UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2016

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 001-36571

T2 Biosystems, Inc.
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	**20-4827488** (I.R.S. Employer Identification No.)
101 Hartwell Avenue **Lexington, Massachusetts** (Address of principal executive offices)	**02421** (Zip Code)

Registrant's telephone number, including area code: **(781) 457-1200**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 7, 2016, the registrant had 30,431,301 shares of common stock outstanding.

T2 BIOSYSTEMS, INC.

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PART I.
FINANCIAL INFORMATION

Item 1.Financial Statements

T2 Biosystems, Inc.

Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 75,111	$ 73,662
Accounts receivable	379	369
Prepaid expenses and other current assets	955	838
Inventories, net	1,338	683
Total current assets	77,783	75,552
Property and equipment, net	13,628	10,655
Restricted cash	260	260
Other assets	331	358
Total assets	$ 92,002	$ 86,825
Liabilities and stockholders’ equity		
Current liabilities:		
Accounts payable	$ 895	$ 1,228
Accrued expenses and other current liabilities	5,036	4,162
Current portion of notes payable	11,495	4,449
Deferred revenue	817	2,146
Current portion of lease incentives	293	268
Total current liabilities	18,536	12,253
Notes payable, net of current portion	21,246	26,121
Lease incentives, net of current portion	864	1,076
Other liabilities	774	436
Commitments and contingencies		
Stockholders’ equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized; 30,431,301 and 24,175,381 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	30	24
Additional paid-in capital	239,692	195,800
Accumulated deficit	(189,140)	(148,885)
Total stockholders’ equity	50,582	46,939
Total liabilities and stockholders’ equity	$ 92,002	$ 86,825

See accompanying notes to condensed consolidated financial statements.

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, 2016	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Revenue:				
Product revenue	$ 580	$ 245	$ 1,168	$ 255
Research revenue	504	804	2,003	1,547
Total revenue	1,084	1,049	3,171	1,802
Costs and expenses:				
Cost of product revenue	1,894	829	4,701	832
Research and development	5,200	6,204	18,160	18,724
Selling, general and administrative	5,935	5,181	18,282	14,086
Total costs and expenses	13,029	12,214	41,143	33,642
Loss from operations	(11,945)	(11,165)	(37,972)	(31,840)
Interest expense, net	(876)	(501)	(2,416)	(1,455)
Other income, net	38	22	133	37
Net loss and comprehensive loss	$ (12,783)	$ (11,644)	$ (40,255)	$ (33,258)
Net loss per share — basic and diluted	$ (0.51)	$ (0.57)	$ (1.64)	$ (1.64)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	25,027,751	20,331,274	24,524,508	20,225,056

See accompanying notes to condensed consolidated financial statements.

T2 Biosystems, Inc.

Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine months ended September 30, 2016	Nine months ended September 30, 2015
Operating activities		
Net loss	$ (40,255)	$ (33,258)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,626	979
Stock-based compensation expense	3,659	2,899
Noncash interest expense	459	288
Deferred rent	(187)	(86)
Changes in operating assets and liabilities:		
Accounts receivable	(10)	(177)
Prepaid expenses and other assets	(118)	(28)
Inventories, net	(654)	(942)
Accounts payable	(132)	258
Accrued expenses and other liabilities	797	303
Deferred revenue	(1,328)	1,119
Net cash used in operating activities	(36,143)	(28,645)
Investing activities		
Purchases and manufacture of property and equipment	(4,594)	(6,100)
Decrease in restricted cash	—	80
Net cash used in investing activities	(4,594)	(6,020)
Financing activities		
Payment of offering costs for issuance of common stock in public offering	(385)	—
Proceeds from issuance of common stock and stock options exercises, net	736	1,168
Proceeds from private investment in public equity	39,723	—
Proceeds from notes payable, net of issuance costs	4,593	—
Repayments of note payable	(2,481)	(235)
Net cash provided by financing activities	42,186	933
Net increase (decrease) in cash and cash equivalents	1,449	(33,732)
Cash and cash equivalents at beginning of period	73,662	73,849
Cash and cash equivalents at end of period	$ 75,111	$ 40,117
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 1,881	$ 1,110
Supplemental disclosures of noncash investing and financing activities		
Accrued property and equipment	$ 133	$ 1,567

See accompanying notes to condensed consolidated financial statements.

T2 Biosystems, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Nature of Business

T2 Biosystems, Inc. (the “Company”) was incorporated on April 27, 2006 as a Delaware corporation with operations based in Lexington, Massachusetts. The Company is an *in vitro* diagnostic company that has developed an innovative and proprietary platform that enables rapid, sensitive and simple direct detection of pathogens, biomarkers and other abnormalities across a variety of unpurified patient sample types. The Company is using its T2 Magnetic Resonance platform (“T2MR”) to develop a broad set of applications aimed at reducing mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. The Company’s initial development efforts target sepsis, hemostasis and Lyme disease, areas of significant unmet medical need in which existing therapies could be more effective with improved diagnostics. On September 22, 2014, the Company received market authorization from the U.S. Food and Drug Administration (“FDA”) for its first two products, the T2Dx Instrument (“T2Dx”) and T2Candida Panel (“T2Candida”).

The Company has devoted substantially all of its efforts to research and development, business planning, recruiting management and technical staff, acquiring operating assets, raising capital, and, most recently, the commercialization of its products.

Liquidity

At September 30, 2016, the Company has cash and cash equivalents of $75.1 million and an accumulated deficit of $189.1 million. The future success of the Company is dependent on its ability to successfully commercialize its FDA approved products, obtain regulatory clearance for and successfully launch its future product candidates, obtain additional capital and ultimately attain profitable operations. Historically, the Company has funded its operations primarily through its August 2014 initial public offering, its December 2015 secondary public offering, its September 2016 private investment in public equity (“PIPE”) financing, private placements of redeemable convertible preferred stock and through debt financing arrangements.

The Company is subject to a number of risks similar to other newly commercial life science companies, including, but not limited to commercially launching the Company’s products, development and market acceptance of the Company’s product candidates, development by its competitors of new technological innovations, protection of proprietary technology, and raising additional capital.

Having obtained authorization from the FDA to market T2Dx and T2Candida, the Company has incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution. In addition, the Company expects that costs and expenses may increase as it continues the research and development of other product candidates and maintains, expands and protects its intellectual property portfolio. The Company may seek to fund its operations through public equity or private equity or debt financings, as well as other sources. However, the Company may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. The Company’s failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on the Company’s business, results of operations and financial condition and the Company’s ability to develop and commercialize T2Dx, T2Candida and other product candidates.

Management believes that its existing cash and cash equivalents at September 30, 2016, together with the additional remaining liquidity of up to $5.4 million available under an Equipment Lease Credit Facility (the “Credit Facility”) entered into in October 2015 to help the Company meet its capital equipment needs (Note 5), will be sufficient to allow the Company to fund its current operating plan for at least the next 12 months.

For more information, refer to the section titled “Liquidity and Capital Resources” in Item 2, Management’s Discussion and Analysis of Financial Condition and Results of Operations and the section entitled “Risk Factors” in the Annual Report on Form 10-K for the year ended December 31, 2015, for additional risks associated with our capital needs.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company’s financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States GAAP as defined in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”). The Company’s condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, T2 Biosystems Securities Corporation. All intercompany balances and transactions have been eliminated.

Unaudited Interim Financial Information

Certain information and footnote disclosures normally included in the Company’s annual financial statements have been condensed or omitted. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company’s Annual Report on Form 10-K for the year ended December 31, 2015.

The accompanying interim condensed consolidated balance sheet as of September 30, 2016, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2016 and 2015, the condensed consolidated statements of cash flows for the nine months ended September 30, 2016 and 2015 and the related financial data and other information disclosed in these notes are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements, and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company’s financial position as of September 30, 2016, and the results of its operations and its cash flows for the three and nine months ended September 30, 2016 and 2015. The results for the three and nine months ended September 30, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016, any other interim periods, or any future year or period.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company’s chief operating decision maker is the Chief Executive Officer. The Company views its operations and manages its business in one operating segment, which is the business of developing and launching commercially its diagnostic products aimed at reducing mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier.

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting the weighted-average number of shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method for outstanding stock options. For purposes of the diluted net loss per share calculation, stock options are considered to be common stock equivalents, but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share applicable to common stockholders was the same for all periods presented.

