# 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 1, 2018**

# T2 BIOSYSTEMS, INC.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-36571** | **20-4827488** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(IRS Employer Identification Number)** |

**101 Hartwell Avenue, Lexington, Massachusetts 02421**
**(Address of principal executive offices, including Zip Code)**

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

**N/A**
**(Former Name or Former Address, if Changed Since Last Report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

**Item 2.02 Results of Operations and Financial Condition**

On November 1, 2018, T2 Biosystems, Inc. (the "Company") issued a press release announcing its financial results for its fiscal quarter ended September 30, 2018 and held a conference call to discuss those results. A copy of the Company's press release and a copy of the transcript of the conference call are furnished with this report as Exhibits 99.1 and 99.2, respectively.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 and Exhibits 99.1 and 99.2 of this Current Report on Form 8-K are being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. Furthermore, such information, including Exhibits 99.1 and 99.2 attached hereto, shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly stated by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release issued November 1, 2018 |
| 99.2 | Transcript of conference call held by T2 Biosystems, Inc. on November 1, 2018 |

## EXHIBIT INDEX

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| --- | --- |
| 99.1 | Press release issued November 1, 2018 |
| 99.2 | Transcript of conference call held by T2 Biosystems, Inc. on November 1, 2018 |

**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 6, 2018

**T2 BIOSYSTEMS, INC.**

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

**Exhibit 99.1**

**T2 Biosystems Reports Third Quarter 2018 Financial Results and Provides Corporate Update**

Quarterly Product Revenue Up 71% Year-Over-Year

Reiterates 2018 Financial Guidance

LEXINGTON, Mass., November 1, 2018 (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 third quarter ended September 30, 2018.

**Third Quarter Business and Financial Performance Highlights:**

- Reported third quarter total revenue of $2.5 million, up 127% year-over-year.
- Reported third quarter product revenue of over $1.2 million, up 71% year-over-year.
- Secured 11 new placements of T2Dx® Instruments in the third quarter and 11 new hospital contracts.
- Increased targeted high-risk patients at newly contracted hospitals by an estimated 77,000.
- Continued enrolling patients in a pivotal clinical trial of the T2Lyme™ Panel and presented new data suggesting the T2Lyme Panel is more accurate than other diagnostic alternatives for identifying *Borrelia* infections for patients suspected of having early-stage Lyme disease.
- Highlighted T2Direct Diagnostics™, including the recently launched T2Bacteria® Panel, through customer and Company presentations at October's IDWeek 2018 and the World Antimicrobial Resistance Congress.

"We are solidly on track and making continual progress with the launch of the T2Bacteria panel, with robust interest from new customers driving 11 new T2Dx Instrument placements and 11 new hospital contracts in the third quarter. The feedback from the first commercial customers has been positive, and we are excited that more and more patients suspected of having sepsis will have access to our potentially lifesaving diagnostic technology," said John McDonough, president and chief executive officer. "Overall, the number of placements in the period keeps us on pace to achieve our revenue and placement guidance for 2018 and also contributes to our confidence and belief that our momentum in the market will enable us to deliver on our longer-term, high-growth goal to double our revenue in 2019 and 2020."

**Additional Financial Results:**

- Research revenues were $1.3 million, compared to $0.4 million in last year's third quarter.
- Costs and expenses, excluding cost of product revenue, were $8.6 million, a 25% decrease over last year's third quarter costs and expenses of $11.4 million and include depreciation and non-cash stock compensation from stock options and performance-based restricted stock grants (RSUs) of $2.4 million compared to $1.8 million in last year's third quarter, an increase primarily due to the vesting of RSUs.
- Operating margins were a loss of $9.2 million, a 26% decrease over last year's third quarter operating margin loss of $12.4 million.

Weighted average shares outstanding were 43.8 million this quarter compared to 31.4 million in last year's third quarter.

In October the company updated its shelf registration on Form S-3 to refresh the ability for future securities sales of up to $100 million, although the company has no intention of selling such securities at this time.

