

**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): **February 17, 2015**

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)

(718) 491-3400
(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))

Item 2.02 Results of Operations and Financial Condition

On February 17, 2015, T2 Biosystems, Inc. (the "Company") issued a press release announcing its financial results for its fiscal quarter and fiscal year ended December 31, 2014 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 February 17, 2015
99.2	Transcript of conference call held by T2 Biosystems, Inc. on February 17, 2015

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: February 19, 2015

T2 BIOSYSTEMS, INC.

By: /s/ John McDonough
John McDonough
President and Chief Executive Officer

2

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued February 17, 2015
99.2	Transcript of conference call held by T2 Biosystems, Inc. on February 17, 2015

3



FOR IMMEDIATE RELEASE

T2 Biosystems Reports 2014 Fourth Quarter, Full Year Results

LEXINGTON, Mass. — February 17, 2015 — T2 Biosystems (NASDAQ:TTOO) today reported operating highlights and financial results for the fourth quarter and year ended December 31, 2014. Recent operational highlights included:

- This month, the Company entered into a multi-year, strategic agreement with Canon U.S. Life Sciences, Inc. to jointly develop a novel diagnostic test to rapidly detect Lyme disease
- In January, results from the first large, multi-center clinical trial for T2Candida and the T2Dx were published in *Clinical Infectious Disease* and demonstrated 91.1% sensitivity and specificity of 99.4% for sepsis pathogen detection in 3-5 hours without the need for blood culture
- In January, an article supporting the use of T2MR® as a platform with the potential to significantly impact the field of diagnostics was published in *The Journal of the American Medical Association (JAMA)*
- In October, the T2Candida® Panel and the T2Dx® Instrument were included in four oral and poster presentations during IDWeek 2014™.

President and CEO John McDonough said, “The pace of commercial and operational progress and activity at T2 Biosystems accelerated as we closed out 2014 and entered the new year. Key clinical publications are providing even greater opportunities and evidence for our expanding sales organization to engage with target facilities throughout the US and we are very encouraged by those initial interactions and the number of institutions that are now in various stages of the adoption process.”

Financial Results

Through the fourth quarter, the Company has generated revenue primarily from research and development agreements and government grants and has not generated any revenue from the sale of products. In the 2014 fourth quarter and full year, T2 Biosystems recorded \$119,000 of research and grant revenue for both periods, compared to \$55,000 and \$266,000 in the prior year periods. These amounts primarily consisted of revenue related to feasibility studies and co-development efforts with third parties.

Total operating expenses for the 2014 fourth quarter and full year were \$9.0 million and \$30.8 million, respectively, compared to \$5.7 million and \$20.0 million for the 2013 periods. The increases in operating expenses for the year were mainly associated with the directT2 pivotal clinical trial and other regulatory support and activity, research and development activities for additional applications of T2MR, expansion of marketing programs, build-out of the US commercial infrastructure, and increases in share-based compensation charges and incremental expenses related to being a public company.

The net loss applicable to common shareholders for the 2014 fourth quarter was \$9.1

million, or \$0.45 loss per share, compared to \$8.3 million (after adjustments for accretion of redeemable convertible preferred stock), or \$5.89 loss per share for the 2013 fourth quarter. The increased loss was principally due to increased operating expenses noted above. For 2014, the net loss applicable to common shareholders was \$36 million, or \$4.15 loss per share, compared to \$27.5 million, or \$19.72 loss per share for 2013. Loss per share calculations for each of the periods reported were impacted by the overall increase in common shares outstanding resulting from the August 7, 2014 initial public offering (IPO).

The Company’s balance sheet as of December 31, 2014, showed total cash and cash equivalents of \$73.8 million.

Conference Call

T2 Biosystems’ management will discuss the Company’s financial results for the fourth quarter and year ended December 31, 2014, and provide a general business update during a conference call beginning at 4:30 p.m. Eastern Standard Time today, Tuesday, February 17, 2015. To join the call, participants may dial 1-877-407-4018 (U.S.) or 1-201-689-8471 (International). To listen to the live call via T2 Biosystems’ website, go to www.t2biosystems.com, in the Events & Presentations section. A webcast replay of the call will be available for 30 days following the conclusion of the call in the Events & Presentations section of the website.