Guarantees

As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while each such officer or director is, or was, serving at the Company's request in such capacity. The term of the indemnification is the officer's or director's lifetime. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' liability insurance coverage that limits its exposure and enables the Company to recover a portion of any future amounts paid.

The Company leases office, laboratory and manufacturing space under noncancelable operating leases. The Company has standard indemnification arrangements under the leases that require it to indemnify the landlords against all costs, expenses, fines, suits, claims, demands, liabilities, and actions directly resulting from any breach, violation or nonperformance of any covenant or condition of the Company's leases.

In the ordinary course of business, the Company enters into indemnification agreements with certain suppliers and business partners where the Company has certain indemnification obligations limited to the costs, expenses, fines, suits, claims, demands, liabilities and actions directly resulting from the Company's gross negligence or willful misconduct, and in certain instances, breaches, violations or nonperformance of covenants or conditions under the agreements.

As of September 30, 2016 and December 31, 2015, the Company had not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

Revenue Recognition

The Company generates revenue from product sales, which includes the sale of T2Dx, consumable diagnostic tests and related services, and research and development agreements with third parties. The Company recognizes revenue in accordance with FASB ASC Topic 605, Revenue Recognition ("ASC 605"). Accordingly, the Company recognizes revenue when all of the following criteria have been met:

i. Persuasive evidence of an arrangement exists
ii. Delivery has occurred or services have been rendered
iii. The seller's price to the buyer is fixed or determinable
iv. Collectability is reasonably assured

If any of the above criteria have not been met, the Company defers revenue until such time each of the criteria have been satisfied.

Product revenue is generated by the sale of T2Dx and consumable diagnostic tests. The Company either sells T2Dx to customers, or retains title and places a T2Dx at the customer site pursuant to a reagent rental agreement. When a T2Dx is directly purchased by a customer, the Company recognizes revenue when all applicable revenue recognition criteria are met. When a T2Dx is placed under a reagent rental agreement, the Company's customers generally agree to long-term agreements, certain of which may include minimum purchase commitments and/or incremental charges on each consumable diagnostic test purchased, which varies based on the monthly volume of test cartridges purchased. Revenue from the sale of consumable diagnostic tests, which includes the incremental charge, is generally recognized upon delivery as a component of product revenue in the Company's consolidated statements of operations and comprehensive loss.

Direct sales of T2Dx include warranty, maintenance and technical support services for one year following the installation of a purchased T2Dx ("Maintenance Services"). After the completion of the initial Maintenance Services period, customers have the option to renew the Maintenance Services for additional one year periods in exchange for additional consideration. In addition, the Company may provide training to customers. The Company defers revenue from the initial sale of a T2Dx equal to the relative fair value of the one year of Maintenance Services and training and recognizes the amounts ratably over the service delivery period.

The Company warrants that consumable diagnostic tests will be free from defects, when handled according to product specifications, for the stated life of the product. To fulfill valid warranty claims, the Company provides a credit to its customers on future orders. Accordingly, the Company defers revenue associated with the estimated defect rates of the consumable diagnostic tests.

The Company does not offer rights of return for T2Dx or consumable diagnostic tests.

Shipping and handling costs incurred associated with products sold to customers are recorded as a cost of product revenue in the consolidated statement of operations and comprehensive loss. Shipping and handling costs billed to customers in connection with a product sale are recorded as a component of product revenue in the consolidated statements of operations and comprehensive loss.

For multiple-element arrangements, the Company identifies the deliverables included within each agreement and evaluates which deliverables represent separate units of accounting. The determination that multiple elements in an arrangement meet the criteria for separate units of accounting requires the Company's management to exercise judgment. The Company accounts for those components as separate elements when the following criteria are met: (1) the delivered items have value to the customer on a stand-alone basis; and, (2) if there is a general right of return relative to the delivered items, delivery or performance of the undelivered items is considered probable and within its control.

The consideration received is allocated among the separate units of accounting based on a selling price hierarchy. The selling price hierarchy is based on: (1) vendor specific objective evidence ("VSOE"), if available; (2) third party evidence of selling price if VSOE is not available; or (3) best estimated selling price ("BESP") if neither VSOE nor third party evidence is available. The Company generally expects that it will not be able to establish selling price using third-party evidence due to the nature of our products and the markets in which the Company competes, and, as such, the Company typically will determine selling price using VSOE or BESP.

When the Company establishes selling price using BESP, consideration is given to both market and Company-specific factors, including the cost to produce the deliverable and the anticipated margin on that deliverable, as well as the characteristics of markets in which the deliverable is sold.

Revenue earned from activities performed pursuant to research and development agreements is reported as research revenue in the consolidated statements of operations and comprehensive loss, using the proportional performance method as the work is completed, limited to payments earned, and the related costs are expensed as incurred as research and development expense. The timing of receipt of cash from the Company's research and development agreements generally differs from when revenue is recognized.

Product Recall

In July 2016, the Company initiated a voluntary recall and replacement of its T2Candida cartridges at certain customer sites because T2Candida was experiencing higher than normal invalid test rates as the T2Candida cartridges aged. As of June 30, 2016, as a result of this voluntary recall, the Company deferred revenue totaling $149,000 and recorded additional costs of product revenue of $41,000 related to returned products, which are no longer usable. As of September 30, 2016, the Company had $51,000 of deferred revenue and $9,000 of warranty reserve remaining, both related to this voluntary recall. The impact of the voluntary recall on T2Candida cartridges in inventory was not material to the condensed consolidated financial statements.

Cost of Product Revenue

Cost of product revenue includes the cost of materials, direct labor and manufacturing overhead costs used in the manufacture of consumable diagnostic tests sold to customers and related license and royalty fees. Cost of product revenue also includes depreciation on revenue generating T2Dx that have been placed with customers under reagent rental agreements; costs of materials, direct labor and manufacturing overhead costs on T2Dx sold to customers; and other costs such as customer support costs, royalties and license fees, warranty and repair and maintenance expense on T2Dx that have been placed with customers under reagent rental agreements.

Research and Development Costs

Costs incurred in the research and development of the Company's product candidates are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including activities associated with performing services under research revenue arrangements, and include salaries and benefits, stock compensation, research related facility and overhead costs, laboratory supplies, equipment and contract services.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

Standards Adopted

In April 2015, the FASB issued ASU No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs* ("ASU 2015-03"). This standard amends existing guidance to require the presentation of debt issuance costs in the balance sheet as a deduction from the carrying amount of the related debt liability instead of a deferred charge. It is effective for annual reporting periods beginning after December 15, 2015, but early adoption is permitted. Adoption of ASU 2015-03 is applied retrospectively. The Company adopted ASU 2015-03 during the nine months ended September 30, 2016, which resulted in a balance sheet reclassification of issuance costs of $22,000 recorded in prepaid expenses and other current assets and $102,000 in other assets to a reduction in the current portion of notes payable and notes payable, net of current portion as of December 31, 2015, respectively. The Company's adoption of this standard did not have an impact on its condensed consolidated results of operations or cash flows for the three and nine months ended September 30, 2016 and 2015.

In April 2015, the FASB issued ASU No. 2015-05, *Customer's Accounting for Fees Paid in a Cloud Computing Arrangement* ("ASU 2015-05"). The standard clarifies that customers in cloud computing arrangements should determine whether the arrangement includes a license of software by applying the same guidance as cloud service providers and eliminates the existing requirement for customers to account for software licenses acquired by analogizing to the guidance on leases. It is effective for annual periods beginning on or after December 15, 2015, including interim periods within those annual periods, and early adoption is permitted. Adoption of ASU 2015-05 can either be applied (1) prospectively to all arrangements entered into or materially modified after the effective date or (2) retrospectively. The Company adopted the guidance prescribed by ASU 2015-05 prospectively, and the new guidance did not have a material effect on its condensed consolidated financial statements.