**Guidance:**

The company is reiterating the full year 2018 financial guidance:

- Total revenue is expected to be in the range of $10.5 million to $12.0 million, which implies an expectation of $1.8 million to $3.3 million in revenue in the fourth quarter. 2018 product revenue is expected to be in the range of $5.0 million to $5.9 million and 2018 research revenue is expected to be in the range of $5.5 million to $6.1 million.
- The company expects to secure placements of 20 to 25 T2Dx Instruments in the second half of 2018, implying that the fourth quarter will include 9 to 14 new system contracts. The company's third quarter performance achieved the goal of adding access to 75,000 high risk patients suspected of sepsis in the second half of 2018. The company expects to add at least 35,000 additional high risk patients in the fourth quarter.
- Operating expenses, excluding cost of product revenue, for the fourth quarter of 2018 is projected to be in the range of $10.8 million to $11.8 million, including non-cash depreciation and stock based compensation expenses from stock options and RSUs of approximately $2.8 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 1-855-327-6837 (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. 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, 2017, filed with the U.S. Securities and Exchange Commission, or SEC, on March 19, 2018, and other filings the company makes with the SEC from time to time. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management’s estimates as of the date of this press release. While the company may elect to update such forward-looking statements at some point in the future, unless required by law, it disclaims any obligation to do so, even if subsequent events cause its views to change. Thus, no one should assume that the Company’s silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. These forward-looking statements should not be relied upon as representing the company’s views as of any date subsequent to the date of this press release.

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T2 BIOSYSTEMS, INC.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Revenue: | | | | |
| Product revenue | $ 1,218 | $ 739 | $ 3,486 | $ 2,105 |
| Research revenue | 1,248 | 369 | 5,222 | 900 |
| Total revenue | 2,466 | 1,108 | 8,708 | 3,005 |
| Costs and expenses: | | | | |
| Cost of product revenue | 3,042 | 2,106 | 9,773 | 5,722 |
| Research and development | 2,725 | 5,880 | 11,193 | 19,577 |
| Selling, general and administrative | 5,873 | 5,559 | 19,238 | 17,192 |
| Total costs and expenses | 11,640 | 13,545 | 40,204 | 42,491 |
| Loss from operations | (9,174) | (12,437) | (31,496) | (39,486) |
| Interest expense, net | (1,836) | (1,718) | (4,910) | (5,008) |
| Other income, net | 243 | 79 | 402 | 260 |
| Net loss and comprehensive loss | $ (10,767) | $ (14,076) | $ (36,004) | $ (44,234) |
| Net loss per share — basic and diluted | $ (0.25) | $ (0.45) | $ (0.91) | $ (1.43) |
| Weighted-average number of common shares used in computing net loss per share — basic and diluted | 43,762,551 | 31,420,726 | 39,363,294 | 30,873,930 |

T2 BIOSYSTEMS, INC.

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

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 60,225 | $ 41,799 |
| Accounts receivable | 1,734 | 467 |
| Prepaid expenses and other current assets | 2,024 | 708 |
| Inventories | 3,337 | 1,344 |
| Total current assets | 67,320 | 44,318 |
| Property and equipment, net | 8,190 | 10,015 |
| Restricted cash | 180 | 260 |
| Other assets | 206 | 268 |
| Total assets | $ 75,896 | $ 54,861 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 551 | $ 648 |
| Accrued expenses and other current liabilities | 4,427 | 6,218 |
| Derivative liability | — | 2,238 |
| Notes payable | 3,399 | 40,696 |
| Deferred revenue | 762 | 1,736 |
| Current portion of lease incentives | 262 | 246 |
| Total current liabilities | 9,401 | 51,782 |
| Notes payable, net of current portion | 38,869 | 1,008 |
| Lease incentives, net of current portion | 553 | 731 |
| Deferred revenue, net of current portion | 91 | — |
| Derivative liability | 2,063 | — |
| Other liabilities | 1,157 | — |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2018 and December 31, 2017 | — | — |
| Common stock, $0.001 par value; 200,000,000 shares authorized; 44,038,754 and 35,948,900 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively | 44 | 36 |
| Additional paid-in capital | 325,740 | 267,421 |
| Accumulated deficit | (302,022) | (266,117) |
| Total stockholders' equity | 23,762 | 1,340 |
| Total liabilities and stockholders' equity | $ 75,896 | $ 54,861 |

**Third Quarter 2018 Financial Results and Business Update**
**Conference Call Script**

**FINAL**

**John McDonough – CEO Commentary**

**John Sprague – CFO Commentary**

**Zack Kubow (W2O) - Moderator**

November 1, 2018 – 4:30 pm ET

Leader Dial-In Number: 1-855-778-9850
Conference ID: 10005653

**Operator:**

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

Please go ahead, sir.

