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: July 30, 2019 (Date of earliest event reported)

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)**	**(I.R.S. Employer Identification Number)**

101 Hartwell Avenue, Lexington, Massachusetts 02421
(Address of principal executive offices and zip code)

(781) 761-4646
(Registrant's telephone number, including area code)

Not Applicable
(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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 July 30, 2019, T2 Biosystems, Inc. (the "Company") issued a press release announcing its financial results for its second quarter ended June 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

Exhibit No.	Description
99.1	Press Release issued July 30, 2019
99.2	Transcript of conference call held by T2 Biosystems, Inc. on July 30, 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: August 1, 2019

T2 BIOSYSTEMS, INC.

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

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

Announces Two Financing Agreements to Potentially Provide up to $60 Million of Additional Capital; Reducing Cash Burn by 30% by Q4 2019

Achieved $1.8 Million in Total Revenue and Secured 12 New T2Dx® Instrument Contracts

Updates 2019 Financial Guidance

Announced Management Update

LEXINGTON, Mass., July 30, 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 second quarter ended June 30, 2019.

Financing Agreement Highlights:

- The Company entered into two financing agreements that enables the potential access to up to $60 million of additional capital, potentially strengthening its financial position.
- Entered into an At-the-Market (ATM) equity offering agreement with Canaccord Genuity LLC pursuant to which Canaccord will, at the Company's option, use reasonable best efforts to sell up to $30 million of our common stock at our direction.
- Entered into common stock purchase and registration rights agreements with Lincoln Park Capital Fund, LLC (LPC), a Chicago-based institutional investor, under which we will have the right and the sole discretion to sell to LPC up to $30 million worth of shares over a 36-month period at market rates based on closing prices in the past 10 days from when a sales of shares may occur, subject to certain limitations under the agreement as further described below under the section titled "Financing Agreement Details".

"We plan to be opportunistic in accessing the capital markets, including through these agreements, and we may not sell the full amount under either agreement. We will remain open to other potential sources of additional capital, both from a traditional financing perspective and through business development opportunities. Combined with our plan to reduce our cash burn by 30% by the fourth quarter and our projected capital requirements, we believe we have a means to efficiently use resources now available to us to achieve our goals," said John McDonough, chief executive officer. "We believe these financing agreements are consistent with our plan to be strategic in the way we access capital. In addition, we continue to pursue business development opportunities as a way to potentially provide non-dilutive cash to our balance sheet."

Second Quarter and Recent Business and Financial Performance Highlights:

- Reported second quarter total revenue of $1.8 million.
- Reported second quarter product revenue of $1.3 million, up 8% year-over-year, from an increase in T2Bacteria Panel testing revenue by over 80% from the first quarter.
- Secured 12 new contracts for T2Dx® Instruments in the second quarter, compared to 9 new contracts in the second quarter of 2018.

- Highlighted products and technology at several medical meetings during the second quarter, including early, positive T2Bacteria® Panel clinical data and experience from commercial customers and data supporting new panel opportunities.
- Published results from T2Bacteria® Panel pivotal clinical study in the Annals of Internal Medicine® journal; additional cost-effectiveness data published in peer-reviewed journals.
- Expanded international business by entering exclusive distribution agreements covering five new markets representing approximately 1,170 hospitals that could benefit from T2's products.

Mr. McDonough added, "During the second quarter T2Bacteria revenue grew over 80% from the first quarter and we continued to secure new customer contracts for T2Bacteria, while also assisting hospitals through the validation and evaluation process so that they can begin testing patients. All of the new hospitals that have completed this process in the U.S. and international markets in 2019 are tracking at or above our expectations in terms of utilization, demonstrating the clinical need for our direct-from-blood rapid diagnostic tests. In some cases, the sales cycle and validation process have taken longer than anticipated, and we are adjusting our product revenue expectations for the year as a result. We have made changes to our commercial team, strategy and tactics in the field to accelerate these timelines and remain confident in the long-term outlook for T2Bacteria growth."