About T2 Biosystems

T2 Biosystems is focused on developing innovative diagnostic products to improve patient health. With two FDA-cleared products targeting sepsis and a range of additional products in development, T2 Biosystems is an emerging leader in the field of in vitro diagnostics. The Company is utilizing its proprietary T2 Magnetic Resonance platform, or T2MR, to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. T2MR enables the fast and sensitive detection of pathogens, biomarkers and other abnormalities in a variety of unpurified patient sample types, including whole blood, eliminating the time-consuming sample prep required in current methods. 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. 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, the performance of the Company’s diagnostic products and the ability to bring such products to market. These and other important factors discussed under the caption “Risk Factors” in the Company’s final

10-Q filed with the Securities and Exchange Commission on November 5, 2014, 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, it disclaims any obligation to do so, even if subsequent events cause its views to change. 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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- Tables to Follow —

T2 Biosystems, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	2013	2014	2013
Research and grant revenue	\$ 119	\$ 55	\$ 119	\$ 266
Operating expenses:				
Research and development expenses	5,210	4,290	19,782	14,936
Selling, general and administrative expenses	3,747	1,404	11,018	5,022
Total operating expenses	8,957	5,694	30,800	19,958
Loss from operations	(8,838)	(5,639)	(30,681)	(19,692)
Interest expense, net	(251)	(93)	(721)	(403)
Other income (expense), net	13	(642)	12	(515)
Net loss	\$ (9,076)	\$ (6,374)	\$ (31,390)	\$ (20,610)
Comprehensive loss	\$ (9,076)	\$ (6,374)	\$ (31,390)	\$ (20,610)
Reconciliation of net loss to net loss applicable to common stockholders:				
Net loss	\$ (9,076)	\$ (6,374)	\$ (31,390)	\$ (20,610)
Accretion of redeemable convertible preferred stock to redemption value	—	(1,910)	(4,570)	(6,908)
Net loss applicable to common stockholders	\$ (9,076)	\$ (8,284)	\$ (35,960)	\$ (27,518)
Net loss per share applicable to common stockholders - basic and diluted	\$ (0.45)	\$ (5.89)	\$ (4.15)	\$ (19.72)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders - basic and diluted	20,041,577	1,405,607	8,674,931	1,395,562

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

	December 31, 2014	December 31, 2013
Assets		
Current Assets:		
Cash and cash equivalents	\$ 73,849	\$ 30,198
Accounts receivable	201	—
Prepaid expenses and other current assets	1,156	195
Inventory	115	—
Total current assets	75,321	30,393
Property and equipment, net	2,760	1,118
Restricted cash	260	340
Other assets	480	34
Total assets	\$ 78,821	\$ 31,885

Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)

Current liabilities:		
Accounts payable	\$ 735	\$ 943
Accrued expenses and other current liabilities	3,662	1,319
Current portion of notes payable	295	1,759
Current portion of deferred rent	87	25
Deferred revenue	80	—
Total current liabilities	4,859	4,046
Notes payable, net of current portion	20,660	3,299
Deferred rent, net of current portion	106	45
Warrants to purchase redeemable securities	—	1,225
Other liabilities	195	—
Commitments and contingencies		
Redeemable convertible preferred stock	—	112,813
Stockholders' equity (deficit):		
Common stock, \$0.001 par value; 200,000,000 and 28,254,907 shares authorized at December 31, 2014 and 2013, respectively; 20,041,645 and 1,411,986 shares issued and outstanding at December 31, 2014 and 2013, respectively	20	1
Additional paid-in capital	156,576	—
Accumulated deficit	(103,595)	(89,544)
Total stockholders' equity (deficit)	53,001	(89,543)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 78,821	\$ 31,885

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T2 Biosystems, Inc.
2014 Fourth Quarter Results
February 17, 2015

Operator: Greetings and welcome to the T2 Biosystems 2014 Fourth Quarter and Year-End Results Conference Call. At this time, all the participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. If anyone should require Operator assistance during the conference, please press star, zero on your telephone keypad. As a reminder, this conference is being recorded.

I would now like to turn the conference over to Mr. Matt Clawson, of Pure Communications. Thank you, Mr. Clawson, you may now begin.