Standards Issued, Not Adopted

In March 2016, the FASB released ASU No. 2016-09 *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09") which is intended to simplify income tax accounting for excess tax benefits, accounting for forfeitures, and employer statutory withholding. Under the current guidance, excess tax benefits that result from an award vesting or settling are recognized in additional paid-in capital in the period that they reduce cash taxes payable. This requires the provision to be computed on a with and without option basis and may result in net operating loss and credit carryforwards on the balance sheet being less than what is available on the tax return. Under the new guidance, the income tax effects of awards will be recognized as a component of income tax expense when the awards vest or are settled (regardless if cash taxes are reduced). For interim reporting purposes, companies will account for excess tax benefits and tax deficiencies as discrete items in the period during which they occurred. The guidance is effective for public entities for fiscal years beginning after December 15, 2016, and interim periods within those years. Early adoption is permitted, however all of the guidance included in the update must be applied when adopted. The Company must use a modified retrospective transition method for adopting and record the cumulative effect of all unrecognized benefits and any change in valuation allowances at the end of the prior tax period as an adjustment to retained earnings. The Company has not elected to early adopt ASU 2016-09 and is evaluating the new guidance and the expected effect on the Company's condensed consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-06, *Derivatives and Hedging (Topic 815): Contingent Put and Call Options in Debt Instruments* ("ASU 2016-06"), which applies to all issuers of or investors in debt instruments with embedded call or put options. ASU 2016-06 clarifies the requirements for assessing whether contingent call or put options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts. Entities performing the assessment under the guidance of ASU 2016-06 are required to assess the embedded call or put options solely in accordance with the four-step decision process. In addition, ASU 2016-06 clarifies what steps are required when assessing whether the economic characteristics and risks of call or put options are clearly and closely related to the economic characteristics and risks of their debt hosts. ASU 2016-06 is effective for financial statements issued for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years using the modified retrospective method for existing debt instruments. The Company is evaluating the new guidance and the expected effect on the Company's condensed consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"), which applies to all leases. Under ASU 2016-02, a right-of-use asset and lease obligation will be recorded for all leases, whether operating or financing leases, while the statement of operations will reflect lease expense for operating leases and amortization and interest expense for financing leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 and interim periods within those years, which is the year ended December 31, 2019 for the Company. Entities are required to use a modified retrospective approach of adoption for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. Full retrospective application is prohibited. The Company is evaluating the new guidance and the expected effect on the Company's condensed consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory* ("ASU 2015-11"). The standard simplifies the subsequent measurement of inventory by requiring inventory to be measured at the lower of cost and net realizable value for entities using the first-in-first out method of valuing inventory. ASU 2015-11 eliminates other measures required by current guidance to determine net realizable value. ASU 2015-11 is effective for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years and early adoption is permitted. The Company has not adopted ASU 2015-11 and does not expect the new guidance to have a material effect on its condensed consolidated financial statements.

In June 2014, the FASB issued amended guidance, ASU No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which is applicable to revenue recognition that will now be effective for the Company for the year ending December 31, 2018, as a result of the deferral of the effective date adopted by the FASB in July 2015. The new guidance must be adopted using either a full retrospective approach for all periods presented or a modified retrospective approach. Early adoption prior to the original adoption date of ASU 2014-09 is not permitted. The new guidance applies a more principles-based approach to revenue recognition. The Company is evaluating the new guidance and the expected effect on the Company's condensed consolidated financial statements.

In 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements – Going Concern* ("ASU 2014-15"), which is effective for annual periods ending after December 15, 2016. Early adoption is permitted. ASU 2014-15 provides new guidance on (1) management's responsibility in evaluating whether or not there is substantial doubt about a company's ability to continue as a going concern within one year from the date the financial statements are issued each reporting period and (2) related financial statement disclosures. The Company has not adopted the guidance prescribed by ASU 2014-15. If this standard had been adopted as of September 30, 2016, the Company believes that it would have concluded there was not substantial doubt about its ability to continue as a going concern. However, the Company faces certain risks and uncertainties, as further described in Note 1, "Nature of Business", that could affect this analysis and result in additional disclosures.

3. Fair Value Measurements

The Company measures the following financial assets at fair value on a recurring basis. The following tables set forth the Company's financial assets carried at fair value categorized using the lowest level of input applicable to each financial instrument as of September 30, 2016 and December 31, 2015 (in thousands):

	Balance at September 30, 2016	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash	$ 42,538	$ 42,538	$ —	$ —
Money market funds	32,573	32,573	—	—
Restricted cash	260	260	—	—
	$ 75,371	$ 75,371	$ —	$ —

	Balance at December 31, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash	$ 1,520	$ 1,520	$ —	$ —
Money market funds	72,142	72,142	—	—
Restricted cash	260	260	—	—
	$ 73,922	$ 73,922	$ —	$ —

For certain financial instruments, including accounts payable and accrued expenses, the carrying amounts approximate their fair values as of September 30, 2016 and December 31, 2015 because of their short-term nature. At September 30, 2016 and December 31, 2015, the carrying value of the Company's debt approximated fair value, which was determined using Level 3 inputs, including a market interest rate.

4. Supplemental Balance Sheet Information

Inventories

Inventories are stated at the lower of cost or market value on a first-in, first-out basis and are comprised of the following (in thousands):

	September 30, 2016	December 31, 2015
Raw materials	$ 448	$ 203
Work-in-process	555	287
Finished goods	335	193
Total inventories, net	$ 1,338	$ 683

Property and Equipment

Property and equipment consists of the following (in thousands):

	September 30, 2016	December 31, 2015
Office and computer equipment	$ 409	$ 395
Software	697	632
Laboratory equipment	4,462	4,112
Furniture	200	187
Manufacturing equipment	884	577
Manufacturing tooling and molds	139	71
T2 instruments and components	8,626	4,960
Leasehold improvements	3,353	3,332
Construction in progress	1,284	1,196
	20,054	15,462
Less accumulated depreciation and amortization	(6,426)	(4,807)
Property and equipment, net	$ 13,628	$ 10,655

Construction in progress is primarily comprised of equipment and leasehold improvement projects that have not been placed in service. T2 instruments and components is comprised of raw materials and work-in-process instruments that are expected to be used, or used to produce Company-owned instruments, based on the Company's business model and forecast, and completed instruments that will be used for internal research and development or reagent rental agreements with customers. Completed T2 instruments are placed in service once installation procedures are completed and are depreciated over five years. The Company has approximately $4.3 million and $1.9 million of Company-owned T2 instruments installed and depreciating as of September 30, 2016 and December 31, 2015, respectively. Depreciation expense for Company-owned T2 instruments placed at customer sites pursuant to reagent rental agreements is recorded as a component of cost of product revenue and totaled approximately $183,000 and $420,000 for the three and nine months ended September 30, 2016, respectively, and $28,000 for the three and nine months ended September 30, 2015. Depreciation expense for T2 instruments used for internal research and development is recorded as a component of research and development expense.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2016	December 31, 2015
Accrued payroll and compensation	$ 2,684	$ 2,418
Accrued research and development expenses	406	458
Accrued professional services	984	542
Other accrued expenses	962	744
Total accrued expenses	$ 5,036	$ 4,162

5. Notes Payable

Loan and Security Agreement

On July 11, 2014, the Company entered into a loan and security agreement (the "Note Agreement") with two lenders to borrow up to $30.0 million for operations. The Note Agreement allows the Company to borrow amounts in two tranches, up to $20.0 million (drawn in amounts not less than $10.0 million upon closing and the remainder drawn in amounts not less than $5.0 million draws) for tranche A and up to $10.0 million for tranche B. The Company borrowed the full $30.0 million available under tranches A and B by December 31, 2015.

Through December 31, 2015, the Company received proceeds of $29.7 million under tranches A and B, net of issuance costs.

The amounts borrowed under the Note Agreement are collateralized by substantially all of the assets of the Company, excluding intellectual property, and bear interest at the one-month LIBOR plus 7.05%, which was 7.57% on September 30, 2016. The Company paid interest only payments on the amounts borrowed under the Note Agreement through July 31, 2016. Beginning August 1, 2016, the Company began repaying and will continue to repay the amounts borrowed in equal monthly installments until the maturity date of July 1, 2019. The Note Agreement requires payment of a final fee of 4.75% of the aggregate original principal of amounts borrowed, which the Company is accruing over the term of the Note Agreement. In addition, amounts borrowed may be prepaid at the option of the Company in denominations of not less than $1.0 million, and any amounts prepaid are subject to a prepayment premium of 1.5% if prepaid prior to the first anniversary of the borrowing date, 1.0% if prepaid prior to the second anniversary of the borrowing date and after the first anniversary of the borrowing date, and 0.5% if prepaid prior to the maturity date and after the second anniversary of the borrowing date. The effective interest rate for the Note Agreement, including final fee interest and non-cash interest, is 10.01%.