"We remain excited about potential business development opportunities that are expected to result in both research and commercial revenues. Anticipated research revenue associated with one such opportunity has been impacted by a delay in the timing of the agreement by about three months. We now expect the contract to be finalized in the second half of the year and still expect to realize the full value of the contract into next year."

Additional Financial Results:

- Research and grant contribution revenues were $0.5 million in the second quarter, compared to $2.7 million in last year's second quarter.
- Costs and expenses in the second quarter, excluding cost of product revenue, were $10.8 million, compared to last year's second quarter costs and expenses of $11.4 million. Total costs and expenses include depreciation and non-cash stock compensation of $2.0 million compared to $4.5 million in last year's second quarter, a decrease primarily due to last year's vesting of performance-based restricted stock units.
- Operating margin in the second quarter was a loss of $13.8 million, compared to last year's second quarter operating loss of $10.9 million.

Weighted average shares outstanding were 44.4 million for the second quarter, compared to 38.3 million in the same period last year.

Guidance:

The Company is updating 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 43 to 53 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 by the fourth quarter of 2019. Operating expenses, excluding cost of product revenue and contingent on closing a research collaboration, are expected to be $10.5 million

to $11.5 million in the third and fourth quarters of 2019 and $7.0 to $8.0 million absent the research collaboration in the fourth quarter. Total costs and expenses will include non-cash depreciation and stock-based compensation expenses of approximately $1.5 million per quarter. We will provide a further update on expected fourth quarter operating expenses at the time of our next earnings release.

- The Company believes that an additional $40 million of capital is required to get to cash flow breakeven.

Financing Agreement Details

T2 entered into an At-the-Market (ATM) equity distribution agreement with Canaccord Genuity LLC. Pursuant to the ATM, Canaccord has agreed to act as our sales agent and at the Company's option, use reasonable best efforts to sell up to an aggregate of $30 million of our common stock. Sales of common stock, if any, under the ATM Program will be made by methods deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. There is no guarantee that we will be able to see all or any of the total amount of shares under the ATM.

T2 entered into a common stock purchase agreement and registration rights agreement (together, the "Agreements") with Lincoln Park Capital Fund, LLC ("LPC"), a Chicago-based institutional investor, for up to $30 million, subject to limitations. Under the terms of the Agreements and subject to the limitations thereunder, T2 will have the right and the sole discretion to sell to LPC up to $30 million worth of shares over a 36-month period. T2 will control the timing and amount of any future investment and LPC will be obligated to make purchases in accordance with the Agreements and at the lower of the current market price or the purchase price looking back at the closing price over the past 10 days and averaging the 3 lowest prices. There are no upper limits to the price at which the shares may be sold to LPC. There are limitations under the agreement as to the number of shares that can be sold on any day, the price at which they are sold and the total number of shares that may be sold under the agreement. In particular, T2 cannot sell more than 20% of its outstanding shares, or 8,902,661 shares as of today, at a price lower than $1.52 per share under the Agreement pursuant to Nasdaq rules without first obtaining shareholder approval, which would equate to $12,908,858 based on the closing price of our common stock on July 29, 2019. If the share price is above $1.52 per share, this share limitation does not apply and, subject to other limitations, the Company may sell up to $30 million worth of shares at the Company's sole option.

LPC has agreed not to cause or engage in any manner whatsoever, in any direct or indirect short selling or hedging of shares of the Company's common stock. No warrants, derivatives, financial or business covenants are associated with the Agreements. As consideration for the commitment of to purchase share, T2 has issued 413,349 shares to LPC as a commitment fee. The Agreements may be terminated by the Company at any time, at its sole discretion, without any cost or penalty.

This press release does not constitute an offer to sell or a solicitation of an offer to buy the securities in these offerings, nor will there be any sale of these securities in any jurisdiction in which such offer solicitation or sale are unlawful prior to registration or qualification under securities laws of any such jurisdiction.

