maturity date from December 31, 2022 to December 31, 2023.

The foregoing summary is qualified in its entirety by reference to the Seventh Amendment, a copy of which will be attached as an exhibit to the Company's Annual Report on Form 10-K for the period ending December 31, 2021.

Item 2.02 Results of Operations and Financial Condition

On February 17, 2022, the Company issued a press release announcing its financial results for its fiscal quarter and full year ended December 31, 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 8.01 Other Events

On February 17, 2022, the Company reported the following preliminary unaudited fourth quarter and full year 2021 financial and operational results and provided guidance on the Company's financial outlook for 2022:

- Achieved full year 2021 total revenue of $28.1 million, including product revenue of $16.6 million, representing an increase of 55% and 43%, respectively, compared to the prior year
- Achieved full year 2021 sepsis test panel revenue of $5.1 million, representing an increase of 46% compared to the prior year
- Achieved full year 2021 research and contribution revenue of $11.4 million, representing an increase of 77% compared to the prior year
- Executed contracts for 32 T2Dx® Instruments in 2021, including 17 instrument contracts during the fourth quarter
- Expanded international commercialization by entering into exclusive distributor agreements in Mexico, Singapore, South Korea, Taiwan, Norway, Finland, and Türkiye
- Strengthened leadership team by hiring industry veterans Aparna Ahuja MD as Chief Medical Officer, and Brett Giffin as Chief Commercial Officer, and significantly expanded sales, marketing, clinical and medical affairs teams
- Initiated U.S. clinical trials for the T2Resistance® Panel and T2Biothreat® Panel in December 2021, enabling potential filing of FDA submissions for both products during 2022
- Amended term loan agreement with CRG, extending both the interest-only period and the maturity date to December 31, 2023

In connection with its annual assessment of the effectiveness of the Company's internal controls over financial reporting, the Company's management identified a material weakness of internal controls related to recording inventory receipt, movements and damage and scrap transactions. The Company's management concluded that this did not result in a misstatement of any previous financial statements and that appropriate remedial actions have already been taken.

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 revenue results and cash balance, financial outlook, timing of filing of an FDA submission, 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. The preliminary, estimated financial results for the fourth quarter and fiscal year 2021 contained in this Current Report on Form 8-K contain forward-looking statements and are subject to the completion of management's and the audit committee's final reviews and our other financial closing procedures and are therefore subject to change. You should not place undue reliance on such preliminary information and estimates because they may prove to be materially inaccurate. The preliminary information and estimates 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 and fiscal year ended December 31, 2021, including all disclosures required by U.S. generally accepted accounting principles, and as our auditors conduct their review of these financial statements. While we believe that such preliminary information and estimates are based on reasonable assumptions, actual results may vary, and such variations may be material.

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 on March 31, 2021, and other

filings the company makes with the Securities and Exchange Commission 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 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 February 17, 2022
99.2	Transcript of conference call held on February 17, 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: February 17, 2022

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

T2 Biosystems Announces Fourth Quarter & Full Year 2021 Financial Results

Full Year 2021 Total Revenue Growth of 55%; Plans to Double Sepsis Revenue and T2Dx Instruments

LEXINGTON, Mass., February 17, 2022 (GLOBE NEWSWIRE)—T2 Biosystems, Inc. (NASDAQ:TTOO), a leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes, today announced financial results for the fourth quarter and full year ended December 31, 2021.

Full Year 2021 and Recent Highlights

- Achieved full year 2021 total revenue of $28.1 million, including product revenue of $16.6 million, representing increases of 55% and 43%, respectively, compared to the prior year
- Achieved full year 2021 sepsis test panel revenue of $5.1 million, representing an increase of 46% compared to the prior year
- Achieved full year 2021 research and contribution revenue of $11.4 million, representing an increase of 77% compared to the prior year
- Executed contracts for 32 T2Dx® Instruments in 2021, including 17 instrument contracts during the fourth quarter
- Expanded international commercialization by entering into exclusive distributor agreements in Mexico, Singapore, South Korea, Taiwan, Norway, Finland, and Türkiye
- Strengthened leadership team by hiring industry veterans Aparna Ahuja MD as Chief Medical Officer, and Brett Giffin as Chief Commercial Officer, and significantly expanded sales, marketing, clinical and medical affairs teams
- Initiated U.S. clinical trials for the T2Resistance® Panel and T2Biothreat® Panel in December 2021, enabling potential filing of FDA submissions for both products during 2022
- Amended term loan agreement with CRG, extending both the interest-only period and the maturity date to December 31, 2023