The Note Agreement does not include any financial covenants, but does contain a subjective acceleration clause whereby upon an event of default, which includes a material adverse change in the business, operations, or conditions (financial or otherwise) of the Company or a material impairment of the prospect of repayment of any portion of the obligations, the lender may accelerate the Company's repayment obligations under the Note Agreement. In the event of default, the lender has first priority to substantially all of the Company's assets. The lender has not exercised its right under this clause, as there have been no such events. The Company believes the likelihood of the lender exercising this right is remote.

The Company assessed all terms and features of the Note Agreement in order to identify any potential embedded features that would require bifurcation or any beneficial conversion features. As part of this analysis, the Company assessed the economic characteristics and risks of the Note Agreement, including put and call features. The Company determined that all features of the Note Agreement are clearly and closely associated with a debt host and do not require bifurcation as a derivative liability, or the fair value of the feature is immaterial. The Company will continue to reassess the features to determine if they require separate accounting on a quarterly basis.

Equipment Lease Credit Facility

In October 2015, the Company signed the $10.0 million Credit Facility with Essex Capital Corporation (the "Lessor") to fund capital equipment needs. Under the Credit Facility, the Lessor will fund capital equipment purchases presented. The Company will repay the amounts borrowed in 36 equal monthly installments from the date of the amount funded. At the end of the 36 month lease term, the Company has the option to (a) repurchase the leased equipment at the lesser of fair market value or 10% of the original equipment value, (b) extend the applicable lease for a specified period of time, which will not be less than one year, or (c) return the leased equipment to the Lessor.

In April 2016 and June 2016, the Company completed the first two draws under the Credit Facility, of $2.1 million and $2.5 million, respectively. The Company will make monthly payments of $67,000 under the first draw and $79,000 under the second draw. The borrowings under the Credit Facility are treated as capital leases. The amortization of the assets conveyed under the Credit Facility is included as a component of depreciation expense.

6. Stockholders' Equity

Stock-Based Compensation

2006 Stock Incentive Plan

The Company's 2006 Stock Option Plan ("2006 Plan") was established for granting stock incentive awards to directors, officers, employees and consultants of the Company. Upon closing of the Company's IPO in August 2014, the Company ceased granting stock incentive awards under the 2006 Plan. The 2006 Plan provided for the grant of incentive and non-qualified stock options and restricted stock grants as determined by the Company's board of directors. Under the 2006 Plan, stock options were generally granted with exercise prices equal to or greater than the fair value of the common stock as determined by the board of directors, expired no later than 10 years from the date of grant, and vest over various periods not exceeding 4 years.

2014 Stock Incentive Plan

The Company's 2014 Plan, as amended in June 2016 ("2014 Plan", and together with the 2006 Plan, the "Plans"), provides for the issuance of shares of common stock in the form of stock options, awards of restricted stock, awards of restricted stock units, performance awards, dividend equivalent awards, stock payment awards and stock appreciation rights to directors, officers, employees and consultants of the Company. Since the establishment of the 2014 Plan, the Company has only granted stock options. Generally, stock options are granted with exercise prices equal to or greater than the fair value of the common stock on the date of grant, expire no later than 10 years from the date of grant, and vest over various periods not exceeding 4 years.

The number of shares reserved for future issuance under the 2014 Plan is the sum of (1) 823,529 shares, (2) any shares that were granted under the Plans which are forfeited, or lapsed unexercised and (3) an annual increase on the first day of each calendar year beginning January 1, 2015 and ending on January 1, 2024, equal to the lesser of (A) 4% of the shares outstanding (on an as-converted basis) on the final day of the immediately preceding calendar year, and (B) such smaller number of shares determined by the Company's board of directors. As of September 30, 2016 there were 280,314 shares available for future grant under the 2014 Plan.

Stock Options

During the nine months ended September 30, 2016, the Company granted options with an aggregate fair value of $6.6 million, which are being amortized into compensation expense over the vesting period of the options as the services are being provided. The following is a summary of option activity under the Plans:

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value
Outstanding at December 31, 2015	3,484,298	$ 8.79	7.64	$ 14,620
Granted	1,389,458	8.48		
Exercised	(160,614)	2.83		912
Cancelled	(450,048)	12.62		
Outstanding at September 30, 2016	4,263,094	8.51	7.62	7,240
Exercisable at September 30, 2016	2,084,863	6.59	6.20	6,543
Vested or expected to vest at September 30, 2016	3,865,325	8.38	7.45	7,196

Included in the stock options granted during the nine months ended September 30, 2016 are 166,066 options to purchase common stock granted to certain executive officers of the Company that vest upon the achievement of certain performance conditions, which include the attainment of specified operating result and regulatory targets, by December 31, 2017. The Company will continually evaluate the probability of achievement of each performance condition and will commence recognition of stock-based compensation expense on these awards in the period the achievement of each performance condition is deemed probable, including a catch-up adjustment from the grant date.

The weighted-average fair values of options granted in the nine month periods ended September 30, 2016 and 2015 were $4.76 per share and $8.91 per share, respectively, and were calculated using the following estimated assumptions:

	Nine months ended September 30, 2016	Nine months ended September 30, 2015
Weighted-average risk-free interest rate	1.42 %	1.69 %
Expected dividend yield	0.00 %	0.00 %
Expected volatility	61 %	55 %
Expected terms	6.0 years	5.9 years

Employee Stock Purchase Plan

The Company's 2014 Employee Stock Purchase Plan (the "2014 ESPP") provides initially for granting up to 220,588 shares of the Company's common stock to eligible employees. The 2014 ESPP plan period is semi-annual and allows participants to purchase the Company's common stock at 85% of the lower of (i) the market value per share of common stock on the first day of the offering period or (ii) the market value per share of the common stock on the purchase date. Each participant can purchase up to a maximum of $25,000 per calendar year in fair market value. In May 2016, participants purchased 40,000 shares of common stock under the 2014 ESPP, resulting in proceeds to the Company of $282,000.

Stock-Based Compensation Expense

The following table summarizes the stock-based compensation expense resulting from awards granted under stock incentive plans, including the 2014 ESPP, that was recorded in the Company's results of operations for the periods presented (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2016	**2015**	**2016**	**2015**
Cost of product revenue	$ 27	$ —	$ 86	$ —
Research and development	292	440	902	1,017
Selling, general and administrative	779	882	2,572	1,882
Total stock-based compensation expense	$ 1,098	$ 1,322	$ 3,560	$ 2,899

For the three and nine months ended September 30, 2016, $32,000 and $99,000 of stock-based compensation expenses was capitalized as part of inventory or T2 instruments and components, respectively.

As of September 30, 2016, there was $11.1 million of total unrecognized compensation cost related to unvested stock options granted under the Plans, including the unrecognized compensation expense of stock options with performance conditions deemed probable of vesting. Total unrecognized compensation cost will be adjusted for future changes in the estimated forfeiture rate. The Company expects to recognize that cost over a remaining weighted-average period of 2.7 years as of September 30, 2016.

Stock Purchase Agreement

Private Investment in Public Equity Financing

On September 21, 2016, the Company sold 6,055,341 shares of its common stock (the "Canon Shares") to Canon U.S.A., Inc. ("Canon") at $6.56 per share, the closing price on this date, for an aggregate cash purchase price of $39.7 million. On or before March 21, 2017, the Company has agreed to prepare and file with the Securities and Exchange Commission (the "Commission") a registration statement on Form S-3 for purposes of registering the resale of the Canon Shares, or if the Company is not eligible for the use of Form S-3 at that time, on or before June 21, 2017, the Company has agreed to prepare and file a registration statement on Form S-1, or on an alternative form that permits the resale of the Canon Shares, with the Commission.

7. Net Loss Per Share

Excluded from the calculation of diluted net loss per share applicable to common stockholders were 4,263,094 and 3,470,936 shares, for the three and nine month periods ended September 30, 2016 and 2015, respectively, related to options to purchase common shares. The shares are excluded because their effect would have been anti-dilutive for the periods presented.