Matt Clawson: Thank you, Operator. Good afternoon everyone and thanks for joining us for T2 Biosystems' 2014 Fourth Quarter and Year-End results call. On the call this afternoon to discuss results and operational milestones for the fourth quarter and full year ended December 31, 2014 are President and CEO John McDonough; Chief Financial Officer Marc Jones; and Dr. Tom Lowery, Chief Scientific Officer. John and Marc will begin the call with some prepared remarks followed by a question-and-answer period.

I would like to remind everyone that comments made by Management in response to questions today 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 results to differ materially from those expressed or implied by those statements including the risk and uncertainties described in T2 Biosystems' filings with the SEC, the risk factor section in its registrations statement on Form S-1 as well as other risks and uncertainties detailed in subsequent SEC filings. The Company undertakes no obligation to publically update or revise any forward-looking statements except as required by law.

With that, I would like to turn the call over to CEO John McDonough for his opening comments. Good afternoon John.

John McDonough: Thanks, Matt. Good afternoon everyone. Thank you for taking the time to join us for our call today. 2014 was a transformative year at T2 Biosystems, and the fourth quarter activity indicated strong momentum as we entered 2015.

As a reminder, our first commercial products, the T2Dx instrument and the T2Candida Diagnostic Panel, were cleared by the FDA in September and

1

commercial activities commenced shortly thereafter. While we expect the sales process and sales cycle to take 6 to 12 months to complete initially, our selling thesis to hospitals is straightforward.

T2Candida identifies the clinically relevant species of Candida, a fungal pathogen known to cause sepsis. Candida infections have the highest mortality rate of all of the sepsis pathogens averaging 40%. Published literature has demonstrated that the initiation of targeted therapy to infected patients within 12 hours can reduce the mortality rate to 11% and save approximately \$30,000 per patient driven by a reduction of the length of stay in the hospital and the intensive care unit. T2Candida runs on the T2Dx instrument, a fully automated instrument that processes the blood sample and provides results in three to five hours.

We know of no other system either on the market or in clinical trials that can test for these pathogens in blood and achieve clinically relevant results without culturing the sample — a process that takes days in most cases. We are also not aware of any technology available that could achieve the clinically relevant sensitivity that would be required to avoid the need for blood culture.

Following the FDA clearance, which we understand occurred in record time, marketing activities ramped and our commercial team was activated. We grew the direct sales team to 7 professionals in November, and we expect to add 3 or more additional sales representatives to the team over the next 60 to 90 days. As word of the technology is spreading, we believe that we are attracting some of the best sales professionals in the industry. We plan to grow the sales force to approximately 15 by the end of 2015.

The sales team is targeting the top 450 hospitals in the United States in terms of volume of high-risk patients. The top 450 hospitals represent about one-third of the estimated \$1.3 billion T2Candida market opportunity in the United States. As of today, we are engaged at some level with approximately 25% of the hospitals on the target list and we have been encouraged with the response and progress coming from those initial interactions.

As we indicated during the IPO process, our goal is to make placements in 30 or so of these high volume hospitals by the end of this year. Our plan is to work very closely with our initial customers, providing comprehensive support in implementing the platform while we learn how to best streamline the adoption and integration process within each hospital.

It is notable that our discussions with initial customer targets have been met with enthusiasm and a strong stated desire among many accounts to be among the first to implement T2Candida. There is a strong belief that our products can save lives and there is confirmation that the implementation of our products will drive significant cost savings within hospitals. To date, 9 hospitals have completed an economic analysis based on that individual hospital, and all of those analyses

2

have confirmed that there will be a strong return on investment when our product is adopted.

As we gain knowledge through the initial implementations and the programs that result in the fastest and greatest outcomes, we plan to replicate that business model to accelerate the size and scale of our customer base to drive significant revenue and growth.