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**Zack Kubow**

Thank you, operator, and good afternoon everyone. Thanks for joining us for the T2 Biosystems third quarter 2018 financial results conference call. On the call to discuss the results and operational highlights for the quarter ended September 30, 2018, are President and CEO, John McDonough, and Chief Financial Officer, John Sprague. The executive team will open the call with some prepared remarks, followed by a question-and-answer period.

I would like to remind everyone that comments made by management today and answers to questions will include forward-looking statements. Those include statements related to T2 Biosystems' future financial and operating results and plans for developing and marketing new products. Forward-looking statements are based on estimates and assumptions as of today and are subject to risks and uncertainties that may cause actual results to differ materially from those expressed or implied by those statements, including the risks and uncertainties described in T2 Biosystems' Annual Report on Form 10-K filed with the SEC on March 19, 2018 and other filings the company makes with the SEC from time to time. The company undertakes no obligation to publicly update or revise any forward-looking statements, except as required by law.

With that, I'd like to turn the call over to President and CEO, John McDonough. John?

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**John McDonough:**

Thank you, Zack. Good afternoon, everyone, and thank you for joining us as we discuss the progress, results and outlook following our third quarter of 2018.

It feels great to report anticipated levels of progress and activity across the key areas for our business during the third quarter, headlined by a continued strong start to the launch of the

T2Bacteria Panel. We also remain on track with our new product pipeline, with several key milestones anticipated over the next 12 to 18 months. I will provide an update on each of these items in my prepared remarks, but first let’s take a high-level look at the financial results and commercial metrics from the quarter. After my remarks, our CFO John Sprague will provide a detailed review of our third quarter financial results and recap our guidance for the rest of the year.

In the third quarter, we reported total revenues of 2.5 million dollars and product revenue of over 1.2 million dollars. This was in-line with our expectations and primarily reflects activity related to sales of the T2Candida Panel and the T2Dx Instrument, as recent new placements related to the T2Bacteria Panel are mostly still in the implementation phase. Product revenue grew 71 percent from the third quarter of 2017, including continued increased T2Candida usage on a same-store basis. Sequentially, we were pleased that product revenue was relatively stable compared to the second quarter of 2018, given the summer seasonality we have seen in the past.

As it relates to the T2Bacteria launch, we achieved positive results in our first full quarter of selling across the key commercial metrics that will be the indicators of future growth. During the third quarter, we continued to build momentum with new instrument contracts, securing 11 contracts for the placement of 11 T2Dx Instruments. This will provide an estimated 77,000 new high-risk patients with access to a T2Dx, giving us more than 170,000 patients added on a year-to-date basis. We expect that the 11 new T2Dx Instruments that are or will be placed, will begin to drive recurring revenue from testing volume over the next 3 to 6 months. We believe this performance puts us in a strong position to achieve our guidance for 20 to 25 new contracts for placements in the second half of 2018 and our third quarter performance alone has exceeded our goal of adding access to 75,000 patients in the second half of 2018 so we will exceed this target and believe that we will add at least 35,000 additional high risk patients in the fourth quarter.

In addition, we had another strong quarter building our sales pipeline, with 15 proposals delivered in the quarter. Over the last 4 quarters, which includes the time period pre-FDA clearance during which customer interest began to grow given the pending FDA decision, we have delivered 76 proposals, which is 2 to 3 times higher than the prior year and indicative of an increased interest in T2Bacteria. To date, 11 of these proposals have turned into signed contracts and the remaining accounts with proposals remain actively engaged, leaving considerable opportunity to secure more contracts in the coming months and quarters.