8. Co-Development Agreement with Canon US Life Sciences

On February 3, 2015, the Company entered into a Co-Development Partnership Agreement (the "Co-Development Agreement") with Canon U.S. Life Sciences, Inc. ("Canon US Life Sciences") to develop a diagnostic test panel to rapidly detect Lyme disease. Under the terms of the Co-Development Agreement, the Company received an upfront payment of $2.0 million from Canon US Life Sciences, and the agreement includes an additional $6.5 million of consideration upon achieving certain development and regulatory milestones for total aggregate payments of up to $8.5 million. In October 2015, the Company achieved a specified technical requirement and received $1.5 million related to the achievement of the milestone. The Company is eligible to receive an additional $5.0 million under the arrangement, in two milestone payments of $2.0 million and $3.0 million, related to the achievement of additional development and regulatory milestones. All payments under the Co-Development Agreement are non-refundable once received. The Company will retain exclusive worldwide commercialization rights of any products developed under the Co-Development Agreement, including sales, marketing and distribution and Canon US Life Sciences will not receive any commercial rights and will be entitled to only receive royalty payments on the sales of all products developed under the Co-Development Agreement.

Either party may terminate the Co-Development Agreement upon the occurrence of a material breach by the other party (subject to a cure period).

The Company evaluated the deliverables under the Co-Development Agreement and determined that the Co-Development Agreement included one unit of accounting, the research and development services, as the joint research and development committee deliverable was deemed to be *de minimis*. The Company is recognizing revenue for research and development services as a component of research revenue in the condensed consolidated financial statements as the services are delivered using the proportional performance method of accounting, limited to payments earned. Costs incurred to deliver the services under the Co-Development Agreement are recorded as research and development expense in the condensed consolidated financial statements.

The Company recorded revenue of $370,000 and $469,000 during the three months ended September 30, 2016 and 2015, respectively, and recorded revenue of $1.5 million and $846,000 during the nine months ended September 30, 2016 and 2015, respectively, under the Co-Development Agreement.

9. Related Party Transactions

On September 21, 2016, Canon became a related party when the Company sold the Canon Shares to Canon at $6.56 per share, the closing price on this date, for an aggregate cash purchase price of $39.7 million. As of September 21, 2016, the Canon Shares represented 19.9% of the outstanding shares of common stock of the Company. In connection with the sale of the Canon Shares, the Company agreed to grant Canon certain board designation rights, including the right to initially appoint a Class I director to the Company's board of directors.

As disclosed in Note 8, on February 3, 2015, the Company entered into a Co-Development Partnership Agreement with Canon US Life Sciences, an affiliate of Canon, to develop a diagnostic test panel to rapidly detect Lyme disease. The Company recorded revenue of $370,000 and $469,000 during the three months ended September 30, 2016 and 2015, respectively, and recorded revenue of $1.5 million and $846,000 during the nine months ended September 30, 2016 and 2015, respectively, under the Co-Development Agreement with Canon US Life Sciences.

10. Subsequent Events

On November 1, 2016, the Company entered into a Co-Development, Collaboration and Co-Marketing Agreement (the "Agreement") with Allergan Sales, LLC ("Allergan Sales") to develop (1) a direct detection diagnostic test panel of six bacteria species directly in whole blood (the "T2Bacteria II Panel") and (2) a direct detection diagnostic test panel of six resistance markers directly in whole blood (the "T2GNR Panel" and, together with the T2Bacteria II Panel, the "Developed Products"). In addition, Allergan Sales will receive the right to co-market the Developed Products under the Agreement.

Under the terms of the Agreement, the Company will receive an upfront payment of $2 million from Allergan Sales and additional milestone payments upon achieving certain developmental milestones for total aggregate payments of up to $4 million. The Company will retain exclusive worldwide commercialization rights of any products developed under the Agreement, including distribution, subject to Allergan Sales' right to co-market the Developed Products. Allergan Sales, at its election, may co-market the Developed Products worldwide and will receive commission payments on its sales of Developed Products under the Agreement.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933 (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy, prospective products and product candidates, their expected performance and impact on healthcare costs, marketing authorization from the U.S. Food and Drug Administration (the "FDA"), regulatory clearance, reimbursement for our product candidates, research and development costs, timing of regulatory filings, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described under the sections in this Quarterly Report on Form 10-Q entitled "Item 1A.—Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Quarterly Report on Form 10-Q. These forward looking statements are subject to numerous risks, including, without limitation, the following:

- *our expectation to incur losses in the future;*
- *the market acceptance of our T2MR technology;*
- *our ability to timely and successfully develop and commercialize our existing products and future product candidates;*
- *the length of our anticipated sales cycle;*
- *our ability to gain the support of leading hospitals and key thought leaders and publish the results of our clinical trials in peer-reviewed journals;*
- *our ability to successfully manage our growth;*
- *our future capital needs and our need to raise additional funds;*
- *the performance of our diagnostics;*
- *our ability to compete in the highly competitive diagnostics market;*
- *our ability to obtain marketing authorization from the FDA or regulatory clearance for new product candidates in the United States or any other jurisdiction;*
- *federal, state, and foreign regulatory requirements, including FDA regulation of our product candidates; and*
- *our ability to protect and enforce our intellectual property rights, including our trade secret-protected proprietary rights in T2MR.*

These forward-looking statements represent our estimates and assumptions only as of the date of this Quarterly Report on Form 10-Q. Unless required by U.S. federal securities laws, we do not intend to update any of these forward-looking statements to reflect circumstances or events that occur after the statement is made or to conform these statements to actual results. The following discussion should be read in conjunction with the financial statements and notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2015, as supplemented or amended from time to time under "Item 1A.—Risk Factors" in our Quarterly Reports on Form 10-Q, and elsewhere in this Quarterly Report on Form 10-Q.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Item 1A.—Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Business Overview

We are an *in vitro* diagnostics company that has developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. We are using our T2 Magnetic Resonance platform ("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. Our initial development efforts utilizing T2MR target sepsis and hemostasis, which are areas of significant unmet medical need where existing therapies could be more effective with improved diagnostics. On September 22, 2014, we received market authorization from the FDA for our first two products, the T2Dx Instrument ("T2Dx"), and the T2Candida Panel ("T2Candida"), for the direct detection of *Candida* species in human whole blood specimens and independent of blood culture from patients with symptoms of, or medical conditions predisposing the patient to, invasive fungal infections. We have launched the commercialization of T2Dx and T2Candida in the United States, and we have built and continue to expand a direct sales force that is primarily targeting the top 450 hospitals in the United States that have the highest concentration of patients at risk for *Candida* infections. Our next three diagnostic applications are called T2Bacteria, T2HemoStat, and T2Lyme, which are focused on bacterial sepsis infections, hemostasis, and Lyme disease, respectively. In Q4 2015, we began collecting patient samples for our clinical trial for T2Bacteria. We hope to commercially launch the T2Bacteria Panel in 2017. We expect that existing reimbursement codes will support our T2Bacteria product candidate, and that the anticipated economic savings associated with T2Bacteria and T2Candida will be realized directly by hospitals. We believe our combined initial annual addressable market opportunity for sepsis, hemostasis and Lyme disease is over $3.7 billion in the United States alone, when the market opportunity for T2Candida, T2Bacteria, T2Lyme and our initial hemostasis diagnostic panel is combined. We believe the benefits of our proprietary technology platform, including the ability to rapidly and directly detect a broad range of targets in a wide variety of sample types, will have potential future applications within and outside of the *in vitro* diagnostics market, including the diagnosis of infectious disease, cancer, cardiac and other wellness applications, as well as environmental, food safety, industrial and veterinary applications.

We have never been profitable and have incurred net losses in each year since inception. Our accumulated deficit at September 30, 2016 was $189.1 million. Substantially all our net losses resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations. Having obtained authorization from the FDA to market T2Dx and T2Candida, we are incurring significant commercialization expenses related to product sales, marketing, manufacturing and distribution. In addition, we expect that our expenses will increase substantially as we continue the research and development of our other product candidates and maintain, expand and protect our intellectual property portfolio. Accordingly, we may seek to fund our operations through public equity or private equity or debt financings, as well as other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop and commercialize T2Dx, T2Candida and our other product candidates.

Our Commercial Products and the Unmet Clinical Need

Our initial FDA-authorized products, T2Dx and T2Candida, utilize T2MR to detect species-specific *Candida* directly from whole blood in three to five hours versus the one to five days required by blood culture-based diagnostics. This allows the patient to receive the correct treatment in four to six hours versus at least 48 hours for blood culture. The T2Candida runs on T2Dx and provides high sensitivity with a limit of detection as low as 1 CFU/mL, even in the presence of antimicrobial therapy.

