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): May 2, 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. ☒

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**TTOO**	**NASD**

Item 2.02 Results of Operations and Financial Condition

On May 2, 2019, T2 Biosystems, Inc. (the "Company") issued a press release announcing its financial results for its fiscal quarter ended March 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 May 2, 2019
99.2	Transcript of conference call held by T2 Biosystems, Inc. on May 2, 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: May 8, 2019

T2 BIOSYSTEMS, INC.

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

T2 Biosystems Reports First Quarter 2019 Financial Results and Provides Corporate Update

Exceeds Q1 Guidance with Delivery of $1.8 Million in Revenue and 11 New Instrument Contracts

Confirms 2019 Guidance of a Doubling of Revenue and Securing 70 – 80 T2Dx Instrument Contracts

LEXINGTON, Mass., May 2, 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 first quarter ended March 31, 2019.

First Quarter and Recent Business and Financial Performance Highlights:

- Reported first quarter total revenue of $1.8 million.
- Exceeded the high end of first quarter revenue guidance by 20%.
- Reported first quarter product revenue of $1.3 million, up 30% year-over-year, reflecting an increase in testing volume and stable capital sales as more new customers selected the reagent rental model.
- Exceeded guidance with 11 T2Dx® Instruments contracted in the first quarter, ahead of guidance of 8 to 10 instruments contracted and compared to 5 instruments in the first quarter of 2018.
- First T2Bacteria® Panel U.S. customers began testing patients at risk of sepsis related blood stream infections during the first quarter.
- Received breakthrough device designation for the T2Resistance™ Panel, remaining on track for availability in Europe through CE Mark and as a research-use-only product in the U.S. in 2019.
- T2Bacteria®, T2Candida® and T2Resistance™ panels featured in integrated symposium and scientific presentations at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) in April.

“We delivered a strong start to 2019 with revenue and new system contracts that surpassed our guidance,” said John McDonough, president and chief executive officer. “Our commercial team is building momentum with ongoing and new customers alike, and we are pleased to be engaging on a more regular basis with motivated institutions that understand T2Bacteria® Panels’ unique value proposition and potential to improve clinical outcomes. During the quarter we also helped several of the first T2Bacteria® Panel customers in the U.S. complete their training and validation process and begin testing patients. We are pleased with the initial feedback and testing volumes and look forward to bringing more customers online in growing numbers throughout the coming quarters.”

Additional Financial Results:

- Research and grant contribution revenues were $0.5 million in the first quarter, compared to $1.3 million in last year’s first quarter.
- Costs and expenses in the first quarter, excluding cost of product revenue, were $11.0 million, compared to last year’s first quarter costs and expenses of $10.5 million. Total costs and expenses include depreciation and non-cash stock compensation of $2.6 million compared to $2.0 million in last year’s first quarter, an increase primarily due to the vesting of performance-based restricted stock units.

- Operating margin in the first quarter was a loss of $13.6 million, compared to last year's first quarter operating loss of $11.4 million.

Weighted average shares outstanding were 44.3 million for the first quarter, compared to 36.0 million in the same period last year.

Guidance:

The company is reiterating its full year 2019 financial guidance and providing second quarter 2019 financial guidance as follows:

- Total revenue is expected to double in 2019 compared to $10.5 million in 2018, including product revenue growth of over 100%. Second quarter 2019 total revenue is expected to be in the range of $1.8 million to $2.1. Second quarter product revenue is expected to be in the range of $1.5 million to $1.8 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 12 to 14 contracts in the second quarter 2019.
- Operating expenses, excluding cost of product revenue, are expected to be $10.5 million to $11.5 million in the second quarter 2019. Total costs and expenses will include non-cash depreciation and stock-based compensation expenses 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 1-855-327-6838 (U.S.) or 1-631-891-4304 (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, 2018, filed with the U.S. Securities and Exchange Commission, or SEC, on March 14, 2019, 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.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2019	2018
Revenue:		
Product revenue	$ 1,314	$ 1,048
Research revenue	142	1,263
Grant contribution revenue	329	—
Total revenue	1,785	2,311
Costs and expenses:		
Cost of product revenue	4,388	3,273
Research and development	3,901	4,718
Selling, general and administrative	7,055	5,755
Total costs and expenses	15,344	13,746
Loss from operations	(13,559)	(11,435)
Interest expense, net	(1,782)	(1,568)
Other income, net	194	90
Net loss and comprehensive loss	$ (15,147)	$ (12,913)
Net loss per share — basic and diluted	$ (0.34)	$ (0.36)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	44,282,345	35,978,306

T2 BIOSYSTEMS, INC.