Management Update – Executive Succession Plan

The Company also announced that founding CEO John McDonough has been named executive Chairman, effective immediately, and that the Company is undertaking a national search for a new CEO. Once that candidate is identified, Mr. McDonough will become non-executive Chairman of the Board. Mr. McDonough will continue in the role of CEO and Executive Chairman until his successor is in place.

Stanley Lapidus, lead independent board member of T2 Biosystems, said, “On behalf of the board, I would like to thank John, the founding CEO of our Company, for guiding the company through its formative stages, initial public offering and early commercial years. We are particularly proud that under John’s leadership, the company has created a technology and market with a whole new approach to diagnostics and has received FDA clearance for three products that many believed were not possible. It is gratifying that we have seen the benefits of these products on patient care in the United States and outside the United States. The board looks forward to working closely with John as we begin the process to find the right person to lead the Company through our next phase of growth. This process could take a number of months and we will make an announcement when we have a new CEO in place.”

Mr. McDonough commented, “It is personally the right time for me and I believe, the right time for T2 to begin the process of finding a successor for the CEO role. I have been honored to have worked diligently at the helm for 12 years and I look forward to working with our Board of Directors in the search process and fostering a smooth transition to my successor while moving to the non-executive Chairman role.”

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. 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, INC.

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

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 28,422	$ 50,805
Accounts receivable	1,179	1,786
Inventories	3,100	2,677
Prepaid expenses and other current assets	713	1,340
Total current assets	33,414	56,608
Property and equipment, net	7,262	7,315
Operating lease right-of-use assets	4,108	—
Restricted cash	180	180
Other assets	206	206
Total assets	$ 45,170	$ 64,309
Liabilities and stockholders' equity		
Current liabilities:		
Notes payable	$ 42,885	$ 42,373
Accounts payable	2,911	744
Accrued expenses and other current liabilities	8,823	6,073
Derivative liability	2,503	2,142
Deferred revenue	677	697
Current portion of lease incentives	—	268
Total current liabilities	57,799	52,297
Lease incentives, net of current portion	—	492
Operating lease liabilities, net of current portion	2,893	—
Deferred revenue, net of current portion	98	133
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized; 44,535,572 and 44,175,441 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	44	44
Additional paid-in capital	332,301	328,514
Accumulated deficit	(347,965)	(317,171)
Total stockholders' (deficit) equity	(15,620)	11,387
Total liabilities and stockholders' equity	$ 45,170	$ 64,309

T2 BIOSYSTEMS, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue:				
Product revenue	$ 1,274	$ 1,220	$ 2,588	$ 2,268
Research revenue	71	2,711	213	3,974
Contribution revenue	459	—	788	—
Total revenue	1,804	3,931	3,589	6,242
Costs and expenses:				
Cost of product revenue	4,820	3,458	9,208	6,731
Research and development	4,048	3,749	7,949	8,467
Selling, general and administrative	6,722	7,611	13,776	13,366
Total costs and expenses	15,590	14,818	30,933	28,564
Loss from operations	(13,786)	(10,887)	(27,344)	(22,322)
Interest expense, net	(2,000)	(1,506)	(3,782)	(3,074)
Other income, net	139	69	332	159
Net loss and comprehensive loss	$ (15,647)	$ (12,324)	$ (30,794)	$ (25,237)
Net loss per share – basic and diluted	$ (0.35)	$ (0.32)	$ (0.69)	$ (0.68)
Weighted-average number of common shares used in computing net loss per share – basic and diluted	44,426,402	38,263,486	44,354,771	37,127,208

Second Quarter 2019 Financial Results and Business Update Conference Call Script

FINAL

John McDonough – CEO Commentary
John Sprague – CFO Commentary
Sandy Estrada – VP Medical Affairs Commentary
Tom Lowery – CSO Commentary
Matt Clawson (W2O) – Moderator

July 30, 2019 – 4:30 pm ET

Operator:

Good afternoon, ladies and gentlemen. Thank you for standing by, and welcome to the T2 Biosystems second 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 Matt Clawson, of the W2O Group.

