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 7, 2019

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))

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 7, 2019, T2 Biosystems, Inc. (the "Company") issued a press release announcing its financial results for its fiscal quarter and year ended December 31, 2018 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 7, 2019
99.2	Transcript of conference call held by T2 Biosystems, Inc. on March 7, 2019

EXHIBIT INDEX

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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 13, 2019

T2 BIOSYSTEMS, INC.

By: /s/ John McDonough
John McDonough
CEO & President

Exhibit 99.1

T2 Biosystems Reports Fourth Quarter and Full Year 2018 Financial Results and Provides Corporate Update

Secured 14 New Instrument Contracts in the Fourth Quarter and 39 total New Instrument Contracts in 2018 that are expected to drive growth in Recurring Test Revenue

Confirms Guidance of a Doubling of Revenue in 2019; Provides Guidance of Securing 70 – 80 T2Dx Instruments Contracts in 2019

LEXINGTON, Mass., March 7, 2019 (GLOBE NEWSWIRE) — T2 Biosystems, Inc. (NASDAQ:TTOO), a leader in the development and commercialization of innovative medical diagnostic products for critical unmet needs in healthcare, announced today the operating highlights and financial results for the fourth quarter and year ended December 31, 2018.

Fourth Quarter and Recent Business and Financial Performance Highlights:

- Reported fourth quarter total revenue of $1.8 million, up 6% year-over-year.
- Reported fourth quarter product revenue of $1.3 million reflecting increased testing volume and stable capital sales as more new customers selected the reagent rental model.
- Secured a record 14 new contracts of T2Dx® Instruments in the fourth quarter, which was at the high end of 2H18 guidance.
- Increased targeted high-risk patients at newly contracted hospitals by over 80,000.
- In February, ranked in top ten of Fast Company's 2019 Most Innovative Companies, Biotech Sector.

Full Year Business and Financial Performance Highlights:

- Reported full year total revenue of $10.5 million, up 123% year-over-year.
- Reported full year product revenue of $4.8 million, up 41% year-over-year.
- Launched the T2Bacteria Panel, the flagship product in the T2Direct Diagnostics Portfolio™, following U.S. FDA clearance in May 2018.
- Secured 39 new contracts of T2Dx® Instruments for the full year, with 25 contracts in 2H18 following the T2Bacteria Panel FDA clearance.
- Increased targeted high-risk patients at contracted hospitals by 250,000.
- Closed equity financing raising $52.6 million in gross proceeds to support commercialization of the T2Direct Diagnostics™ product portfolio, including the ongoing launch of the T2Bacteria Panel.

"2018 was a year of major achievements for the Company highlighted by the FDA clearance of the T2Bacteria Panel, which has driven record levels of new interest from hospitals and allowed us to accelerate the growth of our installed base," said John McDonough, president and chief executive officer. "In the fourth quarter we secured a record 14 new system contracts, contributing to 25 secured in the second half of the year, which came in at the top of our expectations. The earliest of these new T2Bacteria Panel customers have now completed the installation, validation and training processes and are beginning to test patients. Concurrently, we anticipate the body of clinical evidence supporting T2Bacteria Panel will grow this year, along with the sharing of best practices and experience between hospitals. We expect this steady increase of T2Bacteria Panel activity to drive greater recurring revenue through 2019, and along with growing system contracts, will contribute to achieving our revenue growth guidance for 2019 and a doubling of revenue again in 2020."

Mr. McDonough added, “In 2019 we expect to further expand our market opportunity with the T2Resistance Panel, which we expect to launch as a research-use only product in the U.S. and anticipate receiving a CE mark for commercial launch in Europe by the end of 2019. On the development front, we plan to collect data for our pivotal study for the T2Lyme Panel and are encouraged by pre-clinical data that shows the potential to improve patient outcomes.”