“We made substantial progress across our three corporate priorities during 2021: accelerating our sales, enhancing our operations and advancing our pipeline,” stated John Sperzel, Chairman and CEO of T2 Biosystems. “We are excited to continue this momentum in 2022 with plans to double our T2Dx Instruments and sepsis test revenue compared to 2021, improve our product gross margins, and complete the U.S. clinical trials for the T2Resistance and T2Biothreat panels, while we continue to advance the development of our next generation instrument and comprehensive sepsis panel. We are confident continued progress across these initiatives will drive growth and create shareholder value.”

Fourth Quarter 2021 Financial Results

Total revenue for the fourth quarter of 2021 was $7.0 million, a decrease of 10% compared to the prior year period driven by increased sepsis test panel sales and BARDA contract activities offset by decreased COVID-19 test panel sales. Product revenue for the fourth quarter of 2021 was $4.0 million, a decrease of 31% compared to the prior year period, driven primarily by the record COVID-19 test sales in the prior year comparable period. Research and contribution revenue for the fourth quarter of 2021 was $3.0 million, an increase of 52% compared to the prior year period.

Operating expenses for the fourth quarter of 2021 were $11.9 million, an increase of $3.3 million compared to the prior year period, driven by increased BARDA contract research and development activity, and increased commercial and medical affairs headcount.

Net loss for the fourth quarter of 2021 was $12.1 million or a loss of $0.07 per share, compared to a net loss of $9.9 million, or a loss of $0.07 per share, in the prior year period.

Full Year 2021 Financial Results

Total revenue for 2021 was $28.1 million, an increase of 55%, compared to the prior year, driven by increased sepsis test panel sales and BARDA contract activities offset by decreased Covid-19 test panel sales. Product revenue for 2021 was $16.7 million, an increase of 43% compared to the prior year, driven by increased test panel sales. Research and contribution revenue for 2021 was $11.4 million, an increase of 77% compared to the prior year.

Operating expenses for 2021 were $50.3 million, an increase of $12.1 million compared to the prior year driven by increased BARDA contract research and development activity, increased commercial and medical affairs headcount.

Net loss for 2021 was $49.2 million, or a loss of $0.31 per share, compared to a net loss of $46.8 million, or a loss of $0.39 per share, in 2020.

Cash, equivalents, marketable securities and restricted cash were $33.8 million as of December 31, 2021.

2022 Financial Outlook

The Company expects full year 2022 total revenue of $28.0 to $31.0 million, including product revenue of $16.0 to $17.0 million and research and contribution revenue of $12.0 to $14.0 million. The Company expects to close 60 to 70 T2Dx Instrument contracts in 2022 and COVID-19 revenue to decrease from $9.5 to $3.5 million.

Webcast and Conference Call Information

T2's management team will host a conference call today, February 17, 2022, beginning at 4:30pm ET. Investors interested in listening to the call may do so by dialing 877-407-9208 for domestic callers or 1-201-493-6784 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, T2Bacteria® Panel, T2Resistance® Panel, and T2SARS-CoV-2™ Panel and are powered by the Company's proprietary T2 Magnetic Resonance (T2MR®) technology. T2 Biosystems has an active pipeline of future products, including the T2Cauris™ Panel, 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, timing of filing of an FDA submission, 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.

