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 24, 2020

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 February 24, 2020, T2 Biosystems, Inc. (the "Company") issued a press release announcing its financial results for its fiscal quarter and year ended December 31, 2019 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 February 24, 2020
99.2	Transcript of conference call held on February 24, 2020

SIGNATURES

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

T2 BIOSYSTEMS, INC.

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

Date: February 27, 2020

Exhibit 99.1

T2 Biosystems Announces Fourth Quarter and Full Year 2019 Financial Results

LEXINGTON, Mass., February 24, 2020 (GLOBE NEWSWIRE)—T2 Biosystems, Inc. (NASDAQ:TTOO), a leader in the rapid detection of sepsis-causing pathogens, today announced financial results for the fourth quarter and full year ended December 31, 2019.

Fourth Quarter and Recent Business and Financial Performance Highlights

- Achieved fourth quarter total revenue of $3.1 million and product revenue of $1.6 million, representing increases of 71% and 18% respectively, compared to the prior year period
- Received CE mark for the T2Resistance Panel, allowing commercialization throughout the European Union and other CE mark geographies
- Secured new contracts for ten T2Dx Instruments during the fourth quarter of 2019
- Appointed John Sperzel as Chief Executive Officer and Tony Pare as Chief Commercial Officer

Full Year 2019 Business and Financial Performance Highlights

- Awarded a contract for up to $69 million in milestone-based product development funding from a U.S. government agency; one of the largest grants ever awarded to a diagnostics company
- Received a New Technology Add-on Payment (NTAP) for the T2Bacteria Panel from the Centers for Medicare and Medicaid Services (CMS); the first in-vitro diagnostic test with this designation
- Received Breakthrough Device designation from the U.S. Food and Drug Administration (FDA) for T2Resistance Panel, which is now available for research use only (RUO) in the U.S. market
- Signed Breakthrough Technology contract with Premier, Inc., a group purchasing organization, providing access and contracted pricing to approximately 4,000 U.S. hospitals
- Restructured the CRG Term Loan Agreement, extending the interest-only payment period through December 2021 and reducing minimum revenue targets
- Expanded commercial distribution to include thirty-six countries

“The T2 Biosystems team achieved a number of important clinical and operational milestones in 2019,” said John Sperzel, President and CEO of T2 Biosystems. “According to recent data, sepsis is responsible for the death of nearly 11 million people annually, more than all cancers combined. In the battle against sepsis, speed is critical to achieving targeted therapy. T2 Biosystems has the only FDA cleared system for detecting sepsis-causing pathogens directly from blood, without the need to wait days for a positive culture. I believe we have an opportunity to save lives by becoming the standard of care in the detection of sepsis-causing pathogens, and drive long-term sustained growth.”

Fourth Quarter 2019 Financial Results

Total revenue for the fourth quarter of 2019 was $3.1 million, an increase of 71% compared to the prior year period. Product revenue for the fourth quarter of 2019 was $1.6 million, an increase of 18% compared to the prior year period. Research revenue for the fourth quarter of 2019 was $1.5 million, an increase of 200% compared to the prior year period.

Operating expenses for the fourth quarter of 2019 were $11.9 million, an increase of $2.2 million compared to the prior year period.

Net loss for the fourth quarter of 2019 was $14.1 million or a loss of $0.30 per share, compared to a net loss of $15.1 million or a loss of $0.34 per share in the prior year period.

Full Year 2019 Financial Results

Total revenue for 2019 was $8.3 million, a decrease of 21%, compared to the prior year period. Product revenue for 2019 was $5.3 million, an increase of 11% compared to the prior year period. Research revenue for 2019 was $3.0 million, a decrease of 47% compared to the prior year period.

Operating expenses for 2019 were $43.6 million, an increase of 8% compared to the prior year period.

Net loss for 2019 was $59.0 million or a loss of $1.30 per share, compared to a net loss of $51.2 million or a loss of $1.26 per share in 2018.

Cash and equivalents as of December 31, 2019 were $11.0 million. This includes $4.8 million in net proceeds from the sale of 3.8 million shares through the ATM facility during the fourth quarter of 2019.

2020 Financial Outlook

Management projects revenue for the full year 2020 to range from $14.0 million to $17.0 million, including product revenue between $8.0 million and $10.0 million and research and grant contribution revenue of $6.0 million to $7.0 million. Management expects to close approximately 30 T2Dx Instrument contracts during 2020.

