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): March 13, 2023

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 March 13, 2023, the Company issued a press release announcing its financial results for its fiscal quarter and fiscal year ended December 31, 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 March 13, 2023
99.2	Transcript of conference call held on March 13, 2023
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: March 16, 2023

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

T2 Biosystems Announces Fourth Quarter and Full Year 2022 Financial Results

Achieved record sepsis product revenue and sepsis-driven T2Dx Instrument placements in 2022

LEXINGTON, Mass., March 13, 2023 (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 fourth quarter and full year ended December 31, 2022.

Recent Commercial and Financial Highlights

- Achieved full year 2022 total revenue of $22.3 million, including product revenue of $11.3 million and research contribution revenue of $11.0 million.
- Achieved record full year 2022 sepsis and related product revenue of $8.4 million, representing growth of 17% compared to 2021, and record fourth quarter sepsis test revenue in the U.S.
- Achieved record full year 2022 sepsis-driven T2Dx® Instrument placements, totaling 51 contracts, consisting of 27 from the U.S. and 24 from outside the U.S.
- Achieved fourth quarter total revenue of $5.5 million, including product revenue of $2.2 million and research contribution revenue of $3.3 million.
- Strengthened the balance sheet in February 2023 by completing a public offering generating $12.0 million of gross proceeds.

Recent Pipeline and Clinical Highlights

- Advanced U.S. clinical trial for the T2Resistance® Panel and completed the U.S. clinical trial for the T2Biothreat™ Panel, demonstrating high sensitivity and specificity exceeding target performance requirements.
- Initiated studies to expand the T2Bacteria® Panel to include detection of *Acinetobacter baumannii*, the tenth most common sepsis causing pathogen that has a crude ICU mortality rate of 34.0% to 43.4%.
- Received FDA Breakthrough Device Designation and the LymeX Award for the T2Lyme™ Panel, and announced plans to complete the development of, and commercialize, the T2Lyme Panel.

"Throughout 2022, the T2 Biosystems team generated record sepsis and related product revenue and expanded the installed base of T2Dx Instruments through record sepsis-driven instrument contracts. We also advanced our product pipeline, positioning T2 Biosystems to expand our test menu in 2023," stated John Sperzel, Chairman and CEO of T2 Biosystems. "We look forward to continuing this momentum to advance our three corporate priorities – accelerating our sales, enhancing our operations, and advancing our pipeline to support long term growth."

Fourth Quarter 2022 Financial Results

Total revenue for the fourth quarter of 2022 was $5.5 million, a decrease of 21% compared to the prior year period. Product revenue for the fourth quarter of 2022 was $2.2 million, a decrease of 45% compared to the prior year period, driven by an 89% decline in COVID-19 test sales and partially offset by increased sepsis test sales. Research contribution revenues were $3.3 million, an increase of 10% compared to the prior year period driven by the timing of enrollments in the T2Resistance clinical trial.

Product costs for the fourth quarter of 2022 were $3.8 million, a decrease of 30% compared to the prior year period, driven by decreased COVID-19 test sales. Research and development expenses were $4.9 million, a decrease of 9% compared to the prior year period driven by decreased development expenses during the clinical trial phases of the BARDA contract. Selling, general and administrative expenses were $6.7 million, an increase of $2% compared to the prior year period driven by increased selling activity.

Net loss for the fourth quarter of 2022 was $10.4 million, $1.41 per share, compared to a net loss of $12.1 million, $3.65 per share, in the prior year period.

Full Year 2022 Financial Results

Total revenue for 2022 was $22.3 million, a decrease of 21%, compared to the prior year. Product revenue for 2022 was $11.3 million, a decrease of 32% compared to the prior year, driven by decreased Covid-19 test panel sales and partially offset by increased sepsis test panel sales. Research and contribution revenue for 2022 was $11.0 million, a decrease of 3% compared to the prior year.

Operating expenses for 2022 were $56.7 million, an increase of 13% million compared to the prior year driven by increased BARDA contract research and development and U.S. clinical trials activity.

Net loss for 2022 was $62.3 million, $12.28 per share, compared to a net loss of $49.2 million, $15.50 per share, in 2021.

Cash, equivalents, and restricted cash were $11.9 million as of December 31, 2022. In February 2023, we raised $12.0 million through a common stock and warrants sale.

2023 Financial Outlook

The Company expects full year 2023 total sepsis and related product revenue of $11.0 million to $13.0 million, representing growth of 31% to 55%, compared to $8.4 million in 2022. Given the focus on product revenue, the Company is not providing guidance on research and contribution revenue.

