
**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): November 12, 2019

T2 BIOSYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36571
(Commission
File Number)

20-4827488
(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 November 12, 2019, T2 Biosystems, Inc. (the “Company”) issued a press release announcing its financial results for its fiscal quarter ended September 30, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued November 12, 2019
99.2	Transcript of conference call held by T2 Biosystems, Inc. on November 12, 2019

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: November 13, 2019

T2 BIOSYSTEMS, INC.

By: /s/ John McDonough

John McDonough

CEO & President

T2 Biosystems Reports Third Quarter 2019 Financial Highlights and Provides Corporate Update

Breakthrough quarter with CMS NTAP reimbursement and endorsement; new multi-million dollar government contract; Contract with Premier; and \$1.4 million in product revenue

LEXINGTON, Mass., November 12, 2019 (GLOBE NEWSWIRE) — T2 Biosystems, Inc. (NASDAQ:TTOO) (the “Company,” “T2,” or “T2 Biosystems”), a leader in the development and commercialization of innovative medical diagnostic products for critical unmet needs in healthcare, announced today the operating highlights and preliminary financial results for the third quarter ended September 30, 2019. Due to a ransom cyber-attack on the Company’s information technology (“IT”) systems, the Company is reporting full revenue, new contracts and cash flow highlights as a part of this earnings release along with preliminary earnings estimates. We have determined that additional time is needed to input expense and other information into the Company’s enterprise resource planning (“ERP”) system and the Company believes it is on track to finalize that information and file on the Company’s Form 10-Q for the third quarter 2019 by November 18, the extended due date for filing. We will file the appropriate form with the SEC to secure an extension. The Company did not pay a ransom and worked with an external firm experienced in this matter who also determined that there was no evidence that customer or company data was exfiltrated. The Company’s IT systems have recovered from the cyber-attack, other than completing the abovementioned data input process, and the interruption caused by the attack did not materially affect the Company’s operations.

Third Quarter Financial Performance Highlights:

- Reported third quarter total revenue of \$1.6 million.
- Reported third quarter product revenue of \$1.4 million, up 17% year-over-year.
- Secured contracts for 12 T2Dx Instruments in the third quarter, 5 in the United States and 7 outside the United States, compared to a total of 11 new contracts in the third quarter of 2018. The third quarter 2019 new T2Dx Instrument total included 5 instruments associated with the new government contract which commenced in September.

Third Quarter Business Highlights:

- Enhanced reimbursement for testing via approval for a New Technology Add-on Payment (NTAP) by the United States Centers for Medicare & Medicaid Services (CMS) for fiscal year 2020 (starting October 1, 2019).
- Awarded multi-million dollar government contract that will enable a significant expansion of the Company’s current portfolio of diagnostics for the detection of sepsis-causing pathogens, antibiotic-resistance genes, and biothreat pathogens and toxin genes.
- Awarded Breakthrough Technology contract with Premier Inc., granting direct access to its membership of more than 4,000 U.S. hospitals and health systems, supporting the Company’s commercial efforts to drive adoption and utilization of the T2Bacteria and T2Candida Panels.
- The T2Resistance Panel was the first in-vitro diagnostic to graduate from the CARB-X portfolio and was launched as a research use only (“RUO”) test in the United States
- Expanded international business by entering exclusive distribution agreements covering ten new markets, representing approximately 2,384 hospitals that could benefit from T2’s products.
- Restructured Term Loan Agreement with CRG Servicing LLC, extending interest-only payment period through December 2021 and reducing minimum revenue targets.

“During the third quarter we achieved several milestones, including delivering on key business objectives while making progress with changes to our commercial team and strategy to accelerate the new customer sales cycle,” said John McDonough, chairman and chief executive officer at T2. “We continue to see solid quarter-to-quarter growth in T2Bacteria testing revenue, and we are on track to receive a CE mark approval for the T2Resistance Panel before the end of the calendar year. In the near-term, we expect to benefit from a strong sales pipeline and several recent external validators of our technology, including the NTAP from CMS, our new government contract, and the Breakthrough Technology contract with Premier Inc. We also continue to expand our market opportunity with the launch of the T2Resistance Panel RUO, and the addition of new international distribution partners.”