Please go ahead, sir.

Matt Clawson

Thank you, operator, and good afternoon everyone. Thanks for joining us for the T2 Biosystems second quarter 2019 financial results conference call. On the call to discuss the results and operational highlights for the quarter ended June 30, 2019, are President and CEO, John McDonough, and Chief Financial Officer, John Sprague. We are also joined by Tom Lowery, Chief Scientific Officer and Sandy Estrada, Vice President, Medical Affairs. 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, Matt. Good afternoon, everyone, and thank you for joining us as we discuss the progress, results and outlook following the second quarter of 2019.

There continues to be strong interest and building momentum for T2Bacteria and T2Candida in the market, and we are pleased that new T2Bacteria customers that began testing patients during the first half of the year are tracking at or above our expectations in terms of test utilization. To build on this, today we announced several updates that put T2 in a strong position to execute on our growth strategy and drive adoption of T2Bacteria.

First, we are pleased to report that we have entered into two financing agreements that provide us with the possibility to access to up to $60 million of capital at market levels. These agreements provide us with flexibility to access capital and timing of selling shares are at the option of the company, subject to certain limitations on volume. With certain limitations, these vehicles allow capital to be raised solely at the option of the Company and we plan to be opportunistic in accessing the capital markets, including through these agreements, We will remain open to other potential sources of additional capital, both from a traditional financing perspective and through business development opportunities.

Second, we have initiated a plan to potentially reduce our cash burn by up to 30% expected to get quarterly cash burn to less than $8 million per quarter by the fourth quarter of this year, without reducing the scope or efforts behind our commercial strategy and program.

In terms of the second quarter, we continued to secure new contracts and worked with new T2Bacteria customers through the validation and evaluation processes. Combined with steady growth from our T2Candida business, we achieved second quarter product revenue of $1.3 million and delivered 12 new contracts. Most importantly, revenue from T2Bacteria grew over 80% from Q1 as new customers went live in testing patients and testing from live accounts grew.

In June, we saw that the pace of new contract growth in the United States was slightly less than we expected. In addition, the time it takes customers in the United States and International markets to complete the validation and evaluation period was also proving to be longer than expected – tracking to an average of 6 to 9 months instead of 3 to 6 months. Together, these factors – slower new contract adds and slower ramp up periods – are impacting our revenue outlook for the second half of the year.

In addition, due to a delay in the closing of an anticipated contract, we now anticipate that a portion of the research revenue expected this year will shift from 2019 into 2020. The good news is that our confidence in this agreement being signed is unchanged, only the timing has changed – having been pushed back 3-4 months. If we deliver on our contracted activities, we will still receive the full agreed upon revenue, but it will roll over to next year. In addition, we continue to work on other partnership opportunities that could further grow research revenue and expand the applications of our technology to potentially open new market opportunities.

More importantly, we continue to see excitement and interest in our products and have a dynamic sales funnel that gives us confidence that the long-term opportunity for T2Bacteria remains strong and is growing. This is also evidenced by the experience and patient impact being realized by those hospitals who are live and using T2Bacteria to test patients at risk of sepsis. In light of these market dynamics, we continue to evolve our sales strategy based on an analysis of the first half of 2019 to further focus on the key drivers of more rapid contract wins and progress to customer utilization.

I will now provide some detail on the feedback and activity we saw in the field that is driving the measured pace of new contracts and systems coming online, and our go-forward strategy. In situations where our sales interaction is primarily with the hospital lab, we are seeing a slower sales and validation process, while in situations where this interaction is inclusive of the infectious disease and pharmacy specialists on the stewardship committees, we are seeing a faster process. Accordingly, we are placing a greater focus on reaching the infectious disease and pharmacy specialist members of the stewardship committee earlier in the process and honing our team’s capabilities and skills to sell into this group, which is different than selling directly into the hospital lab.