Additional Financial Results:

- Research revenues were $0.5 million in the fourth quarter, up 67% compared to $0.3 million in last year’s fourth quarter. Research revenues were $5.7 million in the full year, up 375% compared to $1.2 million last year.
- Costs and expenses in the fourth quarter, excluding cost of product revenue, were $9.8 million, compared to last year’s fourth quarter costs and expenses of $9.7 million. Total costs and expenses include depreciation and non-cash stock compensation from stock options and performance-based restricted stock grants (RSUs) of $3.0 million compared to $1.8 million in last year’s fourth quarter, an increase primarily due to the vesting of RSUs. Costs and expenses in the full year, excluding cost of product revenue, were $40.2 million, a 14% decrease over last year’s costs and expenses of $46.5 million. Total costs and expenses include depreciation and non-cash stock compensation from stock options and performance-based restricted stock grants (RSUs) of $12.3 million compared to $7.8 million in last year, an increase primarily due to the vesting of RSUs.
- Operating margins in the fourth quarter were a loss of $13.6 million, a 6% decrease over last year’s fourth quarter operating margin loss of $14.4 million. Operating margins in full year were a loss of $45.1 million, a 16% decrease over last year’s operating margin loss of $53.9 million.

Weighted average shares outstanding were 44.1 million for the fourth quarter and 40.6 million for the full year, compared to 35.7 million and 32.1 million in the same periods last year.

Guidance:

The company is providing the following full year 2019 financial guidance:

- Total revenue is expected to double in 2019 compared to $10.5 million in 2018. First quarter 2019 revenue is expected to be in the range of $1.3 million to $1.5 million, reflecting continuing adoption of T2Bacteria and T2Candida Panel test sales and expanding T2Dx® Instruments reagent rentals and sales in the U.S. and internationally.
- The company expects to secure contracts of 70 to 80 T2Dx® Instruments in 2019, including 8 to 10 contracts in the first quarter 2019, which follows the historical seasonal pattern of contracts in the fourth quarter being greater than the first quarter.
- Operating expenses, excluding cost of product revenue, are expected to be $10.5 million to $11.5 million in the first quarter 2019. Total costs and expenses will include non-cash depreciation and stock based compensation expenses from stock options and RSUs of approximately $3.0 million.

Conference Call

Management will host a conference call today with the investment community at 4:30 p.m. Eastern Time to discuss the financial results and other business developments. Interested parties may access the live call via telephone by dialing 1-877-407-9208 (U.S.) or 1-201-493-6784 (International). To listen to the live call via T2 Biosystems' website, go to www.t2biosystems.com, in the Investors/Events & Presentations section. A webcast replay of the call will be available following the conclusion of the call, also in the Investors/Events & Presentations section of the website.

About T2 Biosystems:

T2 Biosystems, a leader in the development and commercialization of innovative medical diagnostic products for critical unmet needs in healthcare, 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, and T2Bacteria® 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.

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 additional patients, timing of testing patients, anticipated product benefits, strategic priorities, product expansion or opportunities, growth expectations or targets, timing of FDA filings or clearances and anticipated operating expenses, 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, 2017, filed with the U.S. Securities and Exchange Commission, or SEC, on March 19, 2018, 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 Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Year ended December 31,		
	2018	2017	2016
Revenue:			
Product revenue	$ 4,805	$ 3,440	$ 1,747
Research revenue	5,695	1,226	2,333
Total revenue	10,500	4,666	4,080
Costs and expenses:			
Cost of product revenue	15,404	12,028	6,872
Research and development	14,489	23,733	24,009
Selling, general and administrative	25,697	22,757	24,077
Total costs and expenses	55,590	58,518	54,958
Loss from operations	(45,090)	(53,852)	(50,878)
Interest expense, net	(6,682)	(8,907)	(4,098)
Other income, net	619	331	172
Net loss and comprehensive loss	(51,153)	(62,428)	(54,804)
Net loss per share — basic and diluted	$ (1.26)	$ (1.94)	$ (2.11)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	40,558,826	32,131,512	26,015,751

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

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 50,805	$ 41,799
Accounts receivable	1,786	467
Prepaid expenses and other current assets	1,340	708
Inventories	2,677	1,344
Total current assets	56,608	44,318
Property and equipment, net	7,315	10,015
Restricted cash	180	260
Other assets	206	268
Total assets	$ 64,309	$ 54,861
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 744	$ 648
Accrued expenses and other current liabilities	6,073	6,218
Derivative liability	2,142	2,238
Notes payable	42,373	40,696
Deferred revenue	697	1,736
Current portion of lease incentives	268	246
Total current liabilities	52,297	51,782
Notes payable, net of current portion	—	1,008
Lease incentives, net of current portion	492	731
Deferred revenue, net of current portion	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; 44,175,441 and 35,948,900 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	44	36
Additional paid-in capital	328,514	267,421
Accumulated deficit	(317,171)	(266,117)
Total stockholders' equity	11,387	1,340
Total liabilities and stockholders' equity	$ 64,309	$ 54,861