Webcast and Conference Call Information

The Company's management team will host a conference call today, March 13, 2023, beginning at 4:30 pm ET. Investors interested in listening to the call may do so by dialing 877-545-0523 for domestic callers or 973-528-0016 for International callers and using conference ID 411579 approximately five minutes prior to the start time. A live and recorded webcast of the call will be available on the "Investors" section of the Company's website at www.t2biosystems.com.

About T2 Biosystems

T2 Biosystems, a leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes, is dedicated to improving patient care and reducing the cost of care by helping clinicians effectively treat patients faster than ever before. T2 Biosystems' products include the T2Dx® Instrument, the T2Bacteria® Panel, the T2Candida® Panel, the T2Resistance® Panel, and the 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.

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 completing clinical trials and filing of an FDA submission, impact of operating expense reductions, 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.

Investor Contact:
Philip Trip Taylor, Gilmartin Group
ir@T2Biosystems.com
415-937-5406

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

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 10,329	$ 22,245
Marketable securities	—	9,996
Accounts receivable	2,163	5,134
Inventories	4,349	3,909
Prepaid expenses and other current assets	2,582	3,110
Total current assets	19,423	44,394
Property and equipment, net	4,533	4,675
Operating lease right-of-use assets	8,741	9,766
Restricted cash	1,551	1,551
Other assets	143	153
Total assets	$ 34,391	$ 60,539
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 1,296	$ 2,832
Accrued expenses and other current liabilities	7,647	8,338
Operating Lease Liability	1,352	—
Warrant Liability	39	—
Deferred revenue	172	518
Total current liabilities	10,506	11,688
Notes payable	49,651	47,790
Operating lease liabilities, net of current portion	8,214	9,359
Deferred revenue, net of current portion	52	28
Derivative liability	1,088	—
Other liabilities	4,849	4,577
Total liabilities	74,360	73,442
Commitments and contingencies		
Stockholders' 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; 7,716,519 and 3,328,017 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	8	166
Additional paid-in capital	494,556	459,151
Accumulated other comprehensive (loss) income	—	(4)
Accumulated deficit	(534,533)	(472,216)
Total stockholders' deficit	(39,969)	(12,903)
Total liabilities and stockholders' deficit	$ 34,391	$ 60,539

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

	Year ended December 31,	
	2022	2021
Revenue:		
Product revenue	$ 11,259	$ 16,646
Contribution revenue	11,046	11,412
Total revenue	22,305	28,058
Costs and expenses:		
Cost of product revenue	21,139	20,703
Research and development	25,932	21,801
Selling, general and administrative	30,744	28,527
Total costs and expenses	77,815	71,031
Loss from operations	(55,510)	(42,973)
Other income (expense):		
Interest income	8	112
Interest expense	(6,084)	(7,596)
Change in fair value of derivative instrument	(1,088)	1,010
Change in fair value of warrant liability	326	—
Other income	125	218
Other expense	(15)	—
Other gains/losses	(79)	(12)
Total other expense	(6,807)	(6,268)
Net loss	$ (62,317)	$ (49,241)
Deemed dividend on Series A redeemable convertible preferred stock	$ (330)	$ —
Net loss attributable to common stockholders	$ (62,647)	$ (49,241)
Net loss per share — basic and diluted	$ (12.28)	$ (15.50)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	5,100,395	3,177,228
Other comprehensive loss:		
Net loss	$ (62,317)	$ (49,241)
Net unrealized (loss) gain on marketable securities arising during the period	2	(4)
Less: net realized (gain) loss on marketable securities included in net loss	2	(9)
Total other comprehensive (loss) gain, net of taxes	4	(13)
Comprehensive loss	$ (62,313)	$ (49,254)

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

	Three Months ended December 31,	
	2022	2021
Revenue:		
Product revenue	$ 2,215	$ 4,012
Contribution revenue	3,268	2,968
Total revenue	5,483	6,980
Costs and expenses:		
Cost of product revenue	3,768	5,362
Research and development	4,876	5,353
Selling, general and administrative	6,673	6,544
Total costs and expenses	15,317	17,259
Loss from operations	(9,834)	(10,279)
Other income (expense):		
Interest income	2	94
Interest expense	(1,528)	(944)
Change in fair value of derivative instrument	704	(1,010)
Change in fair value of warrant liability	147	—
Other income	100	(5)
Other gains/losses	(4)	—
Total other expense	(579)	(1,865)
Net loss	$ (10,413)	$ (12,144)
Deemed dividend on Series A redeemable convertible preferred stock	—	—
Net loss attributable to common stockholders	$ (10,413)	$ (12,144)
Net loss per share — basic and diluted	$ (1.41)	$ (3.65)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	7,405,889	3,323,451
Other comprehensive loss:		
Net loss	$ (10,413)	$ (12,144)
Net unrealized (loss) gain on marketable securities arising during the period	—	(13)
Less: net realized (gain) loss on marketable securities included in net loss	—	5
Total other comprehensive (loss) gain, net of taxes	—	(8)
Comprehensive loss	$ (10,413)	$ (12,152)