Additional Financial Results:

- Research and grant contribution revenues were \$0.2 million in the third quarter (excluding T2Dx Instrument placements), compared to \$1.2 million in last year’s third quarter.
- Costs and expenses, excluding cost of product revenue, are expected to be \$10.5 million to \$11.5 million in the third quarter, compared to \$8.6 million in last year’s third quarter. Total costs and expenses include depreciation and non-cash stock compensation of \$1.8 million (estimated) compared to \$2.9 million in last year’s third quarter, a decrease primarily due to last year’s vesting of performance-based restricted stock units.
- Operating margin loss is expected to be \$13.7 million to \$14.7 million in the third quarter, compared to a loss of \$9.2 million in last year’s third quarter.
- In the third quarter of 2019, the company sold 1.7 million shares (\$2.1 million net proceeds) through its ATM facility and zero shares under its equity credit line.

Weighted average shares outstanding were 46.1 million in the third quarter, compared to 43.8 million in last year’s third quarter.

Guidance:

The Company is reiterating its full year 2019 financial guidance as follows:

- Total revenue is expected to be \$8.7 million to \$9.6 million, including product revenue of \$5.7 million to \$6.1 million and research and grant contribution revenue of \$3.0 million to \$3.5 million.
- The Company expects to secure contracts of 45 to 50 T2Dx Instruments in 2019.
- A combination of cost control efforts and growth in revenue is expected to reduce quarterly cash burn to below \$8 million in the fourth quarter of 2019. Operating expenses, excluding cost of product revenue, are expected to be \$10.5 million to \$11.5 million in the fourth quarter of 2019. Total costs and expenses will include non-cash depreciation and stock-based compensation expenses of approximately \$1.5 million per quarter.
- The Company believes that an additional \$40 million of capital is required to achieve neutral cash flow.

Conference Call

Management will host a conference call today with the investment community at 8:30 a.m. Eastern Time to discuss the financial highlights 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’s 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, which was recently announced as the first and only in-vitro diagnostic test to receive approval for a New Technology Add-on Payment by CMS, are powered by the proprietary T2 Magnetic Resonance 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. For more information, please visit www.t2biosystems.com.

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®

Third Quarter 2019 Financial Results and Business Update Conference Call Script

FINAL

John McDonough – CEO Commentary

John Sprague – CFO Commentary

Tom Lowery – CSO Commentary

Zack Kubow (W2O) – Moderator

November 12, 2019 – 8:30 am ET

Operator:

Good morning, ladies and gentlemen. Thank you for standing by, and welcome to the T2 Biosystems third 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 morning everyone. Thanks for joining us for the T2 Biosystems third quarter 2019 financial results conference call. On the call to discuss the results and operational highlights for the quarter ended September 30, 2019, are Chairman and CEO, John McDonough, and Chief Financial Officer, John Sprague. We are also joined by Tom Lowery, Chief Scientific Officer. 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 Chairman and CEO, John McDonough. John?

John McDonough:

Thank you, Zack. Good morning, everyone, and thank you for joining us as we discuss the progress, results and outlook following the third quarter of 2019.

During the third quarter, we announced a series of major milestones that provide economic drivers and external validation, increasing the momentum and support for T2 Biosystems' near-term and long-term growth potential. These milestones were headlined by being the first and only in-vitro diagnostic company to receive a new technology add-on payment, or NTAP, from CMS that covers approximately two-thirds of the price of the T2Bacteria Panel. We expect this new reimbursement code to also be picked up by private payers in time. The decision summary from CMS also included a strong statement of endorsement by stating this extra reimbursement is being put in place because the T2Bacteria Panel represents a substantial clinical improvement over existing technologies because it reduces the number of patients on inappropriate therapy, thus reducing other interventions as well as reducing length of stay and mortality rates for patients with sepsis-causing bacterial infections. An equally significant milestone was the announcement that we were awarded a new multi-year milestone-based government contract

with an initial milestone value of \$6 million. In addition, we announced a Breakthrough Technology contract with Premier, launched the research use only version of the T2Resistance Panel, and further expanded our international distribution network and market opportunities. We also improved our financial position and eased the need for capital with the restructuring of our CRG term loan, made progress towards a reduction in our cash burn by 30% to \$8 million per quarter by the fourth quarter of 2019 and put in place two financing agreements that provide us with the possibility to access to up to \$60 million of capital at market levels. We will provide an update on each of these items and the related operational progress on today's call, but first I will provide an overview of our financial results for the third quarter.