Fourth Quarter and Full Year 2018 Financial Results and Business Update Conference Call Script

John McDonough – CEO Commentary

John Sprague – CFO Commentary

Zack Kubow (W2O) - Moderator

March 7, 2019 – 4:30 pm ET

Leader Dial-In Number: 1-877-808-1531
Conference ID: 13687886

Operator:

Good afternoon, ladies and gentlemen. Thank you for standing by, and welcome to the T2 Biosystems fourth quarter and full year 2018 financial results conference call. At this time, all participants are in a listen-only mode. Later, we will conduct a question and answer session and instructions will follow at that time. It is now my pleasure to turn the call over to Zack Kubow, of the W2O Group.

Please go ahead, sir.

Zack Kubow

Thank you, operator, and good afternoon everyone. Thanks for joining us for the T2 Biosystems fourth quarter and full year 2018 financial results conference call. On the call to discuss the results and operational highlights for the quarter and year ended December 31, 2018, are President and CEO, John McDonough, and Chief Financial Officer, John Sprague. The executive team will open the call with some prepared remarks, followed by a question-and-answer period.

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 those statements, including the risks and uncertainties described in T2 Biosystems' Annual Report on Form 10-K filed with the SEC on March 19, 2018 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 McDonough. John?

John McDonough:

Thank you, Zack. Good afternoon, everyone, and thank you for joining us as we discuss the progress, results and outlook following the fourth quarter and full year 2018.

2018 was a significant year for T2, headlined by the FDA clearance and market launch of the T2Bacteria Panel, the first and only FDA cleared test to identify sepsis-causing bacteria direct from whole blood. Combined with the T2Candida Panel, we now offer a tool to hospitals that we believe will enable earlier, more effective therapy for patients suspected of blood stream infections that can lead to sepsis.

The ability to identify deadly forms of bacterial and fungal infections directly from whole blood without waiting for the results of a blood culture has been a significant pursuit in medicine for the past century. Additionally, we believe that while pharmaceutical companies have developed more effective means to fight these infections, their utilization has been hampered by the inability to rapidly identify the actual infection. We believe that the medical community and government agencies are now recognizing the difference that T2Direct Diagnostics can mean for preventing sepsis, which is the number one cause of mortality in hospitals and the cause of over $27 billion in hospitalization costs, the most expensive health condition for U.S. hospitals. Before T2Direct Diagnostics, frontline treatment options for patients suspected of sepsis identified pathogens in 1 to 6 days' time with a 50 to 65 percent sensitivity rate – which every single other company offering an FDA cleared product for bloodstream infections is dependent upon. Due to the lengthy time to result and poor sensitivity of blood cultures, hospitals have used a probability-based system based on the premise that if you can guess right quickly enough, mortality rates are reduced by 8 percent for every hour you speed up getting a patient suffering from sepsis on the right targeted drug. With T2Direct Diagnostics, certain pathogens are identified in 3 to 5 hours directly from a patient's blood sample with greater than 90 percent accuracy, which we believe is a huge step forward and a win for patients and the health care system. As I will discuss in more detail, we believe that hospitals with strong antimicrobial stewardship efforts, dedicated to the task and guided by our experience, are becoming the vanguard of physicians and institutions that have found a better option with the 150 dollar T2Bacteria test panel. Results have shown that only one T2 test result can be as accurate as 3.8 blood culture sets – which are required for all other diagnostics of bloodstream infections. We believe that the time has arrived where antibiotic treatment decisions early in the progression of disease can be based on identification of the actual pathogen infecting the patient rather than on guesswork. And while systemic change is cautious in the hospital setting, we believe that the data is beginning to show that a willingness to adjust protocols provides measurable clinical and economic benefits. In addition, we believe there is an opportunity within our selling process and target institutions to identify and engage a customer segment that has shown the willingness to adopt and move fast, which we will discuss on the call today.