Webcast and Conference Call Information

T2's management team will host a conference call today, February 24, 2020, beginning at 4:30pm ET. Investors interested in listening to the call may do so by dialing 1-877-407-9208 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, the T2Bacteria® Panel, and the T2Resistance™ Panel and are powered by the proprietary T2 Magnetic Resonance (T2MR®) technology. T2 Biosystems has an active pipeline of future products, including products for the detection of additional species and antibiotic resistance markers of sepsis pathogens, and tests for Lyme disease.

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

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 11,033	$ 50,805
Accounts receivable	2,825	1,786
Prepaid expenses and other current assets	1,438	1,340
Inventories	3,599	2,677
Total current assets	18,895	56,608
Property and equipment, net	5,845	7,315
Operating lease right-of-use assets	3,360	—
Restricted cash	180	180
Other assets	206	206
Total assets	$ 28,486	$ 64,309
Liabilities and stockholders' equity		
Current liabilities:		
Notes payable	$ 42,902	$ 42,373
Accounts payable	3,753	744
Accrued expenses and other current liabilities	11,207	6,073
Derivative liability	2,425	2,142
Deferred revenue	285	697
Current portion of lease incentives	—	268
Total current liabilities	60,572	52,297
Lease incentives, net of current portion	—	492
Operating lease liabilities, net of current portion	1,873	—
Deferred revenue, net of current portion	46	133
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized; 50,651,535 and 44,175,441 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	49	44
Additional paid-in capital	342,123	328,514
Accumulated deficit	(376,177)	(317,171)
Total stockholders' equity	(34,005)	11,387
Total liabilities and stockholders' equity	$ 28,486	$ 64,309

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

	Year ended December 31,		
	2019	**2018**	**2017**
Revenue:			
Product revenue	$ 5,327	$ 4,805	$ 3,440
Research revenue	563	5,695	1,226
Contribution revenue	2,445	—	—
Total revenue	8,335	10,500	4,666
Costs and expenses:			
Cost of product revenue	16,763	15,404	12,028
Research and development	16,326	14,489	23,733
Selling, general and administrative	27,304	25,697	22,757
Total costs and expenses	60,393	55,590	58,518
Loss from operations	(52,058)	(45,090)	(53,852)
Interest expense, net	(7,348)	(6,682)	(8,907)
Other income, net	400	619	331
Net loss and comprehensive loss	(59,006)	(51,153)	(62,428)
Net loss per share — basic and diluted	$ (1.30)	$ (1.26)	$ (1.94)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	45,507,754	40,558,826	32,131,512

Philip Taylor

Thank you, operator. Thanks for joining us for the T2 Biosystems' Fourth Quarter and Full year 2019 Financial Results Conference Call.

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 March 14, 2019 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'd like to turn the call over to President and CEO, John Sperzel. John?

John Sperzel

Thank you for joining us today. This is my first earnings call since being named T2 Biosystems' Chief Executive Officer last month and I am passionate about our goal to change the standard of care in the identification of sepsis-causing pathogens.

To me, this goal is also personal. In 2017, I was diagnosed with a very rare disorder, spent two months in a cardiac surgical intensive care unit at a leading U.S. hospital, and ultimately received a life-saving heart transplant. While in the hospital, I became infected with *Pseudomonas aeruginosa*, a multidrug-resistant bacteria infection that can lead to sepsis, and death if not treated appropriately. While I was fortunate, the statistics on sepsis-causing pathogens and sepsis mortality are staggering. Patients deserve better. At T2 Biosystems, we deliver life-saving innovations to achieve targeted therapy, faster.

For those who have followed T2 Biosystems, I trust you agree that the company has successfully created a highly-differentiated product offering. In fact, where several diagnostic companies failed, T2 Biosystems has successfully developed the only FDA-cleared products to identify sepsis-causing pathogens directly from blood, without the need to wait days for a positive blood culture. This advancement is truly groundbreaking and we will continue to build on our technological superiority. However, the company has not yet succeeded in two important areas: sales execution and cost reduction. Under my leadership, we are immediately addressing these historical weaknesses.

On today's call, I will briefly highlight the company's achievements in 2019, provide an overview of our market opportunity, and share our corporate priorities and outlook for 2020. I will then turn the call over to John Sprague, who will discuss the detailed financial results for the quarter, before I conclude and we open the call for questions and answers.