Regan Talley, IR

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

Forward-looking statements are based on estimates and assumptions as of today and are subject to risks and uncertainties that may cause actual results to differ materially from those expressed or implied by these statements, including the risks and uncertainties described in T2 Biosystems' annual report on Form 10-K filed with the SEC on 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, CEO

Thank you all for joining our fourth quarter and full year 2022 earnings call. Today, I will discuss our performance in the fourth quarter, the progress we have made across our three corporate priorities, and our outlook for 2023. I will then turn the call over to John Sprague, our Chief Financial Officer, who will review our fourth quarter and full year financial results, before I provide closing remarks and we open the call for questions and answers.

I want to start by recognizing the T2 Biosystems team for achieving a number of sales records and key accomplishments during 2022. Commercially, we achieved record full year 2022 sepsis and related product revenue (i.e., non COVID product revenue) and a record number of full year sepsis-driven T2Dx Instrument contracts. We also ended the year on a high note with record fourth quarter U.S. sepsis test sales. Operationally, we

completed a program to reduce the manufacturing cost of the T2Bacteria® Panel and the T2Candida® Panel, and we reduced our operating expenses and headcount. With our new product pipeline, we completed the clinical evaluation for the T2Biothreat™ Panel, advanced the U.S. clinical trial for the T2Resistance® Panel, and received the LymeX Award and FDA Breakthrough Device Designation for our T2Lyme Panel™.

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. The COVID-19 pandemic emphasized that rapid diagnostics are essential to understanding the status of the patient before they receive treatment. In each of our target markets, which now include sepsis and Lyme disease, we believe our products will enable faster targeted therapy that will lead to improved patient outcomes, reduced cost, and lower mortality rates.

I’d like to provide background on the opportunity T2 Biosystems is uniquely positioned to address, in sepsis and Lyme disease. Sepsis presents one of the greatest challenges to healthcare systems worldwide, claiming approximately 11 million lives each year. In the U.S., sepsis is the #1 cost of hospitalization, costing our healthcare system approximately $62 billion annually; the #1 cause of death in hospitals, claiming the lives of approximately 270,000 Americans 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. These figures should be unacceptable to everyone, everywhere.

Last month, the Los Angeles Times reported a 46% increase in the number of patients who developed sepsis while in California hospitals between 2019 and 2021. The same report highlighted that COVID-19 infection itself also elevates the risk of sepsis, especially among older adults who are hospitalized, as nearly 40% of severe sepsis patients who died at California hospitals in 2021 had COVID-19.

The current standard of care for patients at risk of sepsis relies on broad, empiric protocols to administer antimicrobial therapy, despite the fact that these protocols are only optimal in approximately one-half of cases, and can contribute to the growing threat of antimicrobial resistance. The current standard of care also relies on a positive blood culture to identify the presence of a bloodstream infection, which has two limitations: 1) blood culture can take 1-5 days to turn positive, which can result in delayed targeted treatment, and 2) blood culture is widely known to have poor sensitivity, which can cause false positive or false negative results. For sepsis patients, data shows that each hour of delayed targeted antimicrobial treatment can lead to increased mortality risk of up to 8%, demonstrating that rapid detection of sepsis-causing pathogens and antibiotic resistance genes is critical to achieving targeted treatment decisions and improving patient outcomes.

Given our development progress with the T2Lyme Panel, we have expanded our target market to include Lyme disease. 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. The U.S. Centers for Disease Control and Prevention, or CDC, noted 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, illustrating a significant unmet need for a sensitive diagnostic test to detect early Lyme disease. The initial performance data on our T2Lyme Panel is very encouraging. We believe the T2Lyme Panel will allow clinicians to detect active infections, ensure patients receive appropriate therapy faster, and prevent the negative impact of a delay in delivery of treatment and the overuse of antibiotics.

To 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 each of these corporate priorities, including our recent progress and our 2023 plans.