We achieved third quarter product revenue of \$1.4 million and secured contracts for 12 T2Dx Instruments – five in the United States and seven outside of the United States, which was in line with our expectations based on the changes we made during the third quarter to our U.S.-based commercial approach and changes to the sales team as we reported on our Q2 call. This included five placements associated with fulfillment of the Company's new government contract that initiated in September. Importantly, T2Candida growth remains steady, and more new T2Bacteria customers went live in testing patients. We believe we are on the right track with changes we have made to our commercial strategy and are encouraged by several factors:

- Our sales force is making good progress engaging with pharmacy and infectious disease specialists on the stewardship committees of potential customers.
- This is complemented by our national accounts team, which is focused on large integrated delivery networks and group purchasing organizations, such as Premier. Securing contracts with these organizations provides improved access to their hospitals and health systems. Our team continues to have positive interactions with IDNs and GPOs, and we are hopeful that we will be able to announce additional partnerships similar to Premier in the near future.
- Outside of the United States, our international business is performing well and during the third quarter we entered 10 new markets outside of the United States. We are now in 35 countries and have plans to continue expanding this year.
- Overall, there continues to be strong interest in both the T2Bacteria and T2Candida Panels in the market, and we have a dynamic sales funnel that gives us confidence in the long-term market opportunity for T2Bacteria.

In addition, beginning October first, the NTAP for T2Bacteria went into effect. T2Bacteria is the first and only in-vitro diagnostic test to receive approval for NTAP, which is granted to new technologies that demonstrate substantial clinical outcomes for patients. As a result, hospitals in the United States treating Medicare inpatients with sepsis are now eligible to receive incremental reimbursement through NTAP of up to \$97.50 for the T2Bacteria Panel in addition to the diagnosis-related group, or DRG-based reimbursement. This is compared to all blood culture based products, which are only covered by the DRG code and are not eligible for this reimbursement. This covers approximately two-thirds of the cost of the test for these patients and effectively lowers the cost of the T2Bacteria Panel from \$150 to around \$50 per test. In addition, we anticipate that most private payors will provide the same coverage in time, aligned with historical precedents, further expanding the benefit of the NTAP beyond Medicare patients. The early feedback from our promotion of the NTAP in August and September, and since it has gone into effect, has been positive, both with existing and potential customers. We believe this has the potential to be a major economic driver towards adoption, and clearly demonstrates the substantial difference between the clinical and economic value of our product, versus any product that is based on positive blood culture results.

Turning to our government contract we announced in early September, we are very excited to have extended our funding from the U.S. government beyond that of CARB-X. At a recent conference in Washington, D.C., Dr. Rick Bright, head of the government agency that awarded us the contract, highlighted T2 Biosystems as the first company to graduate from CARB-X and transition to this extended government program. We are excited that through this work, our product portfolio will potentially allow for a significant improvement in the management of patients suspected of sepsis and other blood stream infections. This can potentially result in better clinical outcomes, savings to the hospital and a decline in the prescribing of unnecessary antibiotics that add further cost and drive the development of emerging superbugs that are resistant to current treatment options. We have initiated activity under the agreement and are on track with the program timelines. We expect improved research revenue commencing in Q4 as activity picks up.

I will now turn the call over to Tom Lowery, our Chief Scientific Officer, for a pipeline and technology update. Tom?

Tom Lowery:

Thank you, John. I'll start with a quick update on our pipeline initiatives.

- First is the T2Resistance Panel, which is designed to detect 13 antibiotic resistance genes from both gram-positive and gram-negative pathogens direct from whole blood and will complement the T2Bacteria Panel. The T2Resistance Panel is now available as a research use only test. As a reminder, data from our recent industry presentations demonstrated that the T2Resistance Panel provides at least a two-day time advantage compared to conventional methods that require a positive blood culture for a result. Due to this unique ability, the T2Resistance Panel was granted Breakthrough Designation by the FDA in February of this year. We are pleased to have launched it as research-use only product in the United States at the end of September and are encouraged by the early feedback from interested customers. The panel is also available outside the United States, and we received our first customer orders in October. In addition, studies are underway, and others will start shortly, at multiple sites within the United States, Europe, the Middle East and South Africa. We have submitted for CE-Mark approval and we expect to receive it during the fourth quarter of 2019 as planned, which would enable a product launch for clinical use of T2Resistance outside of the United States by year end.
- Second is the comprehensive panel, which is expected to cover 99% of all bloodborne bacterial infections by means of greater than 36 reported results. This panel is comparable to all of the products in the market that identify infections from positive blood cultures but detects these pathogens directly from the patient sample. This Panel includes 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, or CDC. In layman's terms, when available, we believe this panel has the potential to completely change the industry, providing a pan-pathogen detection paired with resistance testing directly from blood, further improving time to effective therapy and reducing the reliance on blood cultures

and the post-culture testing for species identification and susceptibility results. This panel will run on a next-generation instrument that we believe will lower the cost of goods for our disposable test panels while being able to deliver a high number of results per day. We have begun product development on this new platform, building on prior work we have performed to adapt our technology to create this panel.