Our T2Candida Panel

Our direcT2 pivotal clinical trial was designed to evaluate the sensitivity and specificity of T2Candida on T2Dx. The direcT2 trial consisted of two patient arms: a prospective arm with 1,501 samples from patients with a possible infection and a seeded arm with 300 samples, also obtained from patients with a possible infection. T2Candida and T2Dx demonstrated a sensitivity of 91.1 percent and a specificity of 99.4 percent. In addition, the speed to a species-specific positive result with T2Candida was 4.4 hours versus 129 hours with blood culture. A negative result from T2Candida was obtained in just 4.2 hours versus 120 hours with blood culture. The data and other information from the direcT2 pivotal clinical trial was published in January 2015 in Clinical Infectious Diseases.

Sepsis is one of the leading causes of death in the United States, claiming more lives annually than breast cancer, prostate cancer and AIDS combined, and it is the most expensive hospital-treated condition. Most commonly afflicting immunocompromised, critical care and elderly patients, sepsis is a severe inflammatory response to a bacterial or fungal infection with a mortality rate of approximately 30%. One out of approximately every two to three hospital deaths in the United States is attributable to sepsis. According to data published by the U.S. Department of Health and Human Services for 2011, the cost of treating sepsis is over $20 billion in the United States, or approximately 5% of the total aggregate costs associated with domestic hospital stays. Sepsis is typically caused by one or more of five *Candida* species or over 25 bacterial pathogens, and effective treatment requires the early detection and identification of these specific target pathogens in a patient’s bloodstream. Today, sepsis is typically diagnosed through a series of blood cultures followed by post-blood culture species identification. This method has substantial diagnostic limitations that lead to a delay of up to several days in administration of targeted treatment and the incurrence of unnecessary hospital expense. In addition, the Survey of Physicians’ Perspectives and Knowledge About Diagnostic Tests for Bloodstream Infections in 2015 reported that negative blood culture results are only trusted by 36% of those physicians. Without the ability to rapidly identify pathogens, physicians typically start treatment of at-risk patients with broad-spectrum antibiotics, which can be ineffective and unnecessary and have contributed to the spread of antimicrobial resistance. According to a study published by Critical Care Medicine in 2006, in sepsis patients with documented hypotension, administration of effective antimicrobial therapy within the first hour of detection was associated with a survival rate of 79.9% and, over the ensuing six hours, each hour of delay in initiation of treatment was associated with an average decrease in survival of 7.6%.

We believe our sepsis products will redefine the standard of care in sepsis management while lowering healthcare costs by improving both the precision and the speed of detection of sepsis-causing pathogens. According to a study published in the Journal of Clinical Microbiology in 2010, targeted therapy for patients with bloodstream infections can be delayed up to 72 hours due to the wait time for blood culture results, leading to the conclusion that more-rapid identification of the causative organism would be highly desirable to facilitate targeted treatment in the critical phase of septic illness. In another study published in Clinical Infectious Diseases in 2012, the delayed administration of appropriate antifungal therapy was associated with higher mortality among patients with septic shock attributed to *Candida* infection and, on that basis, the study stated that more rapid and accurate diagnostic techniques appear to be needed. Our pivotal clinical trial demonstrated that T2Candida can deliver actionable results as fast as three hours, with an average time to result of 4.2 hours, compared to the average time to result of one to six or more days typically required for blood-culture-based diagnostics, which we believe will enable physicians to make treatment decisions and administer targeted treatment to patients in four to six hours versus 24 to 144 hours for blood culture. We believe that T2Bacteria will also deliver actionable results within these timeframes because this diagnostic panel operates similarly to T2Candida and is designed to run on the same instrument as T2Candida.

Candida is the fourth leading hospital-acquired bloodstream infection, afflicting more than 135,000 patients per year in the United States, and the most lethal form of common bloodstream infections that cause sepsis, with an average mortality rate of approximately 40%. This high mortality rate is largely due to the elapsed time from *Candida* infection to positive diagnosis and treatment. According to a study published in Antimicrobial Agents and Chemotherapy, *Candida* mortality rate can be reduced to 11% with the initiation of targeted therapy within 12 hours of presentation of symptoms. Additionally, a typical patient with a *Candida* infection averages 40 days in the hospital, including nine days in intensive care, resulting in an average cost per hospital stay of more than $130,000 per patient. In a study published in the American Journal of Respiratory and Critical Care Medicine, providing targeted antifungal therapy within 24 hours of the presentation of symptoms decreased the length of hospital stay by approximately ten days and decreased the average cost of care by approximately $30,000 per patient. Furthermore, in April 2015, Future Microbiology published the results of an economic study regarding the use of T2Candida conducted by IMS Health, a healthcare economics agency. In that economic study, IMS Health demonstrated that an average hospital admitting 5,100 patients at risk for *Candida* infections could save approximately $5.8 million annually due to decreased hospital stays for patients, reduction in use of antifungal drugs, and other associated savings. The economic study further showed T2Candida can potentially reduce the costs of care by $26,887 per *Candida* patient and that rapid detection of *Candida* reduces patient deaths by 60.6%. Most recently, results from a data analysis of T2Candida for the detection and monitoring of *Candida* infection and sepsis were published comparing aggregated results from the use of T2Candida to blood culture-based diagnostics for the detection of invasive candidiasis and candidemia. The analysis included samples acquired from more than 1,900 patients. Out of 55 prospective patient cases that were tested with T2Candida and blood culture, T2Candida detected or likely detected 96.4% of the patients (53 cases) compared to detection of 60% of the patients (33 cases) with blood culture.

Additionally, the speed to result of the T2Candida, run on T2Dx, can help reduce the empiric overuse of ineffective, or even unnecessary, antimicrobial therapy. This inappropriate therapy is a driving force behind the spread of antimicrobial-resistant pathogens, which the United States Centers for Disease Control and Prevention recently called “one of our most serious health threats.”

Our T2Dx Instrument

Our FDA-authorized T2Dx is an easy-to-use, fully-automated, benchtop instrument utilizing T2MR for use in hospitals and labs for a broad range of diagnostic tests. To operate the system, a patient’s sample tube is snapped onto a disposable test cartridge, which is pre-loaded with all necessary reagents. The cartridge is then inserted into T2Dx, which automatically processes the sample and then delivers a diagnostic test result. Test results are displayed on screen or directly through the lab information system.

By utilizing our proprietary T2MR for direct detection, T2Dx eliminates the need for sample purification and analyte extraction, which are necessary for other optical-detection devices. Eliminating these sample processing steps increases diagnostic sensitivity and accuracy, enables a broad menu of tests to be run on a single platform, and greatly reduces the complexity of the consumables. T2Dx incorporates a simple user interface and is designed to efficiently process up to seven specimens simultaneously.

Our T2Bacteria Panel

We are also developing T2Bacteria, a multiplex diagnostic panel that detects six major bacterial pathogens associated with sepsis and, in conjunction with T2Candida and standard empiric therapy regimens, will enable the early, appropriate treatment of 95% of sepsis patients. FDA market authorization of T2Bacteria would expand our target market from 450 hospitals to 2,500 hospitals. T2Bacteria, which will also run on T2Dx, is expected to address the same approximately 6.75 million symptomatic high-risk patients as T2Candida and also a new population of patients who are at increased risk for bacterial infections, including an additional two million patients presenting with symptoms of infection in the emergency room setting. We expect that T2Bacteria will achieve similar performance capabilities and provide similar benefits as T2Candida, including similar time to results and limits of detection.

Our T2MR Platform

T2MR is a miniaturized, magnetic resonance-based approach that measures how water molecules react in the presence of magnetic fields. For molecular and immunodiagnostics targets, T2MR introduces particles to the sample that are coated with target-specific binding agents. If the target is present, the particles bind to and cluster around it, disrupting the surrounding water molecules and altering the magnetic resonance signal.

Another significant unmet clinical need that we believe can be addressed by T2MR is the timely diagnosis and management of impaired hemostasis, which is a potentially life-threatening condition in which a patient is unable to promote the formation of blood clots to stabilize excessive bleeding. For critical trauma patients with impaired hemostasis, diagnostic results are typically required in fewer than 45 minutes to aid clinicians in making the most effective treatment decisions. The need for rapid diagnosis is not met by current diagnostic methods, which typically involve multiple instruments and can take hours to process a patient specimen. As a result, physicians often make critical decisions for treatment of impaired hemostasis with limited or no diagnostic data. Within the hemostasis market, for trauma alone, there are over ten million patients in the United States annually who present with symptoms of impaired hemostasis. Approximately 80% of these patients are treated in a level 1 or 2 trauma center, 85% of which overlap with the 450 hospitals being targeted for T2Candida.