It is important to note that on January 13, the clinical investigators involved in our FDA clinical trial published the data from the study in Clinical Infectious Diseases, a tier 1 publication and probably the most read by the infectious disease community. In addition to restating the data from our clinical trial that

demonstrated 91.1% overall sensitivity and 99.4% overall specificity, the publication cited several patient cases where T2Candida likely detected patients positive for a *Candida* infection that were missed by blood culture. In one case described in the paper, T2Candida detected a *Candida* infection that blood culture missed in 12 successive tests. Seven days after the T2Candida result was obtained, physicians performed an invasive procedure to obtain a tissue culture, which proved that the T2Candida result accurately identified a case of intra-abdominal candidiasis.

This paper demonstrates that the value of T2Candida goes beyond our ability to detect in 3 to 5 hours what blood culture based diagnostics takes 2 to 6 or more days, but that we can detect infections that can be completely missed by blood culture. The publication of this data has been extremely helpful and important to the hospitals we are speaking with regarding adoption.

I'd say the key take-aways from our first quarter of commercial activity are strong receptivity in the market — probably better than we had anticipated, excellent progress within our target hospital group, a deliberate and thoughtful process of adoption (as we anticipated) and a great deal of enthusiasm among those hospitals that are currently in the contracting process.

I'll turn the call over to Marc Jones for a quick run down of the financial results and a summary of our outlook for the key metrics, and I will wrap up our remarks with some color on our recent strategic announcement and how we view additional opportunities outside of our core business.

Marc?

Marc Jones: Thanks, John. As John indicated, we made excellent progress in our fourth quarter in terms of our milestones and infrastructure build. The fourth quarter and full year results reflect an investment of resources commensurate with those efforts, but those costs were well inline with anticipated levels and we are confident that we have established a disciplined cost-conscious culture and will continue to manage the spend well.

3

Through the fourth quarter, we generated revenue primarily from research and development agreements and government grants and have not generated any revenue from the sale of products. In the 2014 fourth quarter and full year, we recorded \$119,000 of research revenue for both periods, which primarily consisted of revenue related to feasibility studies and collaboration efforts with third parties.

Total operating expenses for the 2014 fourth quarter and full year were \$9.0 million and \$30.8 million, respectively, compared to \$5.7 million and \$20.0 million for the 2013 periods. The increases in operating expenses were mainly associated with the direct T2 pivotal clinical trial and other regulatory support and activity, research and development activities for additional applications of T2MR, expansion of marketing programs, build-out of the US commercial infrastructure, and increases in share-based compensation charges and incremental expenses related to being a public company.

The net loss for the 2014 fourth quarter was \$9.1 million, or \$0.45 loss per share, compared to \$8.3 million (after adjustments for accretion of redeemable convertible preferred stock), or \$5.89 loss per share for the 2013 fourth quarter. The increased loss was principally due to increased operating expenses which I just covered.

For 2014, the net loss after adjustments for accretion of redeemable convertible preferred stock was \$36.0 million, or \$4.15 loss per share, compared to a net loss of \$27.5 million, or \$19.72 loss per share for 2013. Loss per share calculations for each of the periods reported were impacted by the overall increase in common shares outstanding resulting from our August 7, 2014 initial public offering. Specifically for the fourth quarter of 2014, which was the first full quarter that included the conversion of the Preferred shares and the issuance of net common shares and the IPO, we had 20 million weighted average shares outstanding. For the 2014 full year, we had 8.7 million weighted average shares outstanding.

The Company's balance sheet as of December 31, 2014 had total cash and cash equivalents of \$73.8 million, which included \$19.7 million in proceeds, net of deferred financing costs, from two draws on the July 11, 2014 debt facility and approximately \$58.1 million in net proceeds from the August 6, 2014 initial public offering. In addition to the cash and the balance sheet, we are able to draw an additional \$10 million from our debt facilities through June 30, 2015.

Before I turn the call back to John for his final comments, I'd like to reiterate the outlook John laid out in our Q3 call.

- We anticipate the ramp of placements this year will be weighted to the second half of this year as our sales force is small and our selling efforts couldn't commence until we received FDA clearance. We expect that

4

60% or more of the initial 30 contracts will likely occur in the second half of 2015.

- When we close the contract with the hospital, we anticipate that it will take three to six months to install and verify the performance of a T2Dx instrument. This is completely consistent with the timeframes realized by other diagnostic platforms when they are initially installed.
- We anticipate that it could take an additional six to 12 months for a customer to ramp the testing of their high risk patients as they most likely will start by testing a segment of the high risk patient population.
- We estimate the average annual revenue per hospital could be as much as \$1 million among the top 450 hospital accounts if they were to test all of their high risk patients.