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 22,245	$ 16,793
Marketable securities	9,996	25,396
Accounts receivable	5,134	5,099
Inventories	3,909	3,636
Prepaid expenses and other current assets	3,110	2,660
Total current assets	44,394	53,584
Property and equipment, net	4,675	3,771
Operating lease right-of-use assets	9,766	11,034
Restricted cash	1,551	551
Marketable securities	—	10,002
Other assets	153	136
Total assets	$ 60,539	$ 79,078
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 2,832	$ 2,058
Accrued expenses and other current liabilities	8,338	7,512
Deferred revenue	518	230
Total current liabilities	11,688	9,800
Notes payable	47,790	45,235
Operating lease liabilities, net of current portion	9,359	10,533
Deferred revenue, net of current portion	28	424
Derivative liability	—	1,010
Other liabilities	4,577	3,350
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; 166,400,892 and 148,078,974 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	166	148
Additional paid-in capital	459,151	431,544
Accumulated other comprehensive (loss) income	(4)	9
Accumulated deficit	(472,216)	(422,975)
Total stockholders' equity (deficit)	(12,903)	8,726
Total liabilities and stockholders' equity (deficit)	$ 60,539	$ 79,078

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

	Year ended December 31,	
	2021	**2020**
Revenue:		
Product revenue	$ 16,646	$ 11,677
Research revenue	—	11
Contribution revenue	11,412	6,442
Total revenue	28,058	18,130
Costs and expenses:		
Cost of product revenue	20,703	21,280
Research and development	21,801	16,112
Selling, general and administrative	28,527	22,094
Total costs and expenses	71,031	59,486
Loss from operations	(42,973)	(41,356)
Other income (expense):		
Interest income	112	14
Interest expense	(6,586)	(5,518)
Other income, net	206	62
Total other expense	(6,268)	(5,442)
Net loss	(49,241)	(46,798)
Net loss per share — basic and diluted	$ (0.31)	$ (0.39)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	158,861,418	121,331,464
Other comprehensive loss:		
Net loss	$ (49,241)	$ (46,798)
Net unrealized gain (loss) on marketable securities arising during the period	(4)	13
Less: net realized gain on marketable securities included in net loss	(9)	(4)
Total other comprehensive loss, net of taxes	(13)	9
Comprehensive loss	$ (49,254)	$ (46,789)

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

	Three Months ended December 31,	
	2021	2020
Revenue:		
Product revenue	$ 4,012	$ 5,834
Contribution revenue	2,968	1,954
Total revenue	6,980	7,788
Costs and expenses:		
Cost of product revenue	5,362	7,476
Research and development	5,353	3,764
Selling, general and administrative	6,544	4,868
Total costs and expenses	17,259	16,108
Loss from operations	(10,279)	(8,320)
Other income (expense):		
Interest income	94	12
Interest expense	(1,954)	(1,610)
Other income, net	(5)	9
Total other expense	(1,865)	(1,589)
Net loss	(12,144)	(9,909)
Net loss per share — basic and diluted	$ (0.07)	$ (0.07)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	166,172,579	148,018,044
Other comprehensive loss:		
Net loss	$ (12,144)	$ (9,909)
Net unrealized gain (loss) on marketable securities arising during the period	(13)	48
Less: net realized (gain) loss on marketable securities included in net loss	5	(3)
Total other comprehensive loss, net of taxes	(8)	45
Comprehensive loss	$ (12,152)	$ (9,864)

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 fourth quarter and full year 2021 earnings conference call. Today, I will highlight the company's strong performance in 2021, provide details on the progress across our three corporate priorities, and share our 2022 priorities. I will then turn the call over to John Sprague, our Chief Financial Officer, who will review our fourth quarter and full year 2021 financial results and share our 2022 financial guidance, before I make some closing remarks and we open the call for questions and answers.

In 2021, the T2 Biosystems team generated total revenue of $28.1 million, including product revenue of $16.6 million, representing growth of 55% and 43%, respectively, compared to the prior year. We entered into contracts for 32 T2Dx Instruments in 2021, including contracts for 17 instruments during the fourth quarter, which exceeded the expectations we set at the beginning of the year.