In 2019, T2 Biosystems generated product revenue of $5.3 million, representing growth of 11% compared to the prior year. The company achieved a number of key milestones that we believe will facilitate greater adoption of our life-saving technology, including the following:

- The T2Bacteria Panel received a New Technology Add-on Payment, or NTAP, from the U.S. Centers for Medicare & Medicaid Services
- T2 Biosystems received a contract award for up to $69 million in milestone-based product development funding from a U.S. Government agency
- The T2Resistance Panel received Breakthrough Device designation from the U.S. Food and Drug Administration (FDA), and
- T2 Biosystems received a Breakthrough Technology contract from Premier, a major U.S. group purchasing organization, providing access to nearly 4,000 U.S. hospitals

Sepsis is a serious global health issue. Last month a study was published in *The Lancet*, a renowned, peer-reviewed medical journal, which concluded that sepsis is significantly more prevalent and lethal than previously thought. The study found that sepsis contributes to one in five hospital deaths globally, and that approximately 11 million people worldwide die from sepsis each year — that's more deaths than all forms of cancer combined. In the United States, sepsis represents nearly $41 billion in healthcare costs and is the most common cause of in-hospital deaths, killing nearly 270,000 people in the U.S. each year. I believe we have an opportunity to change the paradigm in the treatment of sepsis.

Current sepsis treatment protocols rely on empiric, probability-based therapy. A key component of these protocols includes the use of empiric, broad-spectrum antibiotics to cast a wide net in an attempt to treat the most common infections. Identifying and treating sepsis successfully is a race against time, as each hour of delayed targeted treatment increases mortality risk by up to 8%. Not only does rapid detection enable faster targeted antibiotic therapy, it may also reduce unnecessary rounds of exposure to broad-spectrum antibiotics, helping to prevent and combat further growth in antimicrobial resistance.

The T2Dx Instrument platform includes the only FDA-cleared diagnostic panels to rapidly and accurately identify bacterial and fungal pathogens that cause sepsis, directly from a whole blood specimen. The T2Candida, T2Bacteria, and T2Resistance Panels provide species identification and resistance marker detection results in 3 to 5 hours, without the need to wait for a positive blood culture. Alternative pathogen detection systems, such as those offered by Accelerate Diagnostics, BioFire Diagnostics, Cepheid, GenMark Diagnostics, and Luminex, first require positive growth from a blood culture specimen, which can take one to five days.

The need for improved sepsis management is well understood and we believe that our technology provides the best diagnostic tool for healthcare providers to identify sepsis-causing pathogens and target therapy, faster. With a leading technology as our foundation, we have a straightforward plan to address our performance issues and define T2's path forward. We have a lot of work to do and we will move with urgency, focusing on three priorities: 1) accelerating our sales, 2) improving our operations, and 3) advancing our pipeline.

Starting with our first priority, accelerating our sales:

We are making significant changes in our commercial game plan to improve sales execution. In January, we appointed industry veteran Tony Pare as Chief Commercial Officer, and he leads all commercial functions. One team with one mission: to accelerate sales.

Under Tony's leadership, we will focus 80% of our direct commercial resources on the U.S. market. We will change our hospital targeting to focus on departments with high-risk patients, like oncology, transplant, and intensive care. We will focus more on adoption of our technology and increasing the utilization of our tests, as these are better metrics for our business, and less on the number of instruments we sell or place in a given quarter. We will expand our messaging within the hospital to place greater emphasis on clinicians, as they are essential to integrate T2 testing into the sepsis protocols, which will drive adoption and increase test utilization.

We will continue to expand access to hospital accounts through group purchasing organization agreements in the U.S. market. As previously mentioned, we gained access to nearly 4,000 U.S. hospitals through a Breakthrough Technology contract from Premier during 2019. To further expand access and contracted pricing to U.S. hospitals, we are in discussion with other group purchasing organizations and anticipate adding new contracts in 2020.

Previous commercial plans, and sales incentive plans, were focused on instrument placements, resulting in an installed base of T2Dx Instruments with low test utilization. At the end of 2019, our worldwide "active" installed base of T2Dx Instruments was 91, of which 40 were in the U.S. market. The test utilization among the active T2Dx Instrument installed base in the U.S. market was approximately $50,000 annually, which we aim to increase to approximately $100,000 by the end of 2020. Our top customers have achieved annual test utilization exceeding $200,000 per instrument, which is our long-term target. To support this test utilization target, we have aligned our U.S. sales strategy and sales incentive plans to emphasize adoption and test utilization.

Outside the U.S., we will maintain a small team to support a network of commercial distribution partners. We believe there are opportunities to strengthen our international business by partnering with one or more strategic commercial distributors. We are in discussion with several potential partners and anticipate entering into the first such agreement during the first half of 2020.

Given my commercial experience, I will be personally involved in our sales and marketing effort and expect to support our team in targeting and closing key partnerships.