We believe T2MR is the first technology with the ability to detect directly from a clinical sample of whole blood, plasma, serum, saliva, sputum or urine, saving time and potentially improving sensitivity by eliminating the need for purification or the extraction of target pathogens. T2MR has been demonstrated to detect cellular targets at limits of detection as low as one colony-forming unit per milliliter (CFU/mL). More than 100 studies published in peer reviewed journals have featured T2MR in a breadth of applications.

Financial Overview

Revenue

We generate revenue from the sale of our products and from activities performed pursuant to research and development agreements.

Revenue earned from activities performed pursuant to research and development agreements is reported as research revenue using the proportional performance method as the work is completed, limited to payments earned, and the related costs are expensed as incurred as research and development expense.

Product revenue is derived from the sale of our instruments and related consumable diagnostic tests. We recognize product revenue from the sale of our instruments as soon as all applicable revenue recognition criteria have been met. In the majority of cases, we expect to place our instruments, under reagent rental agreements, in hospitals in exchange for long-term agreements, certain of which may include minimum commitments and/or an incremental charge on the purchase of our consumable diagnostic tests. Under this business model, we believe we will recover the cost of placing our instruments in hospitals through the margins realized from our consumable diagnostic tests. Our consumable diagnostic tests can only be used with our instruments, and accordingly, as the installed base of our instruments grows, we expect the following to occur:

- recurring revenue from our consumable diagnostic tests will increase and become subject to less period-to-period fluctuation;

- consumable revenue will become an increasingly predictable and important contributor to our total revenue; and

- we will gain economies of scale through the growth in our sales, resulting in improving gross margins and operating margins.

Revenue from consumables is based on the volume of tests sold and the price of each consumable unit.

Cost of Product Revenue

Cost of product revenue includes the cost of materials, direct labor and manufacturing overhead costs used in the manufacture of our consumable diagnostic tests sold to customers and related license and royalty fees. Cost of product revenue also includes depreciation on the revenue-generating T2Dx Instruments that have been placed with our customers under reagent rental agreements; costs of materials, direct labor and manufacturing overhead costs on the T2Dx Instruments sold to customers; and other costs such as customer support costs, warranty and repair and maintenance expense on the T2Dx Instruments that have been placed with our customers under reagent rental agreements. We manufacture the T2Dx Instruments and some of our consumable diagnostic tests in our facilities. We outsource the manufacturing of components of our consumable diagnostic tests to a contract manufacturer.

We expect cost of product revenue to increase and to initially exceed or represent a high percentage of our product revenue as we continue to invest in our manufacturing facilities and customer service organization and grow our installed customer base. We plan to continue to expand our capacity to support our growth, which will result in higher cost of revenue in absolute dollars. However, we expect cost of product revenue, as a percentage of revenue, to decline as revenue grows in the future.

Research and development expenses

Our research and development expenses consist primarily of costs, including costs incurred for the development of our technology and product candidates, technology improvements and enhancements, clinical trials to evaluate the clinical utility of our product candidates, and laboratory development and expansion, and include salaries and benefits, including stock-based compensation, research-related facility and overhead costs, laboratory supplies, equipment and contract services. Research and development expenses also include costs of delivering products or services associated with research revenue. We expense all research and development costs as incurred.

We expect that our overall research and development expenses may continue to increase in absolute dollars. We have committed, and expect to commit, significant resources toward developing additional product candidates, improving product performance and reliability, conducting ongoing and new clinical trials and expanding our laboratory capabilities.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of costs for our sales and marketing, finance, legal, human resources, business development and general management functions, as well as professional services, such as legal, consulting and accounting services. We expect selling, general and administrative expenses to increase in future periods as we commercialize products and future product candidates that receive marketing authorization or regulatory clearance and as our needs for sales, marketing and administrative personnel grow. Other selling, general and administrative expenses include facility-related costs, fees and expenses associated with obtaining and maintaining patents, clinical and economic studies and publications, marketing expenses, and travel expenses. We also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with being a public company. We expense all selling, general and administrative expenses as incurred.

Interest expense, net

Interest expense, net, consists primarily of interest expense on our notes payable and the amortization of deferred financing costs, partially offset by interest earned on our cash and cash equivalents.

Other income, net

Other income, net, primarily consists of government grant income.

Critical Accounting Policies and Use of Estimates

We have prepared our condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States. Our preparation of these condensed consolidated financial statements requires us to make estimates, assumptions, and judgments that affect the reported amounts of assets, liabilities, expenses, and related disclosures at the date of the condensed consolidated financial statements, as well as revenue and expenses recorded during those periods. We evaluated our estimates and judgments on an ongoing basis. We based our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions.

The items that we disclosed as our critical accounting policies and estimates in Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2015 remain materially consistent. For a description of those critical accounting policies, please refer to our Annual Report on Form 10-K filing for the year ended December 31, 2015.

Results of Operations for the Three Months Ended September 30, 2016 and 2015

	Three months ended September 30, 2016	Three months ended September 30, 2015	Change
	(in thousands)		
Revenue:			
Product revenue	$ 580	$ 245	$ 335
Research revenue	504	804	(300)
Total revenue	1,084	1,049	35
Costs and expenses:			
Cost of product revenue	1,894	829	1,065
Research and development	5,200	6,204	(1,004)
Selling, general and administrative	5,935	5,181	754
Total costs and expenses	13,029	12,214	815
Loss from operations	(11,945)	(11,165)	(780)
Interest expense, net	(876)	(501)	(375)
Other income, net	38	22	16
Net loss	$ (12,783)	$ (11,644)	$ (1,139)

Product revenue

Product revenue was $580,000 for the three months ended September 30, 2016, compared to $245,000 for the three months ended September 30, 2015, an increase of $335,000. The increase was the result of an increase in sales volume of our products, primarily the sale of T2Candida consumable diagnostic tests, driven from growth in our installed T2Dx Instrument base.

Research revenue

Research revenue was $504,000 for the three months ended September 30, 2016, compared to $804,000 for the three months ended September 30, 2015, a decrease of $300,000. The decrease was primarily the result of lower revenue from services delivered under our Co-Development Agreement with Canon US Life Sciences, which decreased $99,000 over the prior year period, as well as a decrease in revenue from research and development agreements utilizing T2MR technology with other third parties.

Cost of product revenue

Cost of product revenue was $1.9 million for the three months ended September 30, 2016, compared to $829,000 for the three months ended September 30, 2015, an increase of $1.1 million. The increase was primarily due to increased sales of T2Candida Panels and T2Dx Instruments to customers, as well as an increase of $176,000 in unabsorbed manufacturing overhead, an increase of $142,000 in depreciation related to T2Dx Instruments placed at customer locations pursuant to reagent rental agreements, and an increase of $132,000 in cost to provide technical support services to customers,.

Research and development expenses

Research and development expenses were $5.2 million for the three months ended September 30, 2016, compared to $6.2 million for the three months ended September 30, 2015, a decrease of $1.0 million. The decrease was driven by $408,000 of lower payroll and related expenses, including $148,000 of decreased stock compensation expense, $321,000 of lower prototype development expenses, as prior year projects did not recur in the current year, $197,000 of lower consulting expenses due to replacing consultants with headcount and lower other research and development expenses of $320,000, which includes lower travel, lab and facilities expenses. Partially offsetting these declines is $242,000 of clinical expenses, associated with the T2Bacteria clinical trial.

Selling, general and administrative expenses

Selling, general and administrative expenses were $5.9 million for the three months ended September 30, 2016, compared to $5.2 million for the three months ended September 30, 2015. The increase of approximately $754,000 was due primarily to increased payroll and related expenses of approximately $492,000, net of $103,000 of decreased stock compensation expense, as we expanded our sales personnel, increased outside services expenditures of $189,000, increased travel expenses of $135,000 related to increased sales personnel, and slight increases to other selling, general and administrative expenses. These expenses were partially offset by a decline of $62,000 in lower marketing program spend and other expenses.