We have made considerable progress across our three corporate priorities: accelerating our sales, enhancing our operations, and advancing our pipeline. We strengthened our leadership, sales, marketing, clinical and medical affairs teams; expanded commercial distribution in Asia Pacific, Latin America, and Europe; increased manufacturing capacity and improved product gross margins; finalized a lease that will significantly reduce future rent expenses; initiated U.S. clinical trials for the T2Resistance and T2Biothreat Panels ahead of schedule, and advanced our next generation products pipeline.

We also made meaningful progress toward our mission: *to fundamentally change the way medicine is practiced through transformative culture-independent diagnostics that improve the lives of patients around the world.* We have our sights set on sepsis.

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. To further complicate matters, the current standard of care continues to rely on a positive blood culture to identify the presence of a bloodstream infection and target therapy for patients suspected of sepsis. Due to their poor sensitivity, blood cultures often require multiple samples of blood from critically ill patients, and take anywhere from 1-5 days to achieve the growth necessary for pathogen identification. Additional testing, such as traditional microbiology or post-culture molecular diagnostic tests, may then be required for determination of species identification and susceptibility.

In the U.S., sepsis is the #1 cost of hospitalization, costing our healthcare system nearly $62 billion annually, the #1 cause of death in hospitals, claiming nearly 270,000 lives each year, and the #1 cause of 30-day hospital readmissions, requiring nearly 20% of survivors to be re-hospitalized in 30 days. By these measures, it would be reasonable to conclude that the current sepsis standard of care for diagnosing and treating patients is failing patients, payers, and providers.

At T2 Biosystems, we are commercializing the first and only FDA cleared products able to detect sepsis-causing pathogens directly in whole blood, in just 3-5 hours, without the need to wait days for a positive blood culture. The rapid detection of sepsis-causing pathogens is critical, as each hour of delayed targeted treatment increases mortality risk by up to 8%. Our value proposition is based on our ability to rapidly identify sepsis-causing pathogens and antibiotic resistance genes, within hours, with high sensitivity and specificity, enabling clinicians to achieve targeted antimicrobial therapy, faster.

The T2Bacteria Panel is designed for the detection of most of the ESKAPE pathogens, as innovation must first address the top clinical need and ESKAPE pathogens are a major healthcare burden. ESKAPE pathogens are responsible for the majority of nosocomial infections and are capable of “escaping” the biocidal action of antimicrobial agents. Also, a systematic review of the clinical and economic impact of antibiotic resistance reveals that ESKAPE pathogens are associated with the highest risk of mortality, thereby resulting in increased health care costs.

Our current positioning is that our sepsis panels are to be used in conjunction with blood culture, and detecting the ESKAPE pathogens directly from whole blood in 3-5 hours, enables targeted therapy to these organisms which are resistant to common empiric therapies. Detecting these commonly resistant organisms in 3-5 hours pre-culture is more critical than rapidly detecting those organisms which typically respond to common empiric therapies.

We believe our pipeline product, the comprehensive sepsis panel, will replace most blood cultures for patients at risk of sepsis. When we launch that product, our positioning will likely shift from being an adjunct test to a primary test to detect sepsis-causing pathogens and antibiotic resistance genes.

To advance our mission and create value across 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 discuss our recent progress and our 2022 plans as it pertains to each of these corporate priorities.

Starting with our first priority – accelerating our sales:

Our sales strategy consists of primary two objectives: 1) significantly expanding our T2Dx Instrument installed base, by selling or placing new instruments, and 2) doubling our sepsis test panel revenue, by driving broad utilization among new and existing customers. We ended the year with strong momentum on both fronts, driving strong instrument adoption and increased sepsis test panel utilization by our hospital customers.

In 2021, we entered into contracts for 32 T2Dx Instruments, including 17 instruments during the fourth quarter. Our installed base of T2Dx Instruments includes 89 in the U.S. and 55 internationally. We generated sepsis panel revenue of $5.1 million representing an increase of 46% compared to the prior year. In the U.S., we achieved annualized sepsis test utilization of $118,000 per legacy T2Dx Instrument, an increase of 37% compared to the prior year. We continue to believe that, over time, annualized sepsis test utilization will reach $200,000 per instrument in the U.S., and we are pleased that utilization is trending in that direction.