During 2018 we also advanced our other new product initiatives, which have the potential to further expand our market opportunity for our core T2Dx platform. Taken together, we believe that our progress in 2018 has positioned the Company to enter a period of sustained and significant growth in the years to come.

I will provide an overview of our key growth initiatives and milestones for 2019, but will begin with a high-level review of the financial results and commercial metrics for the quarter, which provide the foundation for our business outlook heading into the year. After my remarks, our CFO John Sprague will provide a detailed review of our fourth quarter and full year financial results and outline our 2019 financial guidance.

In the fourth quarter, we remained focused on the execution of the T2Bacteria Panel launch and delivered results that were in-line with our expectations. Total revenues were 1.8 million dollars and product revenue was 1.3 million dollars. Product revenue was flat year-over-year and up slightly compared to Q3 2018, reflecting growth in testing volume primarily related to the T2Candida Panel. Capital sales were stable as more new customers selected the reagent rental model in the quarter, which has minimal upfront customer costs and therefore minimal revenue for T2, but stronger margins on recurring sales. As a reminder, new placements related to the T2Bacteria Panel in the second half of 2018 were in the implementation phase in Q4 and we expect these systems to begin to contribute recurring testing revenue this year, and some have already begun to do so in Q1 2019.

More specifically on T2Dx Instruments, we continued to build momentum with new contracts, securing 14 contracts with customers in Q4. This contract number puts us at the high end of guidance previously provided. In total, we estimate that this will provide over 80,000 new high-risk patients with access to a T2Dx Instrument, well ahead of previous guidance. On a full year basis, we secured 39 new T2Dx Instrument contracts covering more than 250,000 high-risk patients, including 25 contracts in the second half of the year.

To put this in context, as of December 31, 2018 we had 89 instruments placed or contracted to be placed, with nearly all of the associated recurring revenue coming from T2Candida Panel utilization. As we enter 2019, we expect the new contracts from the second half of 2018 to complete the 3 to 6 month validation and startup phase and begin testing patients, which will begin to layer on meaningful T2Bacteria Panel sales. Overall, we ended the year right where we expected to be with the launch of the T2 Bacteria Panel, we have a strong sales pipeline of opportunities for the T2Bacteria Panel entering 2019, and we remain confident in the long-term opportunity for T2Direct Diagnostics. John will provide full detail on our guidance, but in short we expect to approximately double our total revenue in 2019 and deliver 70 to 80 new instrument contracts, consistent with prior guidance.

Turning to an update on the T2Bacteria Panel launch, we have recently reviewed our sales and marketing progress, and while we have hit the projected number of contracts, we believe there is growing interest and demand. Based on this analysis, we have altered our strategy from the first 6 months of the T2Bacteria Panel launch due to identifying several encouraging data points that we are integrating into our key initiatives to drive the T2Bacteria Panel launch in 2019.

1) We are encouraged with the feedback from the market and are executing against a robust pipeline of interested hospitals and hospital targets. We delivered 24 new proposals in the fourth quarter, up from 15 in Q3 and continued the strong trend we saw leading into and following the FDA clearance of T2Bacteria. Moving into 2019, we will no longer provide the proposal number for each quarter, as our focus and the results of our activity will shift to securing new contracts and driving utilization.

2) In terms of new contracts, when we analyzed our new customer wins from the second half of 2019, we were encouraged by the data. Every new account in the United States that closed in the second half of the year had a 30 to 90 day sales cycle, which is much faster than our expected average of 6 to 12 months and also faster than anything we saw following the launch of the T2Candida Panel. We believe that the accounts that close quickly typically have active stewardship efforts that are clearly focused on improving sepsis management patient care. Said differently, we believe that a more educated buyer is our best customer and the sales process moves fast with such buyers because they appear to see the potential of our products.

   These faster closing accounts in the second half of 2019 were balanced with a number of potential T2Bacteria Panel customers that are trending towards the more traditional 6 to 12 month sales cycle range and that we will focus on closing in 2019. Given the potential of a rapid sales cycle, starting in Q1 2019 our sales reps are dedicating more time to broad outreach to hospitals in their territories in order to engage with additional accounts that could fall into this category, while also advancing existing, more traditional opportunities. In January, the sales team secured first meetings with over 250 hospitals with whom we were not previously engaged that have expressed interest in one of our solutions. We believe this may accelerate the new account close rate of our sales force, which includes 16 representatives in the United States, and ensure that we maintain a broad pipeline of opportunities.