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

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 37,400	$ 50,805
Accounts receivable	1,773	1,786
Prepaid expenses and other current assets	1,741	1,340
Inventories	2,664	2,677
Total current assets	43,578	56,608
Property and equipment, net	7,128	7,315
Operating lease assets	4,463	—
Restricted cash	180	180
Other assets	206	206
Total assets	$ 55,555	$ 64,309
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 618	$ 744
Accrued expenses and other current liabilities	7,784	6,073
Derivative liability	2,225	2,142
Notes payable	42,450	42,373
Deferred revenue	658	697
Current portion of lease incentives	—	268
Total current liabilities	53,735	52,297
Lease incentives, net of current portion	—	492
Operating lease liabilities, net of current portion	3,259	—
Deferred revenue, net of current portion	141	133
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized; 44,339,243 and 44,175,441 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	44	44
Additional paid-in capital	330,694	328,514
Accumulated deficit	(332,318)	(317,171)
Total stockholders' (deficit) equity	(1,580)	11,387
Total liabilities and stockholders' equity	$ 55,555	$ 64,309

First Quarter 2019 Financial Results and Business Update Conference Call Script

FINAL

John McDonough – CEO Commentary

John Sprague – CFO Commentary

Zack Kubow (W2O)—Moderator

May 2, 2019 – 4:30 pm ET

Leader Dial-In Number: 1-855-778-9850
Conference ID: 10006642

Operator:

Good afternoon, ladies and gentlemen. Thank you for standing by, and welcome to the T2 Biosystems first quarter 2019 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 first quarter 2019 financial results conference call. On the call to discuss the results and operational highlights for the quarter ended March 31, 2019, 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 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 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 first quarter 2019.

Q1 was a milestone quarter as our first customers in the United States went live and are testing patients with the T2Bacteria Panel. We are seeing patients benefiting from earlier detection of infections that could have been life threatening. We will see more hospitals utilizing the T2Bacteria Panel this quarter and are pleased with the early volume of patients being tested at the hospitals that have gone live. In Q1, we delivered revenue and new contracts that exceeded our guidance. This was in part driven by our efforts to focus our sales & marketing team on attracting new customers that are motivated to quickly adopt the T2Bacteria Panel and working with these customers to efficiently navigate the validation and startup phase. This is the first full period in which we employed these new targeting methods, as I will describe again in a few moments, and we saw continued progress demonstrated by more activity at the beginning of the sales funnel followed by a faster sales cycle with many potential customers. We also continued to advance our new product initiatives during the quarter, which have the potential to expand the utility of the T2Dx Instrument for the management of patients suspected of sepsis related blood stream infections, Lyme disease and other infectious diseases.

I will provide an update on our commercial and pipeline activities in more detail, but will begin with a high-level review of the financial results and commercial metrics for the quarter. After my remarks, our CFO John Sprague will provide a detailed review of our first quarter financial results and our 2019 financial guidance, including our expectations for the second quarter.

In the first quarter, we continued to drive adoption of the T2Bacteria Panel and grow our T2Candida Panel business, delivering results that were ahead of our expectations. Total revenues were 1.8 million dollars, exceeding guidance of 1.3 to 1.5 million dollars. Product revenue was 1.3 million dollars, up 30% year-over-year. This reflects growth in testing volume for the T2Candida Panel and T2Bacteria Panel utilization from customers that completed their 3 to 6-month validation and startup phase and began commercial testing late in the quarter. As more customers that entered new contracts in the second half of 2018 come online during or after the second quarter, we expect T2Bacteria Panel volume and recurring revenue to ramp up. Capital sales were stable in Q1 as many new customers continue to select the reagent rental model, which has minimal upfront customer costs and therefore minimal up front revenue for T2 Biosystems, but stronger margins on recurring sales. We continue to expect that the reagent rental program will constitute the majority of new customer arrangements in the U.S. going forward.

The other key metric for our business in 2019 is the number of new contracts secured for T2Dx Instrument placements, which represents a future driver of ongoing recurring testing revenue from T2Bacteria and T2Candida panel utilization. In the first quarter, we secured 11 new contracts, which is ahead of our guidance of 8 to 10 contracts and against the typical Q1 hospital adoption headwind. As of March 31, 2019, we had 97 instruments placed or contracted to be placed worldwide.

Overall, our revenue and new contract performance in the first quarter keeps us on track to achieve our 2019 goals for revenue growth and new instrument contracts.