As you model our expenses going forward, we anticipate total Q1 operating expenses to grow in the range of 30% over Q4 largely resulting from the ongoing impact of commercialization investments we made in the fourth quarter of 2014, the calendar timing of certain R&D and marketing program expenses in Q1, 2015 and incremental expenses related to the development collaboration with Canon. We anticipate approximately \$850,000 in non-cash expenses — primarily depreciation and stock-based compensation — during the period. We expect only marginal growth in expenses from Q2 through Q4 of 2015.

Additionally, through our partnership with Canon and other research development projects, we expect to book over \$200k in partner revenue in Q1.

With that, I will turn it back over to John.

John McDonough: Great, thanks Marc. Before we turn it over for Q&A, I would like to spend a few moments discussing our recently announced strategic news.

As you may have seen, earlier this month we announced that we entered into a multi-year, strategic agreement with Canon U.S. Life Sciences. We will be jointly developing a diagnostic test panel that can rapidly detect Lyme disease. If you are not aware, Lyme disease is a bacterial infection that is spread by ticks and is typically caused by 3 different bacteria species. If left untreated, Lyme Disease can cause chronic joint inflammation, neurological disorders and cognitive defects. The CDC estimates that more than 350,000 people are affected by Lyme disease each year, but the number of diagnosed cases is less than a tenth of that due to under reporting and poor diagnostic protocol and tests.

Importantly, about 3.4 million tests are run for Lyme disease each year. Those tests include serology, PCR and blood culture, which have low sensitivity and take approximately two to three weeks to provide results. Canon and T2

5

Biosystems see as significant opportunity to apply T2MR, in much the same way we are with our sepsis products. By detecting the specific bacterial species directly in whole blood in 3 to 5 hours, at limits of detection as low as 1 cfu/mL, there is the potential to significantly impact the health and well being of patients by enabling targeted species-specific therapy earlier, which may also take significant costs out of the healthcare system. Reimbursement structures are already in place, and we estimate this market opportunity at roughly \$700 million in the United States.

The deal with Canon provided \$2 million up front and additional milestone payments that could total \$8.5 million. We will retain exclusive worldwide commercialization rights of any products developed out of the collaboration and, if commercialized, we would pay Canon royalty payments.

We expect to commence this project shortly and are hopeful that we can enter an FDA clinical trial in less than 3 years.

Canon is a world-class company and is very keen on additional life science programs, so we will continue to explore ways to work together on other programs.

In addition to Canon, we continue to see a growing level of interest from third-parties who are interested in working with us to develop new applications based on the T2MR platform. We will continue to be highly selective in this process but see collaborations as one way to pursue the many application opportunities for T2MR without having to do it all ourselves. We will continue to report on these opportunities as they move from feasibility and research to full-scale development projects when appropriate.

Shifting to our internal pipeline, we continue to make progress on the development of our next two products, T2Bacteria focused on detecting bacterial targets associated with sepsis, and T2HemoStat, an instrument and diagnostic panel that will deliver rapid critical hemostasis measurements initially targeting the screening of trauma patients. These development efforts are on track with the timelines we discussed during the IPO with T2Bacteria on track to enter an FDA pivotal trial in the second half of this year and T2HemoStat on track to enter an FDA pivotal trial in the first half of 2016. We estimate that our total addressable market including T2Candida, T2Bacteria, T2HemoStat and now T2Lyme is over \$3.7 billion.

That concludes our update on the period, but I want to leave you with this thought. There is a clear and urgent need for fast and accurate sepsis diagnostic panels. That was demonstrated by the FDA's efficient clearance process, the new data included in the publication in Clinical Infectious Diseases and is now playing out with the positive reaction and interest we are receiving in the marketplace. We are pleased with the results from the early stages of our

6

commercial launch of T2Dx and T2Candida and are working diligently with the medical community to deliver our diagnostic panel to hospitals, physicians and patients, and we are very encouraged with their initial response.

With that, I'll turn the call over to the Operator for questions. Operator?

7