To further penetrate the market we have materially expanded our commercial team. In the U.S., we have 20 sales territories providing geographic hospital coverage; increased from just 2 sales territories in 2020. We recently hired Brett Giffin as Chief Commercial Officer, and he leads our commercial growth initiatives and is directly responsible for global sales, marketing, service and customer support. We are excited to have Brett leading the team and we feel great about the size and structure of the commercial team, and the quality of the Regional Account Managers we have hired.

At the beginning of 2021, we hired Aparna Ahuja, MD as Chief Medical Officer. She has led a total rebuild of our medical, clinical, and regulatory teams. In the past, our team was limited to Pharm Ds, and today we have a highly diverse and talented team of infectious disease MDs, laboratory professionals, and Pharm Ds. Our clinical and medical affairs teams are raising awareness by amplifying clinical value messaging for our products. The team 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. During 2021, T2 Biosystems' products were mentioned in over 50 Publications, Posters, and Presentations.

As recently announced, we continue to expand our international distribution network which allows our products to be marketed and sold in more countries. Hospitals around the world face similar challenges when caring for patients suspected of sepsis and we are leaning into this opportunity. In the second half of 2021, we initiated commercialization in Singapore, South Korea, Taiwan, and Mexico by entering into distributor agreements in each of these countries. Shipments to our distribution partners were initiated in the second half of 2021, with 2 T2Dx Instruments shipped to Singapore during the third quarter and 4 T2Dx Instruments shipped to South Korea during the fourth quarter. Early in 2022, we have continued to expand our distribution networks with agreements in Norway, Finland and Türkiye.

While sepsis remains the core competency and the top commercial priority for T2 Biosystems, the introduction of our T2SARS-CoV-2 Panel in 2020 has allowed us to significantly increase our installed base of T2Dx Instruments and gain access to U.S. hospitals that were previously unfamiliar with our products and services.

The expanded installed base of 45 T2Dx instruments being used for COVID-19 testing will eventually play a meaningful role in increasing sepsis test panel sales because each of these customers has committed to evaluating our sepsis tests. We are optimistic that many of these hospitals will have the capacity to evaluate our sepsis products this year and we fully expect that these customers will convert to our sepsis panels over time.

Despite the broad use of at-home COVID-19 antigen tests, hospitals continue to rely on molecular or PCR tests, including the T2SARS-CoV-2 Panel, to identify acute COVID-19 infections. The early 2021 surge in COVID-19 infection rates has translated to strong demand for our T2SARS-CoV-2 Panel from U.S. hospitals during the first quarter of 2021, and while we believe there will be continued demand for our T2SARS-CoV-2 Panel, we expect a decrease in sales of our COVID-19 test compared to 2021.

Taking into account our current installed base of instruments, our expanded sales and medical affairs teams, and growing international distributor network, we expect to double our core sepsis business in 2022, as compared to 2021, including doubling our T2Dx Instrument units from 32 to between 60 and 70, and doubling our sepsis test revenue from $5.1 to $10.2 million. Encouragingly, in the first quarter we are seeing customers with an increased ability to evaluate new technology, and several of our new U.S. hospital customers that we closed during the first quarter will implement our sepsis test panels immediately.

Moving to our second corporate priority – enhancing our operations:

To sustain growth and drive adoption and utilization of our products over the long-term we continue to implement changes to our operations that enable a more efficient business model.

Throughout 2021, we have focused on scaling our manufacturing capabilities and strengthening our supply chain. Over the past year, we have scaled our manufacturing from being able to produce 2,000 tests per week to over 7,000 tests per day. To achieve this level of production, we reviewed business and manufacturing processes, as well as our business tools. We assessed multiple tools and determined that one of the best ways to improve our efficiency was by implementing a new Oracle ERP system, which we implemented during the third quarter of 2021. As a result of these initiatives, we are seeing significant improvement in our product gross margins.