As of September 30, 2018, we have 77 instruments placed or contracted to be placed, covering 170 hospitals worldwide. We estimate that each instrument in the U.S. may generate approximately 300 thousand dollars in recurring revenue every year once hospitals go live and ramp up testing of patients with T2Bacteria and T2Candida, which we estimate could take 12 to 18 months after the systems go live and begin to test patients.

Let’s turn now to discuss the ongoing launch of T2Bacteria. We continue to be highly active in the market, with our growing sales and marketing teams focused on converting the many hospitals that have expressed an interest in our products both before and after our FDA approval this summer, into active customers:

1) First, we are working with existing T2Candida customers to add T2Bacteria to their contracts. Our main priorities here have been to engage with customers, outline the contractual and practical processes for adding the T2Bacteria Panel, and understand their timelines. To-date, 6 existing customers have executed contract addendums to add T2Bacteria and we have received positive feedback from the majority of our other T2Candida customers. Over time, we anticipate the majority of our customers will add T2Bacteria.

2) Second, our targeted accounts include hospitals that treat a high volume of patients with bloodstream infections that can lead to sepsis, and, in most cases, our strategy is to gain a foothold at these institutions through the Emergency Department. There is strong interest from many of these hospitals, and we are encouraged that in many cases there is high interest on the customer side that is starting to allow us to move quickly through the sales process. That said, it is important to note that we still assume the average sales cycle for new hospitals will be in the range of 6 to 12 months until we begin to become a more standard testing technology.

3) Third, our team is working to support customers with installed systems to more efficiently progress through the installation and verification process, which has typically taken 3 to 6 months including delivery, calibration, training and the beginning of utilization of the platform. This is typical of other new diagnostic platforms, as is a gradual ramp in testing volume over time – even with fully validated and running commercial sites.

We are supporting our sales efforts with a variety of marketing initiatives, including e-marketing and educational webinars providing peer-to-peer education. We also are leveraging major industry meetings to showcase our products and to feed and drive the sales process. In early October, we had a strong presence at the ID Week meeting in San Francisco. In addition to our in-booth company activity, we had several customer poster presentations that were well accepted and strongly reinforced our value proposition. And last week, we highlighted the T2Bacteria and T2Candida Panels at the World Antimicrobial Resistance Congress. T2 was featured in a keynote presentation to a high-level audience of top thought leaders in stewardship, infectious disease, government, policy makers and academia. The speakers included infectious disease expert and T2 customer Dr. Cornelius Clancy, our Chief Scientific Officer, Tom Lowery, and a brave sepsis patient Mary Millard. Mary experienced tremendous suffering and has incurred approximately 3 million dollars of health care expenses to-date from downstream injuries and required ongoing treatments because a *Pseudomonas* bloodstream infection, a pathogen associated with sepsis, that took days to detect and treat appropriately. While she is lucky to be alive, for a patient in her circumstance today, the T2Bacteria Panel could detect that specific *Pseudomonas* pathogen within hours, likely allowing for effective treatment and removing a tremendous burden on the patient and on the healthcare system.

In terms of the commercial team, we grew the team from 12 to 15 by the end of the third quarter and remain on track to achieve our goal of 16 sales representatives by the end of the year. We have a strong team in place and are clearly benefitting from the top-grading of the majority of the team that we completed over the past 12 months.

In addition, to support the T2Bacteria launch we are building a small team of Medical Liaisons led by Sandy Estrada, who recently joined the team as our Vice President of Medical Affairs. Sandy is a Doctor of Pharmacy by training and implemented T2Candida at Lee Memorial Health System in Florida, one of our super-user accounts and the basis for some of the ongoing real-world clinical and economic research, so Sandy is ideally suited for this role. Her team is leading the clinical conversation process with customers, backing up the sales force with next-level support and implementation strategies and serving as an important resource for implementing our products once a contract is signed. This team, importantly, also frees up our sales reps to spend more time on the road visiting facilities, building awareness and securing new customer contracts. We currently have 2 Medical Liaisons supporting Sandy and the rest of the commercial team and are planning to hire 2 more in the near term.

Overall, our team is off to a great start with the launch of T2Bacteria, and we are proud to be changing the clinical conversation and the economic equation as it relates to sepsis prevention and management.