Moving to our second priority, improving our operations:

To achieve short and long-term success, our cost structure must not only reflect our aspirations, but must also be grounded in today's reality. We must make smart investments in the areas that best support our strategy, while applying greater discipline to reduce spending and how we manage expenses in all other areas.

In 2019, T2 Biosystems incurred annual operating expenses of $43.6 million and cost of product revenue of $16.8 million. These figures do not reflect the size and scope of our current business and must be reduced.

We will aggressively attack our cost structure, including operating expenses and cost of product revenue, and we anticipate significant change during 2020. We plan to be bold in reducing our cost structure, and believe T2 Biosystems will be a stronger company as a result.

Moving to our third priority, advancing our pipeline:

Earlier, I mentioned our intent to build on our technological superiority. In 2020, we are focused on advancing programs funded by the $69 million milestone-based government contract awarded in September 2019, including a next generation instrument and expanded panel, and a novel biothreat panel, while also maintaining focus on expanding our current portfolio offering with the T2Resistance Panel.

Our T2Resistance Panel, which detects 13 antibiotic resistance genes in gram-positive and gram-negative pathogens, recently received CE mark and is available in the U.S. as a research-use-only test. Multiple sites are currently conducting studies on T2Resistance, and we are in dialogue with the FDA regarding the design of a pivotal study to secure FDA approval.

We are excited about the next generation instrument and comprehensive panel, designed to cover greater than 99% of all bloodborne bacterial infections including pan-gram positive and pan-gram negative results for greater than 250 species, in addition to all bloodborne antibiotic resistant threats identified by the Centers for Disease Control and Prevention. This would be another transformative development in the management of sepsis, with the potential to replace most blood cultures performed for species identification and susceptibility results.

Going beyond sepsis, but also under the government contract, we are developing a novel biothreat panel. This is expected to be the first ever, ultra-high sensitivity, direct-from-blood panel for the detection of multiple biothreat pathogens and toxin genes.

Now I’ll turn the call over to John Sprague for an update on our fourth quarter financial results and additional details on our 2020 guidance.

John Sprague

Thank you, John. Total revenues for the fourth quarter 2019 were $3.1 million, an increase of 71% compared to the prior year period.

Product revenues for the fourth quarter of 2019 were $1.6 million, an increase of 18% compared to the prior year period. Growing test panel and instrument sales are driving the increase in product revenues. The company signed contracts for 10 new T2Dx Instruments during the fourth quarter, bringing the total to 45 new T2Dx Instruments for the full year.

Research and grant contribution revenues for the fourth quarter of 2019 were $1.5 million, an increase of 200% compared to the prior year period.

Costs and expenses during the fourth quarter of 2019 were $15.5 million, flat compared to the prior year period. Cost of product revenues were $3.6 million compared to $5.6 million in last year's fourth quarter and decreased due to lower overhead spending. Research and development expenses were $4.3 million compared to $3.3 million in last year's fourth quarter and include expenses incurred under the government contract of $2.4 million in the fourth quarter of 2019. Selling, general and administrative expenses were $7.6 million compared to $6.5 million in last year's fourth quarter and include one-time expenses related to the CEO transition of approximately $1.0 million.

Net loss was $14.1 million, ($0.30) per share, compared to a net loss in last year's fourth quarter of $15.1 million, ($0.34) per share. Weighted average shares outstanding were 47.9 million compared to 44.1 million in last year's fourth quarter.

Our cash and cash equivalents were $11.0 million at December 31, 2019. We sold 3.8 million shares for $4.8 million in net proceeds through our ATM facility in the fourth quarter and no shares under the equity credit line. We are currently compliant with the terms of our CRG debt facility and we expect we will continue to comply in future periods. Stock option exercises and shares sold under the ATM and equity credit line may affect weighted average shares outstanding.

Guidance for the full year 2020 is as follows:

We expect full year 2020 total revenues of $14.0 million to $17.0 million, including product revenues of $8.0 million to $10.0 million and research and grant contribution revenues of $6.0 million to $7.0 million. We expect approximately 40% of revenue to be in the first half of the year, with the remaining 60% in the second half of the year.

We expect to close 30 T2Dx Instrument placement contracts in 2020, aligning with our focus on driving test utilization in the current installed base along with new strategic customer placements.

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

John Sperzel

During my first week as T2's CEO, I met with as many people as possible. What I found were talented, passionate people who are ready to fight – and ready to win. The team understands that we must do things differently and they are committed to change.

As I stated in my opening remarks, we are building our game plan around three priorities: accelerating our sales, improving our operations, and advancing our pipeline.

We look forward to providing updates on our progress toward these priorities throughout the year. We will now open it up to questions. Operator?