In the third quarter of 2021, we signed a lease that will consolidate our existing operations into a single 70,000 square foot, state-of-the-art life sciences facility in Billerica, Massachusetts, to accommodate current and future growth. This new facility will serve as our corporate headquarters and main manufacturing hub. It will also house all of our R&D labs that will aid in the advancement of our future products. This move, which we expect will commence in the second half of 2022, will produce a significant reduction in rent expense, accommodate our manufacturing expansion, and reduce costs through efficiencies gained in working in and maintaining one facility.

During 2022, we also plan to make strategic investments in tooling, automation, and efficiency projects to further scale our manufacturing capabilities and continue to improve cost of goods.

Moving to our third priority – advancing our pipeline:

We made significant progress advancing our product pipeline throughout 2021. We are continuing to prioritize the programs under our milestone-based product development contract awarded by the U.S. Biomedical Advanced Research Development Authority, or BARDA, which is valued at up to $69 million. The four products that we are advancing under the BARDA contract are the T2Resistance Panel, the T2Biothreat Panel, the comprehensive sepsis panel, and the next-generation instrument.

As a reminder, during the third quarter, our scientific team successfully completed the milestones described under Option 1 of the BARDA contract. BARDA subsequently chose to exercise Option 2A of the contract, which is planned for the period between October 2021 and March 2022 and is valued at $6.4 million. Upon the successful completion of Option 2A, we are optimistic that BARDA will choose to exercise Option 2B.

In December 2021, we initiated the U.S. clinical trials for the T2Resistance Panel and the T2Biothreat Panel, both ahead of our previously announced schedule. The clinical trials are designed to evaluate the performance of the T2Resistance and T2Biothreat panels and support submissions to the U.S. Food and Drug Administration.

The T2Resistance Panel, which runs on our T2Dx Instrument, is a direct-from-blood test panel that detects 13 antibiotic resistance genes from both Gram-positive and Gram-negative bacterial pathogens, which are known to cause antibiotic-resistant infections that may lead to sepsis. It provides accurate results in 3-5 hours without the need to wait days for a positive blood culture. The T2Resistance Panel, which is currently marketed and sold in Europe under a CE mark, was granted Breakthrough Device designation from the FDA, which provides for a prioritized FDA review process. The clinical trial, which will include up to 1,500 patients across 10 U.S. hospitals, is estimated to cost T2 Biosystems $2.5 million and is expected to be completed in 2022, enabling filing of an FDA submission potentially during 2022.

The T2Biothreat Panel, which also runs on our T2Dx Instrument, is a direct-from-blood test panel that provides results in 3-5 hours, and simultaneously detects six biothreat pathogens identified as threats by the U.S. Government. The clinical trial, which includes positive samples being prepared and analyzed at a high-containment Biosafety Level 3 laboratory and negative samples being analyzed at a single site, is estimated to cost T2 Biosystems $450,000 and is expected to be completed in 2022, enabling filing of an FDA submission potentially during 2022.

The comprehensive sepsis panel is a direct-from-blood test panel that will run on our next generation instrument. The new test panel is designed to detect greater than 95% of all bloodstream infections caused by bacterial and *Candida* species, and antibiotic resistant markers identified as threats by the Centers for Disease Control and Prevention, in a single test with a time to result of approximately 3 hours. We believe this test panel can be positioned as the primary test for patients at risk of sepsis, and substantially change the blood culture based laboratory workflow.

The next-generation instrument, which is being developed in conjunction with our comprehensive sepsis panel, is designed to be fully-automated, on-demand, and random access. This is similar to our current T2Dx Instrument but incorporates faster turnaround times and is designed to detect an increased number of pathogens and resistance genes from a single, whole blood sample. The design is approaching completion, and based on the currently outlined schedule, we expect to have a fully functioning Beta unit in the first half of 2022. Once the build-out is complete, we will merge prototypes with the assay and begin full scale system wet testing.