Starting with our first priority – accelerating our sales:

Our U.S. go-to-market strategy includes a direct sales force targeting hospitals. We are focused on increasing the adoption of our products, with emphasis on increasing sales of our sepsis test panels and expanding the installed base of our T2Dx Instruments, while also solidifying commercial plans for our T2Lyme Panel. Our commercial team – which includes sales, marketing, medical affairs, service and support – is completely aligned and reports to a single leader. We are focused on educating customers on the clinical value of our sepsis products, including leveraging the peer-reviewed publications that support the use of the T2Candida and T2Bacteria panels. The team is also focused on expanding the patient selection criteria to increase sepsis test utilization. I'm pleased that we are gaining traction in the market, evidenced by our strong finish in 2022, and that our customers are benefitting from the support of our Scientific Advisory Board and our Key Opinion Leaders, who serve as references for clinical integration models.

In 2022, we achieved record full year sepsis and related product revenue, or non-COVID product revenue, of $8.4 million, representing growth of 17% compared to 2021, and we achieved record fourth quarter U.S. sepsis test revenue. We also achieved record full year sepsis-driven T2Dx Instrument units, totaling 51 instruments, comprised of 27 from the U.S. and 24 from outside the U.S. Our growing installed base of T2Dx Instruments was 181 at the end of 2022, including 106 in the U.S. and 75 internationally.

The expanding adoption of our sepsis products was evidenced by the sale of a T2Dx Instrument to one of the leading U.S. laboratory service providers, to be used within one of the provider's managed-hospital laboratories. We also sold two T2Dx Instruments to one of our existing customers, a leading healthcare system in Pennsylvania, to support their expanding sepsis testing needs. We are pleased to continue the trend of additional instrument orders from the same account, which we believe validates the clinical and economic value of our technology.

Outside of the U.S., we believe there is a large market opportunity for our instruments and sepsis test panels. Our international go-to-market strategy involves partnering with a network of exclusive distributors that sell and support our products in target countries. During 2022, we sold 24 T2Dx Instruments internationally and we expanded our commercial footprint by adding distributors in South Africa, and countries in Scandinavian and Baltic regions. In 2023, we plan to further expand our distribution networks to drive adoption and introduce our products in additional high-value markets, including additional countries in Europe, Middle East, Latin America and Asia Pacific.

Looking ahead in 2023, we plan to focus our commercial efforts in areas where we can generate more profitable revenue. Our top priority will be increasing the use of our sepsis test panels with existing hospital customers. The medical affairs team is integrated with our commercial team and equipped with the data, KOL, Scientific Advisory Board and reference account support to make extremely compelling clinical and economic cases to drive broader patient selection and increased utilization. We have been successful driving utilization in small to mid-size hospitals where sepsis management protocols have the ability to be updated more quickly, and we will continue target these hospitals in 2023. We believe that the sepsis treatment gap has widened, as shown by the management of COVID-19 patients throughout the pandemic, and we understand our customers that already have T2Dx instruments are prepared to address the challenges posed by sepsis.

Given our commercial focus in 2023, we believe the most accurate measure of our success will be our ability to generate product revenues and we are choosing to provide guidance accordingly. We expect total 2023 sepsis and related product revenue of $11.0 million to $13.0 million, representing growth of 31% to 55%, compared to $8.4 million we achieved in 2022. This guidance assumes no revenue from the sale of our T2-SARS-CoV-2 Panel. We expect growth to be driven by increased sales of our sepsis test panels, supported to by sales of T2Dx instruments. Potential FDA clearance of the T2Resistance Panel would represent a meaningful catalyst for product revenue, both as a standalone product and due its expected positive impact on the adoption of the T2Bacteria Panel.

Moving to our second priority – enhancing our operations:

Given the current economic environment, operating efficiently is critical to our success. During the second quarter of 2022, we reduced our overall cost structure, including reductions in headcount, which now stands at 160 employees, and operating expenses. As part of the headcount reductions, we eliminated the position of Chief Operations Officer, and as a result our VP of Operations and VP of Quality Assurance & Regulatory Affairs are now reporting directly to me.

During 2022, we made process improvements to the T2Bacteria and T2Candida panels to reduce manufacturing costs and gain manufacturing efficiencies. We believe these improvements will contribute to improved product gross margins, which we expect to begin positively impacting our financials in 2023.

In recent weeks, we have experienced what we believe is raw material issue that was identified during our routine internal quality inspection. This has limited our ability to manufacture sufficient volume of cartridges to meet current customer demand. As this was identified during in-process inspection, the product that was shipped to customers or distributors was not affected. As a result, while customer demand remains strong, we currently have a backorder for some of our test panels which we hope to ship by the end of March.