3) In terms of utilization, we have received positive feedback on the service provided by our team of medical liaisons. This team is led by Sandy Estrada, who implemented the T2Candida Panel at Lee Memorial Health System in Florida, one of our flagship accounts. They are working directly with the sales team in the sales process to ensure the value of testing patients is understood by new customers and to support the validation and start up process by sharing best practices and strategies to maximize the benefit of the T2Dx Instruments for their patients. The first T2Bacteria Panel customers signed in 2018 are starting commercial activity in Q1 2019, and as more accounts go live over the course of the year we believe our medical liaisons will increase customer satisfaction and support growth in T2Bacteria Panel utilization.

4) On the marketing front, we have several activities and campaigns planned for 2019 to support the momentum of the T2Bacteria Panel launch and expand awareness of the benefits of the T2Direct Diagnostic platform. Highlighting the T2Bacteria Panel clinical data is one of the key components of our strategy, as we have seen the importance of data in the adoption of the T2Candida Panel. In the first half of this year, we expect the results of the T2Bacterial Panel pivotal FDA clinical trial to be published in a peer-reviewed medical journal. For many physicians and healthcare providers, the publication of this data in a peer-reviewed journal is an important validator of our technology. Over the

course of the year, we expect that the clinical evidence to continue to build, with more clinical results to be added to many studies already reported using the T2Bacteria Panel expected at the 29th European Congress of Clinical Microbiology & Infectious Diseases, or ECCMID, which will take place in Amsterdam from April 13 to 16. In total, we have 5 scientific posters accepted for presentation at ECCMID and we are sponsoring a major symposium with U.S. & European experts in T2Direct Diagnostics. We will also have a strong presence at several U.S. and European customer meetings in February and March leading into ECCMID, providing multiple opportunities to highlight T2 Direct Diagnostics and our emerging T2Bacteria Panel data set.

In the first 2 months of this year we have received additional external validation of our technology. On January 30th, our chief scientific officer Tom Lowery participated in the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, or PACCARB, in Washington, DC. At the request of PACCARB, Tom provided information on T2Direct Diagnostics in support of their current task of identifying new priority areas for the next iteration of the U.S. Government's 2020-2025 National Action Plan for Combating Antibiotic-Resistant Bacteria. If you did not have the opportunity to view the live webcast of the meeting, a replay is now available on YouTube and at the PACCARB website, and I encourage you to view Tom's participation, which highlights our technology and the interest from PACCARB.

In February, T2 Biosystems was ranked in the top ten of the world's Most Innovative Biotech Companies by Fast Company based on the FDA clearance and launch of T2Bacteria. We are honored to be listed with a mix of well-known and emerging companies that are transforming industries and shaping society.

5) Outside of the United States, we have a team of 6 direct sales and marketing professionals managing our international distributors covering parts of Europe and the Middle East. In 2019, this team will be focused on going deeper in these existing markets with both the T2Bacteria and T2Candida Panels, while also supporting entry into new countries.

Turning to our new product pipeline, we have several opportunities to expand our market opportunity and leverage our core technology.

1) The newest pipeline opportunity I'd like to highlight is expanding on our T2Carba Resistance+ Panel, which I have highlighted on previous calls and for which we developed in partnership with Allergan and CARB-X, and introduced at IDWeek in late 2018. The T2Carba Resistance+ Panel was the first direct-from-blood antimicrobial resistance panel and could be used to determine if a patient is resistant to the first-line therapy associated with certain deadly gram-negative bacterial infections. We have since expanded on the initial panel, which was focused on carbapenemase resistance genes, and are announcing a more comprehensive panel called the T2Resistance Panel. This panel includes detection and identification of 13 resistance genes from both gram-positive and gram-negative