- Outside of sepsis, we are developing a first-of-its-kind biothreat panel under our government contract. This is expected to be the first-ever ultra-high sensitivity direct-from-blood panel for detection of multiple biothreat pathogens and toxin genes. We believe this biothreat panel addresses a large, new market opportunity and is another example of how our platform can address market needs that cannot be addressed by other platforms.

Turning to our other development programs, we continue to work on our T2Lyme diagnostic panel with our ongoing pivotal study, having expanded the clinical trial protocol to patients without an EM rash, which is the bullseye rash associated with Lyme. With this expanded target patient population, the T2Lyme panel may potentially have a much broader indication for use when brought to market. Based on continued feedback from the FDA and the dynamics of the Lyme disease testing market, we believe that the most expeditious path for commercializing the T2Lyme panel may be by offering the test with a single partner as a lab developed test. This doesn't preclude our ongoing work on pursuing an FDA cleared panel but provides a more near-term revenue opportunity. The majority of Lyme disease testing is currently carried out by reference labs, and we have had several discussions with leading reference laboratories to partner for the commercialization of T2Lyme and potentially for the development of additional panels for Lyme and other tick-borne pathogens. Although at this time we are not providing a date for when we expect to enter into a partnership agreement, our goal is to potentially have T2Lyme validated in our partner's lab and ready for launch in time for next year's tick season in the Northeast.

Lastly, there continues to be interest in the T2Candida auris Panel RUO from hospitals around the world that are dealing with the emerging superbug, *Candida auris*. Our panel can help these hospitals in addressing the containment and elimination of this superbug. We have received orders for the T2Candida auris Panel RUO from customers in the Middle East and South Africa, in addition to Europe, underscoring the growing global awareness and interest in this panel. These customers are using the panel for three separate use cases:

1. First, routine testing in patients where prevalence is very high, such as in South Africa and some locations in the Middle East;
2. Second, in Europe and Australia to test patients from countries where *Candida auris* is prevalent; and
3. Third, to validate the Panel for use in advance of an outbreak. Due to the very high mortality rates associated with *Candida auris* and difficulty in addressing an affected health care facility, we are seeing some customers maintain a reserve of T2Candida auris Panel RUO tests just in case of an outbreak.

Outside of our development programs, I want to close by highlighting that we are pleased to see support from the CDC's National Healthcare Safety Network for non-blood culture-based testing, like T2Bacteria and T2Candida. Effective January 1, 2020, the CDC's new guidance for the use of non-culture-based testing methodologies will go into effect. Under this guidance, non-culture-based tests, like T2Candida and T2Bacteria, will not increase a hospital's Central Line-Associated Bloodstream Infection, or CLABSI rates. Ultimately, this is a positive endorsement of the unique characteristics of non-culture based tests and we believe it will encourage hospitals to use non-culture based tests like ours to identify infected patients more rapidly and sensitively than is possible with culture based tests.

Let me give you a personal example from one hospital with whom I've met. After explaining that a single T2 test can catch infections missed by a single set of blood cultures the lead of infection control said to me very resolutely, "I don't want to catch infections that I'm missing." Now that may sound bizarre. It certainly did when I heard it. However, under the old CLABSI surveillance rule, a significant percentage of a hospital's annual CMS reimbursement could be reduced due to a hospital having a high CLABSI rate as compared to its peer group. As one KOL in the field recently published, this created a perverse unintended incentive for hospitals to limit testing in order to avoid an increase in CLABSI rates, and thereby avoid jeopardizing such a large amount of their annual reimbursement. Fortunately, due to advocacy of our customers and the insight of those at the CDC, the CDC made this change to accommodate new technology and avoid this unintended consequence. We expect use of our tests to be boosted by this important change.

I will now turn the call over to John Sprague, our chief financial officer, for an update on our financial results.

John Sprague:

Thank you, Tom.

As noted in our press release, due to a recent ransom cyber-attack on our information technology systems, we have determined that additional time is needed to finalize the Company's Form 10-Q for the third quarter of 2019. We will be filing the 10-Q on a delayed basis as soon as it can be finalized, which we expect to be in the next five days. We will file the appropriate form with the SEC to secure an extension. Accordingly, the expense and earning results we are reporting today are preliminary. The interruption caused by the attack did not materially affect the Company's operations. Importantly, the Company did not pay a ransom and worked with an external firm experienced in cyber-attacks who also determined that no customer or company data was exfiltrated.