From a facilities perspective, we believe that we will continue to meet our current manufacturing needs with our operations at our Lexington and Wilmington, MA facilities. As previously reported, the Company entered into a lease agreement in September 2021, to lease a facility in Billerica, MA in order to consolidate our office, laboratory and commercial manufacturing spaces. In January 2023, the landlord terminated the lease due to the Company’s alleged breach of the agreement, and the landlord subsequently filed a complaint in the Massachusetts Superior Court. The Company disagrees with the

landlord’s allegations and in March 2023, filed a response to the Landlord’s complaint and a counter-claim alleging that, in fact, the Landlord breached its obligations under the contract and unlawfully drew on the security deposit, in addition to breaching its covenants of good faith and fair dealing, making fraudulent misrepresentations, and engaging in deceptive and unfair trade practices.

Finally, during the first quarter of 2023, we strengthened our balance sheet by raising $12 million in gross proceeds. We will continue to be disciplined with our operating expenses and execute on our revenue growth plan with our existing commercial resources to increase our operating leverage and extend our cash runway.

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 by a milestone-based product development contract awarded to us by the U.S. Biomedical Advanced Research Development Authority, or BARDA, which is valued at up to $62 million if all options are exercised.

Our new product pipeline is focused on two goals; 1) developing new tests to expand the test menu on the T2Dx Instrument and, 2) developing a next-generation instrument and comprehensive sepsis test panel.

In the near term, we are developing five new tests aimed at expanding the menu on our FDA-cleared T2Dx Instrument, each representing 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 molecular diagnostic test designed to simultaneously detect six biothreat pathogens identified as threats by the CDC, including the organisms that cause anthrax, tularemia, glanders, melioidosis, plague, and typhus. If not treated promptly, infections with these pathogens can result in mortality rates of 40-

90%. In the event of a public health emergency involving biothreat pathogens, rapid and accurate diagnostic testing is expected to play a central role in minimizing health and economic impact. We have recently completed the U.S. clinical evaluation and announced that the results demonstrated very high sensitivity and specificity across all six biothreat targets, exceeding target performance requirements. We are very pleased with the results and we have shifted our focus to filing the submission with the FDA for U.S. regulatory clearance and subsequently pursuing commercial sales, with the goal of protecting Americans from the threat of deliberate or naturally occurring outbreaks of biothreat pathogens. The T2Biothreat Panel has been funded under our contract with BARDA.

The T2Resistance Panel is a direct-from-blood molecular diagnostic test designed to simultaneously detect 13 antibiotic resistance genes known to cause antibiotic resistant infections, in just 3-5 hours, without the need to wait days for a positive blood culture. The T2Resistance Panel, which is marketed and sold in Europe under CE mark, detects resistance genes that may confer resistance to common antimicrobials such as carbapenems, methicillin, and vancomycin. We expect to complete patient enrollment, of approximately 1500 patients, in our ongoing U.S. clinical trial during the second quarter, and plan to file our submission to the FDA upon completion of the study. As a reminder, the T2Resistance Panel was granted Breakthrough Device Designation by the FDA, which provides for a prioritized review process upon submission. The T2Resistance Panel has been funded under our contract with BARDA.

The T2Lyme Panel is a direct-from-blood molecular diagnostic test designed to detect *Borrelia burgdorferi*, the bacteria that is the major cause of Lyme disease in the U.S. The T2Lyme Panel is intended to test individuals with signs and symptoms of Lyme disease and aid in the diagnosis of early Lyme disease. We believe the T2Lyme Panel will provide a significant advantage over the currently recommended serological testing that requires the presence of antibodies, which can take the body four to six weeks to create, post infection. During 2022, the FDA granted Breakthrough Device Designation for the T2Lyme Panel, allowing for a prioritized review process upon submission to the

FDA, and we received a patent from the U.S. Patent and Trademark Office covering the T2Lyme Panel. In addition, we announced that the T2Lyme Panel was a winner in the Lyme Innovation accelerator, also known as 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 that includes up to $10 million in funding. Our plan is commence commercialization of the T2Lyme Panel as a Laboratory Developed Test and subsequently commence a U.S. clinical trial to support submission for FDA clearance.