In April, we brought on a new Vice President of U.S. sales, Scott Isacksen, who is helping to drive this process. Scott has over 25 years of experience in healthcare sales, including significant experience building teams selling into the hospital and working in the antibiotics space. Importantly, he has sold to the same members of stewardship committees that we are focused on, as well as to hospital labs,

although to a lesser extent. We believe his background and experience will be helpful as we evolve our sales strategy and place more focus on pharmacy and infectious disease specialists, who appreciate the impact our products can have and can educate the lab and serve as an advocate for T2 in the sales process, as necessary. In addition to Scott we also added a National Accounts program focused on the large integrated delivery networks and group purchasing organizations.

Our refined strategy is also focused on accelerating utilization in existing accounts and helping customers move through the validation and evaluation process as fast as possible. The timeline for this process is extending beyond the 3-6 month period we had previously seen and expected, as more accounts are adding on a “mini-evaluation” phase after they have completed the process in order to fine tune their algorithm for which patients they will initially test with our products. Shortening the start up period is an important opportunity because once new accounts go live, we have been encouraged by the commercial ramp. This gives us confidence that we can see similar results with other customers and therefore we are placing a major focus on supporting them through the process, driven by our clinical specialists. As we have more customers up and running, this will help drive new contracts and utilization with other new customers as we can share utilization data and experiences.

Outside of the United States, our international business is performing well, though we are seeing some similar trends in terms of extended timeframes from implementation to live testing of patients. Interest is very high and our distribution partners are excited by the market opportunities in their respective territories. During the first half 2019, we entered distribution agreements covering five new international markets – Estonia, Greece, Ireland, Saudi Arabia and South Africa. We are now in 32 countries and have plans to continue expanding this year.

Taken altogether, we believe our strategy in the United States and expanded international market opportunity will allow us to deliver at least 10-15 new contracts in each of the third and fourth quarters of 2019 while also moving a greater portion of new U.S. T2Bacteria customers into full commercial mode. For context, if we are able to ramp up our existing global installed base alone to full utilization, we believe we could generate $30 to $35 million in product revenue annually on a recurring basis. So as the installed base grows, this annual opportunity grows with it.

As I said earlier, we are excited about the clinical benefits being realized by patients and hospitals based on T2Bacteria. I will now turn the call over to Sandy Estrada, our VP of Medical Affairs, for an update on T2Bacteria from a clinical perspective.

Sandy Estrada:

Thank you, John, and good afternoon. Through the first half of the year, we have been encouraged to see the first several U.S.-based T2Bacteria customers begin testing patients and beginning to scale that effort. I am excited to report that we have received a number of specific reports of T2 having a significant impact on patient care.

The first case I want to highlight comes from a hospital customer in the emergency department. A nursing home patient came to the ER with suspected pneumonia and was started on vancomycin, ceftazidime and clindamycin. T2Bacteria and blood cultures were ordered. T2Bacteria resulted positive for *K. pneumoniae* and negative for all other targets. Based on the institutions antibiotic protocol, therapy was changed to meropenem to effectively cover the *K. pneumoniae*. In addition, vancomycin

and clindamycin were discontinued due to *S. aureus* being negative. The patient rapidly improved, the patient's white blood cell count declined to normal and the patient was able to transfer back to the nursing home to complete seven days of meropenem therapy. In this case, the initial blood culture remained negative; without T2Bacteria the patient would have likely remained on three ineffective antibiotics and not received effective antibiotic therapy because they were blood culture negative, impacting patient care, costs and antimicrobial resistance.

The second case also comes from a hospital in the emergency department. An end-stage renal disease patient presented to the ER after becoming unresponsive during dialysis treatment. Sepsis was suspected and the patient was started on vancomycin and piperacillin-tazobactam. Both a T2Bacteria test and blood culture were obtained. The T2Bacteria test was positive for *S. aureus* and negative for all other targets, and as a result, pipercillin-tazobactam was discontinued. Importantly, the utilization of T2Bacteria in this scenario allowed for the almost immediate de-escalation (after one dose) of unnecessary and potentially therapy could have been toxic to the kidneys.