Third quarter 2019 financial results:

Third quarter 2019 total revenues were \$1.6 million compared to last year's third quarter revenues of \$2.5 million.

Product revenues, including \$0.2 million for instruments placed related to our new government contract, were \$1.4 million, 17% higher than last year's third quarter product revenues of \$1.2 million and were driven by growing T2Bacteria Panel, T2Candida Panel and T2Dx Instrument sales. We delivered contracts for 12 new systems, including five placements associated with the new government contract in the third quarter of 2019 and 35 year-to-date.

Research and grant contribution revenues, which does not include T2Dx Instrument placements associated with the new government contract, were \$0.2 million compared to \$1.2 million in last year's third quarter.

We anticipate costs and expenses, excluding costs of product and research contribution revenue, of \$10.5 million to \$11.5 million, including system restoration costs of \$0.5 million related to the cyber-attack, compared to \$8.6 million in last year's third quarter. Total costs and expenses include depreciation and non-cash stock compensation of \$1.8 million (estimated) in the third quarter compared to \$2.9 million in last year's third quarter, a decrease primarily due to last year's vesting of performance-based RSUs.

We anticipate an operating margin loss of \$13.7 million to \$14.7 million, compared to a loss of \$9.2 million in last year's third quarter.

We anticipate net interest expense and other income of \$1.7 million compared to \$1.6 million in last year's third quarter.

We anticipate a net loss of \$15.4 million to \$16.4 million, (\$0.33) to (\$0.36) per share, compared to a net loss in last year's third quarter of \$10.8 million, (\$0.25) per share. Weighted average shares outstanding were 46.1 million compared to 43.8 million in last year's third quarter.

2019 Outlook:

The following forward-looking statements reflect estimates based on information as of November 12, 2019 and are subject to uncertainty.

We expect full-year 2019 total revenues of \$8.7 million to \$9.6 million and we expect product revenues in the range of \$5.7 million to \$6.1 million. We expect research and grant contribution revenues for the full year in the range of \$3.0 to \$3.5 million.

We expect fourth quarter product revenues of \$1.7 million to \$2.0 million.

We expect to close 45 to 50 T2Dx Instrument placement contracts in 2019, and 10 to 15 in the fourth quarter of 2019.

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

Historically, it took new instruments an average of 3 to 6 months to go live and begin patient testing. As John outlined today, for T2Bacteria this timing has extended beyond six months for many customers and is averaging closer to 9 months. During this period, the Company typically receives nominal revenue unless the hospital purchases the instrument, 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 we expect average utilization to be in the range of 1,000 to 2,000 tests per year after testing ramps up. 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 have taken actions to reduce our cash burn rate to under \$8 million per quarter in the fourth quarter of this year, which will allow us to continue executing on our growth strategy while reducing expenses to be in-line with our updated revenue expectations. Operating expenses, excluding cost of product revenue, will be \$10.5 to \$11.5 million including the research collaboration in the fourth quarter of 2019. Total costs and expenses include non-cash depreciation and stock compensation of approximately \$1.5 million per quarter. The timing of performance-based RSU vesting may affect non-cash stock-compensation expense.

Our cash and cash equivalents were \$16.2 million at September 30, 2019, which we expect to take us to the first half of 2020 without accessing any additional capital from our ATM and equity credit line. We sold 1.7 million shares (\$2.1 million net proceeds) through the ATM facility in the third quarter and zero 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 of 46.1 million.

Thank you and back to John McDonough for closing remarks.

John McDonough:

Thank you, John.

In conclusion, the third quarter of 2019 was filled with watershed milestones each providing a significant benefit to the economics, commercial ramp, and exposure for the Company. The potential of our technology has been recognized by CMS, the U.S. government, the CDC, Premier, the FDA and customers that have adopted our technology and tracked the results. We are leveraging these endorsements and the growing body of clinical and economic evidence to drive adoption of T2Bacteria, shorten sales cycles, and make our tests available to more patients as soon as possible. We are also focused on expanding our national accounts programs and working closely with customers to highlight the impact our products are having on their patients. The external endorsements and the impact we are seeing in hospitals leave us both excited and convinced that our products need to be, and will ultimately become, standard of care. Thanks to the internal T2 Biosystems team for their commitment and tireless efforts in pursuing our mission and to our investors for your belief and support.

With that, we will now open the call for questions. Operator?