We are planning to provide additional information on our new product pipeline during an investor and analyst day in the second quarter of 2022, where we will take a deeper dive into each of these product development initiatives, as well as our commercial and medical affairs plans and initiatives.

With that, I will now turn the call over to John Sprague to go over the details of our fourth quarter and full year 2021 financial results, and our financial outlook for 2022.

John Sprague

Thank you, John.

Total revenue for the fourth quarter of 2021 was $7.0 million, a decrease of 10% compared to the prior year period driven by increased sepsis test panel sales and BARDA contract activities offset by decreased Covid-19 test panel sales. Product revenue was $4.0 million, a decrease of 31% compared to the prior year period. Research and contribution revenues were $3.0 million, an increase of 52% compared to the prior year period.

Product costs for the fourth quarter of 2021 were $5.4 million, a decrease of $2.1 million compared to the prior year period, driven by decreased Covid-19 test panel sales and manufacturing cost efficiency initiatives. Research and development expenses were $5.4 million, an increase of $1.6 million driven by increased BARDA contract activity. Selling, general and administrative expenses were $6.5 million, an increase of $1.7 million driven by increased commercial and medical affairs headcount.

Net loss for the fourth quarter of 2021 was $12.1 million, $0.07 per share, compared to a net loss of $9.9 million, $0.07 per share for the prior year period.

Cash, marketable securities and restricted cash were $33.8 million as of December 31, 2021. We did not use the ATM facility in the third or fourth quarter of 2021 and we have used it minimally in 2022. CRG has extended the interest only period and loan maturity to December 31, 2023 and we are in compliance with the remaining covenants of the loan agreement.

Total revenue for 2021 was $28.1 million, an increase of 55% compared to the prior year driven by increased sepsis test panel sales and BARDA contract activities offset by decreased Covid-19 test panel sales. Product revenue was $16.6 million, an increase of 43% compared to the prior year. Research and contribution revenue was $11.4 million, an increase of 77% compared to the prior year.

Product costs for 2021 were $20.7 million, a decrease of $600 thousand compared to the prior year period, driven by decreased Covid-19 test panel sales and manufacturing cost efficiency initiatives. Research and development expenses were $21.8 million, an increase of $5.7 million driven by increased BARDA contract activity. Selling, general and administrative expenses were $28.5 million, an increase of $6.4 million driven by increased commercial and medical affairs headcount.

Net loss for 2021 was $49.2 million, $0.31 per share, compared to a net loss of $46.8 million, $0.39 per share for the prior year.

As we previously disclosed we are not in compliance with NASDAQ’s $1.00 listing requirement. We plan to regain compliance by executing on our operating plans and organically drive our share price to compliance and we currently have no plans for a reverse stock split.

We expect full year 2022 total revenue of $28.0 to $31.0 million, including product revenue of $16.0 to $17.0 million and research and contribution revenues of $12.0 to $14.0 million. We expect to close 60 to 70 T2Dx Instrument contracts in 2022 and COVID-19 revenue to decrease from $9.5 to $3.5 million.

Thank you and back to John Sperzel for closing remarks.

John Sperzel

Thank you, John.

We made meaningful progress across the business during 2021 and, as expressed in our financial outlook, we are confident in our ability to build on this momentum. As we look ahead in 2022, we believe there are numerous catalysts to create value for stakeholders, including plans to double our T2Dx Instrument placements and sepsis test revenue compared to last year, expand our international distribution network, build a world class Scientific Advisory Board and increase awareness of our sepsis products through Key Opinion Leader engagement, generate additional evidence to support the clinical and economic value of our products, complete the U.S. clinical trials for the T2Resistance Panel and T2Biothreat Panel and file submissions with the FDA, and advance the next generation instrument and comprehensive sepsis panel under the BARDA contract.

We are off to a great start in 2022, with strong demand for our T2Dx Instrument and test panels. We have entered into eight instrument contracts in the U.S. in the first six weeks of the year, and our team has a strong sales funnel. We are extremely excited about the future for T2 Biosystems and confident in our ability to change the standard of care for patients at risk of sepsis.

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