The third case comes from a hospital with an admitted patient. An 81-year-old female was admitted with fever, weakness and confusion. She had a history of urinary tract infections, and the hospital took blood and urine cultures and provided IV antibiotics. The initial blood and urine cultures grew *E. coli* and the patient clinically improved on ceftriaxone and was eligible for discharge, however the treating physician wanted to wait to confirm that a follow-up blood culture was negative for 48 hours. Interestingly enough, one of the patient's family members was aware of T2Bacteria and requested the test be ordered to confirm that the *E. coli* was no longer present in the blood so the patient could be safely discharged. The hospital did not have T2Bacteria, however another hospital in their system was able to be run T2Bacteria for them. The T2Bacteria test resulted negative for *E.coli* and the patient was able to be discharged a day earlier, preventing additional cost as well as risk to the patient such as hospital associated infections, confusion and falls. We are now entering discussion with this hospital to obtain their own T2Dx instrument.

These are just three cases out of many that demonstrate the clinical value of T2Bacteria, the limitations of blood culture-based testing methods, and the importance of rapid pathogen identification and treatment. We are seeing the benefit of T2Bacteria across four categories of clinical uses: (1) T2 positive results that yield a faster time to effective therapy, (2) T2 negative results that lead to earlier antibiotic de-escalation, (3) T2 positive results that help avoid premature discharge and readmission in the emergency department, and (4) T2 negative results that help support earlier patient discharge. We are posting clinical cases every week and more can be found on our website.

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

Tom Lowery:

Thanks Sandy. Those are certainly exciting patient case studies. Since our last call in early May, T2 has participated in several medical meetings that provided us the opportunity to showcase T2Bacteria, T2Candida, T2Resistance and potential future applications of our technology. We plan to continue this activity at conferences this fall such as IDWeek 2019 in October, including in-booth presentations highlighting clinical cases and a poster presentation on T2Resistance.

At these meetings, we highlighted new T2Bacteria customer patient cases and experiences, which is an important part of our strategy to drive new interest and adoption. If you have not, I encourage you to view the presentation videos available on our website. In addition to presenting customer data on T2Bacteria and T2Candida, we also highlighted our new product pipeline and data supporting potential future uses of our technology. I will recap a few of the highlights now.

In the near-term, there is growing excitement and anticipation for the T2Resistance research-use-only panel, which we plan to make available by the end of the third quarter. The data from our presentations demonstrated that the T2Resistance Panel provides at least a two-day time advantage compared to conventional methods that are all based on blood culture and take up to 95 hours for a result. The feedback on this data and capability has been positive and we believe there is increasing demand for this panel. In addition to the research-use-only version, we remain on track for a CE Mark version by the end of this year which will allow for a commercial launch and for full scale testing of patients for clinical use outside of the US. We are excited about the enthusiasm we are seeing in Europe and other regions of the world for T2Resistance.

We have reached an exciting juncture in our T2Lyme development program. Our clinical data clearly demonstrates that the sensitivity of T2Lyme far exceeds that of currently on-market direct-from-blood PCR tests offered by CLIA laboratories, which are not available onsite at hospitals. We have completed two head-to-head clinical studies showing T2Lyme detects many more positives than these conventional PCR methods. Our initial clinical data shows that the overall percent agreement of T2Lyme with confirmed infection by culture from tissue biopsy exceeds that of seroconversion, the CDC recommended 2-tier test and blood PCR methods. Additionally, our specificity is 100%.

Based on review of our panel and early clinical data, FDA asked us to expand the scope of our intended use and pivotal study to include patients without an EM rash for both early and late stage Lyme disease. We now have frozen banked blood samples from over 300 patients. These patients include those with confirmed, probable, symptomatic Lyme disease with and without an EM rash. We are working with FDA on our proposed intended use and on their preferred approach for analyzing data from our clinical samples. As a result, our T2Lyme clinical study timeline will be extended, and if approved it will have a much broader label when we go to market.