pathogens. These include detection of clinically important carbapenem resistance genes that are listed on the CDC Urgent Threat list for antibiotic resistance. All of these results are available within 3 to 5 hours, direct-from-blood and blood culture-independent like our other T2Dx Panels, which we believe will expedite accurate treatment for antibiotic resistant bloodstream infections. The infections detected by the T2Resistance Panel are life threatening, can lead to sepsis, and result in high mortality rates. Under the current standard of care, diagnosing bloodstream infections caused by resistant pathogens requires a positive blood culture and subsequent analyses that can take 3 or more days to receive an actionable result. With T2Resistance, we believe that the time to receive an actionable result will be shortened to just a few hours. Feedback from potential customers indicates that real-world use could include both running on certain positive T2Bacteria Panel results in certain patients and expand into screening certain patients before they are empirically treated with drugs for gram negative and gram positive infections. We are encouraged by this feedback, and plan to roll out the T2Resistance Panel as a research use only product in the United States and to receive a CE mark enabling a market launch in Europe before the end of this year. From an FDA perspective, we are delighted that the FDA has granted Breakthrough Device designation for the T2Resistance Panel. The FDA's breakthrough device program is intended to expedite patient's access to breakthrough technologies that will provide effective treatment or diagnosis of life-threatening or irreversibly debilitating conditions or diseases, by expediting their development, assessment, and review. We are honored to receive this breakthrough designation from the FDA and appreciate the productive partnerships with CARB-X and their funding agencies BARDA and the Wellcome Trust. We look forward to working towards bringing the first ever culture-independent direct-from-blood test for resistance markers to market.

2) The second pipeline opportunity is the T2Lyme Panel, in which we began enrolling patients in a pivotal FDA study in 2018. We will continue collecting data for our pivotal study in 2019 and are already encouraged by the pre-clinical data on this panel. If these results carry through to our FDA trial and we can secure regulatory approval, we will be positioned to offer a new tool to diagnose Lyme disease in an approximately 700-million-dollar market.

In addition to these opportunities, our R&D team continues to work on expanding our testing menu for existing and future applications and we look forward to sharing additional updates on our pipeline as appropriate.

With that, let me turn the call over to John Sprague who will review our fourth quarter and full year 2018 financial results in greater detail. John?

John Sprague:

Thank you, John.

Fourth quarter 2018 financial results:

Fourth quarter 2018 total revenues were $1.8 million, a 6% increase over last year's fourth quarter revenues of $1.7 million and within the range of guidance.

Product revenues, primarily T2Candida Panel and T2Dx Instrument sales, were $1.3 million, level with last year's fourth quarter product revenues and were driven by growing T2Candida Panel sales and the timing of T2Dx Instrument sales. T2Bacteria Panel sales are just commencing to ramp after our July 2018 launch due to hospital new diagnostic's validation protocols of 3 to 6 months.

Research revenues were $0.5 million compared to $0.3 million in last year's fourth quarter.

Costs and expenses, excluding costs of product revenue, were $9.8 million, compared to $9.7 million in last year's fourth quarter and were $1.0 million below the low range of guidance and include depreciation and non-cash stock option compensation and restricted stock unit, or RSU, grants of $3.0 million in the fourth quarter compared to $1.8 million in last year's fourth quarter, an increase primarily due to the vesting of performance-based RSUs.

Operating margins were a loss of $13.6 million, compared to a loss of $14.4 million in last year's fourth quarter.

Net interest expense and other income was $1.6 million compared to $3.8 million in last year's fourth quarter and decreased due to the absence of a derivative charge in 2018.

Our net loss was $15.1 million, ($0.34) per share, compared to a net loss in last year's fourth quarter of $18.2 million, ($0.51) per share. Weighted average shares outstanding were 44.1 million compared to 35.7 million in last year's fourth quarter.

Our cash and cash equivalents were $50.8 million at December 31, 2018. We believe our cash and financing sources are sufficient through the first half of 2020.

2018 financial results:

We delivered 14 new system contracts in the fourth quarter of 2018 and 25 in the second half of 2018, which was at the high end of our guidance.

On our last call, we estimated that these instrument were expected to provide access to at least 75,000 patients suspected of sepsis in the second half of the year, and the fourth quarter achievement alone of more than 80,000 exceeded that goal. The number of high-risk patients is important as it represents the current existing market opportunity for the T2Candida and T2Bacteria Panels if every patient at hospitals under contract were tested at the time they showed symptoms of infection. However, this metric is becoming increasingly difficult to accurately track and report, and ultimately will become less meaningful as we expand our installed base and drive adoption into this high-risk population, which will be reflected in our utilization and recurring T2Bacteria and T2Candida Panel sales. Therefore, we will discontinue this metric in 2019.