Pipeline and Other Commercial Efforts

Before turning the call over to John Sprague for the details of our Q3 financial performance, I'd like to provide a brief update on our pipeline and development efforts.

1. We continue to enroll patients in our FDA clinical trial for the T2Lyme diagnostic panel. The study will evaluate the clinical performance of T2Lyme compared to skin biopsy and/or detection of the C6 antigen. We expect this clinical trial to continue into 2019. In September, we presented new pre-clinical data suggesting that the T2Lyme Panel is more accurate than other diagnostics for identifying Borrelia infections for patients suspected of having early-stage Lyme disease. The data was presented at a conference hosted by the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the National Environmental Health Association (NEHA). It showed that the T2Lyme Panel was the most accurate diagnostic compared to tissue culture, with a 78% positive percent agreement (PPA) and 100% negative percent agreement (NPA). This compares to a 56% PPA and 92% NPA for the currently recommended diagnostic, two-tier serology. The 100% negative percent agreement of the T2Lyme Panel indicates greater specificity over serology resulting in less incidence of false positive results. We are encouraged by these results and look forward to continuing with our pivotal FDA trial. If approved, we believe T2Lyme can become the standard of care in an approximately 700-million-dollar market, and importantly improve patient outcomes by directly detecting the bacteria that enters the bloodstream from a tick bite potentially weeks before it is possible with current testing options.

2. On the development front, we have completed our final Allergan milestone for the T2Gram Negative Resistance Diagnostic Panel being developed through a partnership with Allergan and also supported by CARB-X. The panel, which will officially be known as the T2Carba Resistance+ Panel, could be used in the future to determine if a patient is resistant to the first-line therapy associated with certain deadly gram negative bacterial infections. The T2Carba Resistance+ Panel is the first-ever direct-from-blood antimicrobial resistance panel. This panel detects carbapenemase resistance genes, including KPC, NDM, OXA, VIM, and IMP, as well as AmpC (DHA, CMY), and Enterobacter and Klebsiella species. We met the Allergan milestone, ahead of schedule, and now plan to make it available to research customers in the first half of 2019. We introduced this panel at ID Week and plan to showcase T2Carba Resistance+ at medical meetings in 2019 and evaluate the timing and requirements for a clinical trial to support a submission to the FDA. As a reminder, T2 Biosystems owns exclusive worldwide distribution rights to the T2Carba Resistance+ Panel.
3. We are also making good progress in the development of an additional resistance panel as part of our collaboration with CARB-X. The panel focuses on additional bacterial species and resistance markers, including ESBL and gram-positive resistance. This panel in combination with our T2Carba Resistance+ Panel comprehensively addresses the most serious superbugs and resistance genes on the antibiotic-resistance threat list published by the CDC.

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

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**John Sprague:**

Thank you, John.

**Third quarter 2018 financial results:**

Third quarter 2018 total revenue was $2.5 million, a 127% increase over last year's third quarter revenues of $1.1 million.

Product revenues, primarily T2Candida Panel and T2Dx Instrument sales, were $1.2 million, a 71% increase over last year's third quarter product revenues of $0.7 million.

Research revenues were $1.3 million compared to $0.4 million in last year's third quarter.

Costs and expenses, excluding cost of product revenue, were $8.6 million, compared to $11.4 million in last year's third quarter and include depreciation and non-cash stock compensation from stock options and restricted stock unit, or RSU, grants of $2.4 million in the third quarter compared to $1.8 million in last year's third quarter, an increase primarily due to the vesting of performance-based RSUs.

Operating margins were a loss of $9.2 million, compared to a loss of $12.4 million in last year's third quarter.

Net interest expense and other income, net, were $1.6 million compared to $1.6 million in last year's third quarter.

Our net loss was $10.8 million, ($0.25) per share, compared to a net loss in last year's third quarter of $14.1 million, ($0.45) per share. Weighted average shares outstanding were 43.8 million compared to 31.4 million in last year's third quarter.

Our cash and cash equivalents were $60.2 million at September 30, 2018. We believe our cash and financing sources are sufficient through at least the first half of 2020, providing sufficient runway to demonstrate that the launch of T2Bacteria has changed the commercial trajectory of the company.