Turning to an update on the T2Bacteria Panel launch, we continue to see several positive indicators in the field as we work to raise awareness of the T2Bacteria Panel, expand and execute against our new customer pipeline, and ultimately get new systems to begin commercial testing of patients as soon as possible. Most importantly, we are beginning to see the impact of T2Bacteria on patients as hospitals go live and begin testing patients. For example, at one hospital, a patient entered the Emergency Department with signs and symptoms of infection. A T2 was run on the patient but they were sent home as other diagnostics came back negative. The T2 turned positive in a few hours for an e coli infection and the patient was immediately brought back and properly treated. A blood culture confirmed the infection, but 24 hours later. Another cancer patient was on antibiotics for 5 days after which they ran a T2Bacteria test. T2Bacteria was positive in 4 hours and the antibiotics were changed as the patient was resistant to vancomycin.

Patient stories like this, where therapy is changed for the benefit of patients and hospital economics, in part allowed us in Q1 to continue to secure new customer wins with hospitals, including some with 30 to 90-day sales cycles, in-line with our experience during the first 6 months of the launch. We also were successful in broadening our outreach in order to attract more hospitals with a similar profile – institutions with strong stewardship efforts focused on improving sepsis management and related patient care – and therefore are more likely to have a similar rapid adoption pathway. This builds on our original targeting, which focused on hospital size and projected patient volume. In addition, we were pleased that our team was also able to close contracts with customers that had a more traditional 6 to 12-month sales cycle.

As I just mentioned, we are excited to report that during the first quarter, the first of the new T2Bacteria Panel accounts signed in the second half of 2018 began commercial testing following the 3 to 6-month validation and startup phase, which is required by the government. We are pleased that we are seeing the validation period stay in this range due to methods we have put in place, as it is not uncommon for this period to extend to 6 to 12 months with other laboratory diagnostic products. The volume of testing of patients at hospitals going live is also in line or slightly ahead of our expectations. We are supporting our customers through the transition to live testing of patients utilizing our team of medical-science liaisons. The early feedback that this team has been collecting from the field has been positive. In general, the early utilization protocols at these hospitals has been aligned with our expectations – hospitals are starting testing with a specific group of patients suspected of sepsis, with plans to expand to a broad group of patients in their protocols as they gain experience with the test.

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, along with enabling customers to publish and present new data from their institutions. We continue to expect the results of the T2Bacteria Panel pivotal FDA clinical trial to be published in a peer-reviewed medical journal soon. In fact, it is currently accepted by a top-tier journal and is scheduled for publication. As soon as the embargo has been lifted we expect to announce the publication. For many physicians and healthcare providers, the publication of this data in a peer-reviewed journal is an important validator of our technology.

In April, we hosted an integrated symposium, attended by an estimated 350 to 400 people, highlighting key clinical data about the T2Bacteria and T2Candida panels at the European Congress of Clinical Microbiology & Infectious Diseases, or ECCMID, in Amsterdam. The symposium included a panel of four speakers, and I want to share a couple of short quotes to give you a sense of how T2Bacteria is being accepted by key opinion leaders:

- One speaker stated, “In 3 clinical trials, T2Candida and T2Bacteria have demonstrated exceptional, remarkable and consistent results.”
- Another speaker also advised “if you get a discrepant result with T2 and blood culture, treat on the T2 result!”

With these comments and their full presentations, these physicians underscored one of the beauties of T2 tests—there is no interference from antimicrobials like blood culture, resulting in more detected patients by T2. In addition, several case studies were reviewed demonstrating how T2Direct Diagnostics are getting patients on more rapid therapy for infections with Candida, bacteria, and resistant pathogens. In total there were clinical presentations from seven leading clinicians and users highlighting the most recent scientific data on the T2Bacteria and T2Candida panels. Our trade show booth traffic was heavy and interest in our products is high.

We also had a strong presence at several U.S. and European customer meetings in February and March leading into ECCMID, providing multiple opportunities to highlight T2Direct Diagnostics and our emerging T2Bacteria Panel data set. Looking forward, we expect to have a robust presence at the American Society for Microbiology, or ASM Microbe annual meeting in June. This is expected to include live presentations, in-booth physician presentations, an evening customer VIP reception, and other events and marketing initiatives that will enable us to engage with customers and highlight the T2Bacteria and T2Candida panels.