Revenues for 2018 were $10.5 million and increased 123% over revenues of $4.7 million for 2017 and were driven by growing T2Candida Panel sales and T2Dx Instrument sales.

Product revenues, primarily T2Candida Panel and T2Dx Instrument sales, were $4.8 million, a 41% increase over last year's product revenues of $3.4 million.

Research revenues were $5.7 million compared to research revenues last year of $1.2 million.

Costs and expenses, excluding costs of product revenue, were $40.2 million compared to $46.5 million last year and include non-cash depreciation and stock option compensation and RSUs of $12.3 million compared to $7.8 million last year and increased primarily due to the vesting of performance-based RSUs.

Operating margins were a loss of $45.1 million, compared to a loss of $53.9 million last year.

Net interest expense and other income was $6.1 million compared to $8.5 million last year.

Our net loss was $51.2 million, ($1.26) per share, compared to a net loss of $62.4 million, ($1.94) per share last year. Weighted average shares outstanding were 40.6 million compared to 32.1 million last year.

2019 Outlook:

The following forward-looking statements reflect estimates based on information as of March 7, 2019 and are subject to uncertainty.

We re-affirm our guidance as outlined on our third quarter 2018 conference call.

Overall, we expect revenue to double in each of 2019 and 2020 as our customer base grows and accounts go live testing with T2Bacteria. In 2019, we expect Product Revenue to grow over 100% and for Research Revenue to grow by 40%. For the first quarter of 2019, we expect revenue in the range of $1.3 million to $1.5 million, with revenue ramping over the course of the year.

In 2019, we expect to close contracts for the placement of 70 to 80 instruments, roughly double the number in 2018. This includes 8 to 10 contracts expected in the first quarter, which aligns with hospital purchasing seasonality and historically has been our lowest T2Dx Instrument quarter, especially outside the United States.

As John mentioned, it typically takes new instruments an average of three to six months to go live and patient testing commences as hospitals are required to validate any new diagnostic tests and instruments. During this period, the company typically receives nominal revenue unless the instrument has been purchased by the hospital, which in the United States occurs about 15% of the time. International distributors typically purchase instruments at a 30% discount off the list price of $100,000 per instrument.

We expect a continuation of average sales prices of $150 per test for the T2Bacteria Panel and $200 per test for the T2Candida Panel. International distributors typically receive about a 30% discount per test panel.

We estimate that a single T2Dx Instrument is capable of running about 3,000 tests per year, but expect average utilization to be in the 1,000 to 2,000 test range after testing ramps up over time. Therefore, we expect each T2Dx Instrument to generate an average of about $300,000 in annual revenue from the combination of T2Bacteria and T2Candida Panel testing.

We expect quarterly operating expenses to be $10.5 million to $11.5 million in 2019 and during the first quarter, including non-cash depreciation and stock option and RSU compensation of approximately $3.0 million per quarter. Non-cash stock compensation expenses may be impacted by the timing of performance-based RSU vesting.

We estimate that we will achieve cash flow break-even between $65 million and $75 million in annual revenue. We expect our gross margins to be approximately 45% to 50% at these revenue levels.

Our weighted average shares outstanding of 44.1 million may be impacted by stock option exercises.

Thank you and back to John McDonough for closing remarks.

John McDonough:

Thank you, John.

In summary, we believe 2018 was a landmark year for the Company and are pleased that we delivered on our operational and financial goals for the year. The T2Bacteria Panel launch is progressing as planned and we have a comprehensive strategy in place to continue building momentum, secure new T2Dx Instrument contracts, and drive utilization. We believe change is happening and will accelerate in the hospital environment, as will the subsequent impact on our financials. In 2019 we also anticipate important milestones for our new product pipeline, providing incremental growth opportunities for the company. Taken all together, we expect that this should allow us to double our revenue in each of the next 2 to 3 full years.

Thank you for your participation in today's call and for your continued interest in T2 Biosystems. That concludes our prepared remarks for this evening. Operator, we'll now open the call for questions.