In October we updated our shelf registration on Form S-3 to refresh our ability for future securities sales of up to $100 million, although we have no intention of selling such securities at this time.

**First nine months of 2018 financial results:**

Revenues for the nine months ended September 30, 2018 were $8.7 million and increased 190% over revenues of $3.0 million for the nine months ended September 30, 2017.

Product revenues, primarily T2Candida Panel and T2Dx Instrument sales, were $3.5 million, a 67% increase over last year's product revenues to date of $2.1 million.

Research revenues were $5.2 million compared to research revenues last year to date of $0.9 million.

Costs and expenses, excluding cost of product revenue, were $30.4 million compared to $36.8 million last year to date and include non-cash depreciation and stock compensation from stock options and RSUs of $8.0 million year to date compared to $5.2 million last year to date and increased primarily due to the vesting of performance-based RSUs.

Operating margins were a loss of $31.5 million, compared to a loss of $39.5 million year to date last year.

Net interest expense and other income, net, were $4.5 million compared to $4.7 million last year to date.

Our net loss was $36.0 million, ($0.91) per share, compared to a net loss of $44.2 million, ($1.43) per share year to date last year. Weighted average shares outstanding were 39.4 million compared to 30.9 million last year to date.

**2018 Outlook:**

The following forward-looking statements reflect estimates based on information as of November 1, 2018 and are subject to uncertainty.

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

We expect total 2018 revenue to be $10.5 million to $12.0 million, which implies an expectation of $1.8 million to $3.3 million in revenue in the fourth quarter. Product revenue is expected to be in the range of $5.0 million to $5.9 million for 2018 and research revenue is expected to be in the range of $5.5 million to $6.1 million.

We expect revenue to at least double in each of 2019 and 2020 as the customer base grows and accounts go live testing with T2Bacteria and to achieve total revenue in 2020 in the range of at least $50 million.

In the second half of 2018, we expect to close contracts for the placement of 20 to 25 instruments. We delivered 11 new system contracts in the third quarter, implying that the fourth quarter will include 9 to 14 new system contracts.

On our last call, we estimated that these instrument placements were expected to provide access to at least 75,000 patients suspected of sepsis in the second half of the year, and the third quarter fully achieved that goal. We believe that we will add at least 35,000 additional high risk patients in the fourth quarter, thereby exceeding our target significantly. The number of high-risk patients is important as it represents the current existing market opportunity for the T2Candida and T2Bacteria Panels if every patient at hospitals under contract were tested at the time they showed symptoms of infection. However, as we stated on our last call, this metric is becoming increasingly difficult to accurately track and report, and ultimately will become less meaningful as we expand our installed base and drive adoption into this high-risk population, which will be reflected in our utilization and recurring T2Bacteria and T2Candida panel sales. Therefore, we will likely discontinue this metric after reporting results for the fourth quarter and full year 2018.

As John mentioned, it typically takes new instrument placements 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 the average sales price for the T2Bacteria panel to be $150 and for T2Candida Panel to hold at $200 per test. International distributors typically receive about a 30% discount.

We estimate that a single T2Dx Instrument is capable of running about 3,000 tests per year. Over time, as patient testing grows in the hospital, we expect each T2Dx Instrument to generate about $300,000 in annual revenue from the combination of T2Bacteria and T2Candida testing.

We expect quarterly operating expenses to be in the range of $10.8 million to $11.8 million in the fourth quarter 2018, including non-cash depreciation and stock based compensation of approximately $2.0 million and non-cash stock based compensation from performance-based RSUs of $0.8 million. Non-cash stock based 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 43.8 million may be impacted by stock option exercises.

Thank you and back to John McDonough for closing remarks.

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**John McDonough:**

Thank you, John. In summary, we continue to meet our goals and to make commercial progress. We are also encouraged by the ongoing roll-out of the T2Bacteria launch. We are delivering new system placements and contracts in line with expectations and are firmly on track to meet our guidance for the year, with momentum expected to continue to build in 2019 and beyond, as our installed base continues to grow and we drive higher volumes of recurring testing revenue. We remain confident that this will allow us to at least double our revenue in each of the next 2 to 3 full years.

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