An increasingly important application of our technology is the T2Candida auris RUO panel, which can help address the recently emerging superbug, *Candida auris*. This is highly relevant as hospitals prioritize the containment and elimination of this superbug. We recently had a customer in Europe begin using this panel for monitoring and controlling outbreaks in their hospitals. We believe is indicative of growing awareness and interest in this panel.

Outside of the traditional healthcare sector, we presented new data that shows that T2MR Technology can detect biothreat pathogens, enabling future panels that detect biothreat pathogens with no pre-culture required in whole blood, environmental samples, other biofluids, and swab samples with unprecedented sensitivity, like our other tests.

Lastly, we presented new data showing that the T2MR Technology has the potential to detect more than 250 pathogen species, providing coverage for greater-than-or-equal-to 99% of bloodstream infections. Our technology has also demonstrated the ability to potentially detect resistance markers for all blood-borne antibiotic resistance threats identified by the CDC. These diagnostic capabilities could allow us to develop a panel that provides comprehensive coverage of bloodstream infections – a next-generation product that has the potential to replace the use of blood culture, especially as an up-front screen for infections.

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

John Sprague:

Thank you, Tom. I will begin today with an overview of our new financing agreements, and then provide a review of the second quarter results and our updated guidance.

Today we announced that we have established an ATM facility and an equity credit line, which combined may enable us to possibly raise up to $60 million, subject to limitations. These will allow us to be laser focused on the execution of the T2Bacteria launch and the advancement of key development opportunities. Subject to the limitations of each agreement and under law, shares can be sold at our option and we anticipate accessing the capital under these agreements opportunistically and judiciously. We are pleased to have these agreements in place as a potential source of additional financing.

The key features of these agreements follow:

- Through the ATM, we can opportunistically and at our option direct Canaccord to use commercially reasonable best efforts to sell our common stock at prevailing market rates and raise up to $30 million.
- Through the equity line of credit, at our option we can sell shares of our common stock each day at market rates and raise up to $30 million. Pricing is equal to the average of the lowest closing share price of 3 days during the past 10 consecutive business days. Our partner, Lincoln Park Capital, is obligated to purchase shares of our common stock when we choose to draw on the equity line of credit,— subject to a cap on the total number of shares equal to 20% of our outstanding common stock if the price we are selling share is at or below $1.52 per share.
- Both options, subject to the limitations of each agreement, are not commitments by the company to issue shares, which is consistent with our strategy of opportunistically accessing capital on attractive terms based on market conditions.
- Both facilities enjoy low fees and simple capital structures relative to other potential sources of financing and include only the sale of straight common stock without warrants or other yield enhancements.

Second quarter 2019 financial results:

Second quarter 2019 total revenues were $1.8 million compared to last year’s second quarter revenues of $3.9 million.

Product revenues, primarily T2Candida Panel, T2Bacteria Panel and T2Dx Instrument sales, were $1.3 million, 8% higher than last year’s second quarter product revenues of $1.2 million and were driven by growing T2Bacteria Panel, T2Candida Panel and T2Dx Instrument sales. T2Bacteria Panel sales are ramping up and we are pleased to report that revenue increased over 80% from the first quarter of this year. We delivered 12 new system contracts in the second quarter of 2019 and 23 in the first half of 2019.

Research and grant contribution revenues were $0.5 million compared to $2.7 million in last year's second quarter.

Costs and expenses, excluding costs of product revenue, were $10.8 million, compared to $11.4 million in last year's second quarter and were at the low end of guidance. Total costs and expenses include depreciation and non-cash stock compensation of $2.0 million in the second quarter compared to $4.5 million in last year's second quarter, a decrease primarily due to last year's vesting of performance-based RSUs.

Operating margins were a loss of $13.8 million, compared to a loss of $10.9 million in last year's second quarter.

Net interest expense and other income was $1.9 million compared to $1.4 million in last year's second quarter.