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

1) As discussed on our year-end call, we are advancing the T2Resistance Panel, which received Breakthrough Device designation from the FDA, for the detection and identification of 13 resistance genes from both gram-positive and gram-negative pathogens. The infections detected by the T2Resistance Panel are life threatening, can lead to sepsis, and result in high mortality rates. Similar to our other tests, results with the T2Resistance Panel will be available within 3 to 5 hours versus several days, direct-from-blood and blood culture-independent. We remain on track with our development activities and continue to anticipate making the T2Resistance Panel available 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. In fact, as a stepping stone to completing the T2Resistance Panel, we have launched a subset of the panel, called the T2Carba Resistance Panel as an RUO and three separate hospitals have been testing this new panel. Results from this resistance panel were enthusiastically presented at ECCMID showing that our T2Direct Diagnostics enables resistance marker information without the need for a positive blood culture providing results 1 to 3 days earlier than blood culture dependent methods. The clinical data from and customer enthusiasm for this panel underscore the value of providing direct-from-blood results for pathogen identification and also resistance marker detection.

2) In addition to the T2Resistance Panel, we also continue to advance our CARB-X partnership program to expand our panels to include additional bacterial species and resistance markers, including ESBL and gram-positive resistance markers. We are ahead of schedule in our CARB-X program and appreciate the productive collaboration with CARB-X and its funding agencies.

3) Outside of the detection of blood stream infections, we developed the T2Lyme Panel, which is being investigated in a pivotal FDA study that started in 2018. The 2019 tick season began in March and our trial sites are currently enrolling patients in the study. Assuming it is successful and that we can secure regulatory approval, we expect to 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 first quarter 2019 financial results in greater detail. John?

John Sprague:

Thank you, John.

First quarter 2019 financial results:

First quarter 2019 total revenues were $1.8 million compared to last year's first quarter revenues of $2.3 million, 20% above the high end of guidance.

Product revenues, primarily T2Candida Panel and T2Dx Instrument sales, were $1.3 million, 30% higher than last year's first quarter product revenues of $1.0 million and were driven by growing T2Candida Panel and T2Dx Instrument sales. T2Bacteria Panel sales continue to ramp after our July 2018 launch as hospitals complete their 3 to 6 month new diagnostic's validation protocols.

Research and grant contribution revenues were $0.5 million compared to $1.3 million in last year's first quarter.

Costs and expenses, excluding costs of product revenue, were $11.0 million, compared to $10.5 million in last year's first quarter and were at the mid-point of guidance. Total costs and expenses include depreciation and non-cash stock compensation of $2.6 million in the first quarter compared to $2.0 million in last year's first 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 $11.4 million in last year's first quarter.

Net interest expense and other income was $1.6 million compared to $1.5 million in last year's first quarter.

Our net loss was $15.1 million, ($0.34) per share, compared to a net loss in last year's first quarter of $12.9 million, ($0.36) per share. Weighted average shares outstanding were 44.3 million compared to 36.0 million in last year's first quarter.

Our cash and cash equivalents were $37.2 million at March 31, 2019. We believe our cash and financing sources are sufficient through the first half of 2020.

2019 Outlook:

The following forward-looking statements reflect estimates based on information as of May 2, 2019 and are subject to uncertainty.

For the full year 2019, we are reiterating our financial guidance and providing second quarter guidance as follows:

Overall, we expect total revenue to double in 2019, with product revenue expected to grow over 100%. For the second quarter of 2019, we expect total revenue in the range of $1.8 million to $2.1 million. Second quarter product revenue is expected to be in the range of $1.5 million to $1.8 million. We expect revenue to continue to ramp over the course of the year reflecting continued adoption of T2Bacteria and T2Candida Panel test sales and expanding T2Dx® Instruments reagent rentals and sales in the U.S. and internationally.

For new contracts, we expect in 2019 to close contracts for the placement of 70 to 80 instruments, roughly double the number in 2018. This includes 12 to 14 contracts expected in the second quarter.

As you consider product revenue growth, please keep in mind the following guidelines that we have outlined on prior calls:

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 when hospitals fully ramp up testing of patients.

We continue to expect quarterly operating expenses to be $10.5 million to $11.5 million in 2019, and total costs and expenses will include non-cash depreciation and stock 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 44.3 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 are off to good start to 2019 with good results for product revenue and new system contracts in the quarter. Our sales pipeline is strong and growing, more T2Bacteria customers are starting to come online, and the early utilization and feedback has been encouraging. Moving forward, our commercial team will remain laser focused on executing our strategy to continue building momentum, securing new T2Dx Instrument contracts, and driving utilization. On the development front, we are moving closer to important milestones for our new panels, providing incremental growth opportunities for the company.

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.