Candida auris is a direct-from-blood molecular diagnostic test that we plan to add to the T2Candida Panel, to expand the number of pathogens detected on the test panel. *Candida auris* is a multidrug-resistant pathogen recognized by the CDC as a serious global health threat. According to CDC, *Candida auris* is difficult to identify with standard laboratory methods, which can lead to inappropriate treatment, and some strains are resistant to all three available classes of antifungals. We believe adding *Candida auris* to our existing T2Candida Panel will provide a significant time advantage compared to other blood culture-based methods.

Acinetobacter *baumannii* is a direct-from-blood molecular diagnostic test that we plan to add to the T2Bacteria Panel, to expand the number of pathogens detected on the test panel. Acinetobacter *baumannii* can cause bloodstream infections, especially in critically ill patients, which can range from benign transient bacteremia to septic shock, and has been reported to have a crude ICU mortality rate of 34% to 43%. Acinetobacter infections rarely occur outside of health care settings in the United States and can disproportionately impact those with weakened immune systems, chronic lung disease or diabetes. Acinetobacter can be resistant to many antibiotics, including carbapenems, highlighting the importance of rapid detection and targeted antimicrobial treatment.

Longer-term, we are developing our next-generation sepsis products, including a new instrument and a comprehensive sepsis test panel. The next-generation instrument is designed to be fully automated and random access, similar to our T2Dx Instrument, but

incorporates faster turnaround times and the ability to detect an increased number of targets from a single, whole blood sample. The comprehensive sepsis test panel is a direct-from-blood test designed to detect >95% of all bloodstream infections caused by bacterial and *Candida* species, and antibiotic resistance genes identified as threats by the CDC, in a single test with a time to result of approximately three hours. The next-generation instrument and comprehensive sepsis test panel have been funded under our contract with BARDA.

We are currently operating in Option 3 of the BARDA contract, having successfully met all development milestones under the Base Phase, Option 1, Option 2A, and Option 2B. We anticipate filing a no-cost extension with BARDA, under Option 3, to allow time for the completion of the T2Resistance U.S. clinical trial. Further funding from BARDA may resume following the completion of Option 3 and BARDA's exercise of Option 4. Given the uncertain timing, we are not providing guidance on 2023 BARDA revenue at this time.

With that, I will now turn the call over to John Sprague to provide a detailed update of our fourth quarter financial results and our financial outlook for 2023.

John Sprague

Thank you, John.

Total revenue for the fourth quarter of 2022 was $5.5 million, a decrease of 21% compared to the prior year period. Product revenue was $2.2 million, a decrease of 45% compared to the prior year period, driven by the expected 89% decline in COVID-19 test sales and partially offset by increased sepsis test sales. Research contribution revenues were $3.3 million, an increase of 10% compared to the prior year period, driven by the timing of enrollments in the T2Resistance clinical trial.

Product costs for the fourth quarter of 2022 were $3.8 million, a decrease of 30% compared to the prior year period, driven by decreased COVID-19 test sales. Research

and development expenses were $4.9 million, a 9% decrease compared to the prior year period, driven by decreased development expenses during the clinical trial phases of the BARDA contract. Selling, general and administrative expenses were $6.7 million, an increase of 2% compared to the prior year period driven by increased selling activity.

Net loss for the fourth quarter of 2022 was $10.4 million, $1.41 per share, compared to a net loss of $12.1 million, $3.65 per share for the prior year period.

Cash, equivalents and restricted cash were $11.9 million as of December 31, 2022. We raised $2.2 million through ATM sales in the fourth quarter of 2022 and in February 2023, we raised $12.0 million through a common stock and warrants sale. 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.

For guidance, we expect 2023 total sepsis and related product revenue of $11.0 million to $13.0 million, representing growth of 31% to 55%, compared to $8.4 million in 2022. Given our focus on product revenue, we are not providing guidance on research and contribution revenue.

Thank you and back to John Sperzel for closing remarks.

John Sperzel

Thank you, John.

In 2022, T2 Biosystems achieved record full year sepsis and related product revenue globally, record fourth quarter sepsis test revenue in the U.S., and record full year sepsis-driven T2Dx Instrument contracts. We are pleased with our growing commercial momentum in the market. Operationally, we have taken steps to reduce product costs and operating expenses, which we believe put us on a path to improved profitability and reduced cash burn. Our product pipeline is advancing through progress with our clinical

trials in the U.S. for the T2 Resistance Panel and with the completion of the T2 Biothreat Panel trial. Additionally, we received FDA Breakthrough Device Designation and the LymeX Award for our T2Lyme Panel. As we look ahead to 2023, we are well positioned to continue to advance our three corporate priorities including 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?