Our net loss was $15.6 million, ($0.35) per share, compared to a net loss in last year's second quarter of $12.3 million, ($0.32) per share. Weighted average shares outstanding were 44.4 million compared to 38.3 million in last year's second quarter.

2019 Outlook:

The following forward-looking statements reflect estimates based on information as of July 30, 2019 and are subject to uncertainty.

For the full year 2019, we are revising our financial guidance as follows:

For the full year 2019, total revenue is expected to be $8.7 million to $9.6 million and we expect product revenues in the range of $5.7 million to $6.1 million. This considers lower than previously anticipated T2Bacteria system placements, partially offset by continued growth with T2Bacteria customers that are online, T2Candida and growth in our international business. Research and grant contribution revenues for the full year are expected to be in the range of $3.0 to $3.5 million, contingent on a possible research collaboration. As John noted, we have a pending contract that is expected to close 3 months later than previously anticipated.

For the third quarter, we expect product revenue to be in the range of $1.4 million to $1.5 million.

For 2019 we expect to close 43 to 53 T2Dx Instrument placement contracts, or 20 to 30 contracts in the second half of the year, and 10 to 15 in the third and fourth quarters.

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 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 we 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. This is confirmed by our early experience with T2Bacteria customers that went live during the first half, as these customers are on track or ahead of expectations in terms of ramping to this run rate.

We expect to take actions to reduce our cash burn rate to under $8 million per quarter by 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 and contingent on closing a research collaboration, are expected to be $10.5 million to $11.5 million in the third and fourth quarters of 2019 and $7.0 to $8.0 million absent the research collaboration in the fourth quarter. Total costs and expenses include non-cash depreciation and stock compensation of approximately $1.5 million per quarter. Non-cash stock compensation expenses may be impacted by the timing of performance-based RSU vesting.

Our cash and cash equivalents were $28.4 million at June 30, 2019, which we expect to take us through the second quarter 2020 without any additional capital from our ATM and equity credit line. We are currently compliant with the terms or our CRG debt facility. Our weighted average shares outstanding of 44.4 million may be impacted by stock option exercises and shares sold under the ATM and equity credit line.

Thank you and back to John McDonough for closing remarks.

John McDonough:

Thank you John. Before closing the call, I want to briefly address the leadership succession plan we announced in conjunction with our second quarter results. I am excited to report that I have been appointed Chairman of the company. After nearly 12 years serving as the founding CEO of T2 Biosystems, we will begin a process that will lead to a transition to a new CEO. I am delighted to move into this new role and I look forward to working with our Board – and ultimately a new CEO – through this process and beyond. We have created a breakthrough technology and in fact a new market with a whole new approach to diagnostics. We have received FDA clearance for three products, that we were told 10 years ago, was not possible. We have seen the benefits of these products on patient care in the United States and outside the United States and our commercialization efforts have just begun. At the same time, I have had the privilege to build the best management team I have ever worked with and a team that is totally committed to patient care. We are reshaping medicine as it relates to the treatment of sepsis. I have always believed that a CEO should transition at least after 10 years and for that and for personal reasons, this is the right time for me to transition the CEO role. I will be working closely with the Board as we begin the process to find the right person to lead the Company through our next phase of growth and I look forward to working with this person through a smooth transition while taking on

this new role after he or she comes on board. We have just initiated a national search for a new CEO, and while it is difficult to predict the timeline of the succession, I plan to remain in my current position until a successor is identified and onboarded to ensure a seamless transition.

It is my firm belief and that of many industry luminaries, that the T2MR technology is one of the seminal breakthroughs in the identification of human pathogens and resistance markers directly from patient samples, and as such will be responsible for the sparing of countless lives over time. It has been my pleasure to have played this role in bringing it to market and establishing it as a new standard in rapid sepsis diagnostics.

I want to take a moment to thank all of my past and current T2 colleagues for their hard work and dedication to our mission, and I look forward to continue pursuing our goals as Chairman of our Board of Directors. I look forward to seeing you at upcoming conferences and meetings.

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