Interest expense, net

Interest expense, net, was $876,000 for the three months ended September 30, 2016, compared to $501,000 for the three months ended September 30, 2015. Interest expense, net, increased by $375,000 due to higher borrowing levels on our notes payable.

Other income, net

Other income, net, was $38,000 of net income for the three months ended September 30, 2016, compared to $22,000 for the three months ended September 30, 2015. Other income, net, increased by $16,000 due to higher income from our money market funds.

Results of Operations for the Nine Months Ended September 30, 2016 and 2015

	Nine months ended September 30,		
	2016	2015	Change
	(in thousands)		
Revenue:			
Product revenue	$ 1,168	$ 255	$ 913
Research revenue	2,003	1,547	456
Total revenue	3,171	1,802	1,369
Costs and expenses:			
Cost of product revenue	4,701	832	3,869
Research and development	18,160	18,724	(564)
Selling, general and administrative	18,282	14,086	4,196
Total costs and expenses	41,143	33,642	7,501
Loss from operations	(37,972)	(31,840)	(6,132)
Interest expense, net	(2,416)	(1,455)	(961)
Other income, net	133	37	96
Net loss	$ (40,255)	$ (33,258)	$ (6,997)

Product revenue

Product revenue was $1.2 million for the nine months ended September 30, 2016, compared to $255,000 for the nine months ended September 30, 2015, an increase of $913,000. The increase was the result of an increase in sales volume of our products, primarily the sale of T2Candida consumable diagnostic tests, driven from growth in our installed T2Dx Instrument base.

Research revenue

Research revenue was $2.0 million for the nine months ended September 30, 2016, compared to $1.5 million for the nine months ended September 30, 2015, an increase of $456,000. The increase was primarily the result of higher revenue from services delivered under our Co-Development Agreement with Canon US Life Sciences, which increased by $643,000, partially offset by decreased revenue from research and development agreements utilizing T2MR technology with other third parties.

Cost of product revenue

Cost of product revenue was $4.7 million for the nine months ended September 30, 2016, compared to $832,000 for the nine months ended September 30, 2015. The increase of $3.9 million was primarily the result of increased sales of T2Candida Panels and T2Dx Instruments to customers, as well as an increase of approximately $1.5 million of cost to provide technical support services to customers, approximately $886,000 of unabsorbed manufacturing overhead, and $380,000 of depreciation related to T2Dx Instruments placed at customer locations pursuant to reagent rental agreements.

Research and development expenses

Research and development expenses were $18.2 million for the nine months ended September 30, 2016, compared to $18.7 million for the nine months ended September 30, 2015, a decrease of $564,000. The decrease was primarily due to lower prototype development expenses of $893,000, as prior year projects did not recur in the current year, lower travel costs of $155,000, and decreased other research and development costs of $304,000, which includes lower consulting, facility and lab expenses. Partially offsetting the decrease were an increase of $616,000 in clinical expenses, primarily related to the T2Bacteria clinical trial and increased payroll and payroll-related expenses of $172,000, net of lower stock compensation expense of $115,000.

Selling, general and administrative expenses

Selling, general and administrative expenses were $18.3 million for the nine months ended September 30, 2016, compared to $14.1 million for the nine months ended September 30, 2015. The increase of approximately $4.2 million was due primarily to increased payroll and related expenses of approximately $3.1 million, including $690,000 of increased stock compensation expense, as we expanded our sales personnel, increased consulting, audit, public relations and patent fees of $875,000, increased travel expenses of $544,000 related to increased sales personnel and increased other selling, general and administrative expenses of $112,000. Partially offsetting these increases were lower marketing program expenditures of $449,000.

Interest expense, net

Interest expense, net, was $2.4 million for the nine months ended September 30, 2016, compared to $1.5 million for the nine months ended September 30, 2015. Interest expense, net, increased by $961,000 due to higher borrowing levels on our notes payable.

Other income, net

Other income, net, was $133,000 of net income for the nine months ended September 30, 2016, compared to $37,000 for the nine months ended September 30, 2015. Other income, net, increased by $96,000 due to higher income from our money market funds.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception, and as of September 30, 2016, we had an accumulated deficit of $189.1 million. We anticipate that we will continue to incur losses for at least the next couple of years. We expect that our costs and expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

We have been funding our operations principally from the sale of common stock and preferred stock, the incurrence of indebtedness, and revenue from research and development agreements.

As of September 30, 2016, we had cash and cash equivalents of approximately $75.1 million. We believe that our existing cash and cash equivalents, and additional liquidity of up to $5.4 million available under an Equipment Lease Credit Facility (the "Credit Facility") that was entered into in October 2015, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. Should our current operating plans not materialize as expected, and we are unable to obtain additional capital from the sources described on a timely basis, we may be required to change our current operating plans to reduce future expenses, which are within our control, in order to fund operations at reduced levels for at least the next 12 months.

Cash flows

The following is a summary of cash flows for each of the periods set forth below:

	Nine months ended September 30,	
	2016	2015
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (36,143)	$ (28,645)
Investing activities	(4,594)	(6,020)
Financing activities	42,186	933
Net increase (decrease) in cash and cash equivalents	$ 1,449	$ (33,732)

Net cash used in operating activities

Net cash used in operating activities was approximately $36.1 million for the nine months ended September 30, 2016, and consisted primarily of a net loss of $40.3 million adjusted for non-cash items including depreciation and amortization expense of $1.6 million, stock-based compensation expense of $3.7 million, non-cash interest expense of $459,000, deferred rent of $187,000, and a net change in operating assets and liabilities (use of cash) of $1.4 million, primarily related to an increase in inventory of $654,000 to support our commercial demand, prepaid expenses of $118,000 related to the amortization of insurance premiums and a decrease in deferred revenue of approximately $1.3 million primarily related to the recognition of revenue from our Co-Development Agreement with Canon US Life Sciences, partially offset by an increase in accounts payable and accrued expenses of $665,000 related to increased audit, clinical study and payroll accruals.

Net cash used in operating activities was approximately $28.6 million for the nine months ended September 30, 2015, and consisted primarily of a net loss of $33.3 million adjusted for non-cash items including depreciation and amortization expense of $979,000, stock-based compensation expense of $2.9 million, non-cash interest expense of $288,000, deferred rent of $86,000, and a net change in operating assets and liabilities (source of cash) of $533,000, primarily related to an increase in deferred revenue of approximately $1.1 million from an up-front payment received pursuant to our Co-Development Agreement with Canon US Life Sciences, an increase in accounts payable and accrued expenses of $561,000 related to growth in the business, partially offset by $942,000 in purchases of inventory, an increase in accounts receivable of $177,000 related to increased research and product revenue, and cash outflows from other working capital items totaling $28,000.

Net cash used in investing activities

Net cash used in investing activities was approximately $4.6 million for the nine months ended September 30, 2016 and consisted of costs to acquire components of and manufacture Company-owned instruments of $3.7 million, which are classified as property and equipment, $725,000 of purchases of laboratory and manufacturing equipment incurred to support commercialization efforts and research and development programs and $200,000 of other equipment and software purchases to support internal functions.

Net cash used in investing activities was approximately $6.0 million for the nine months ended September 30, 2015, and consisted of costs to develop Company-owned instruments of $3.5 million, which are classified as property and equipment, and purchases of laboratory equipment and leasehold improvements of $2.6 million incurred to support the growth of the business, partially offset by proceeds of $80,000 from the release of certain restricted cash balances.

Net cash provided by financing activities

Net cash provided by financing activities was approximately $42.2 million for the nine months ended September 30, 2016, and consisted primarily of proceeds from our September 21, 2016 PIPE financing with Canon of $39.7 million, in which we sold 6,055,341 shares of common stock at the closing price of $6.56 per share. Net cash provided by financing activities also consisted of $736,000 of proceeds from the exercise of stock options and sale of common stock under our 2014 Employee Stock Purchase Plan and $4.6 million of proceeds from the Credit Facility. Partially offsetting these sources of cash were $2.5 million of repayments of notes payable and $385,000 of payments of issuance costs from our December 2015 secondary offering.

Net cash provided by financing activities was approximately $933,000 for the nine months ended September 30, 2015, and consisted of $1.2 million of proceeds from the exercise of stock options and sale of common stock under our 2014 Employee Stock Purchase Plan, partially offset by $235,000 of repayments of notes payable.

Contractual Obligations and Commitments

Other than as described below, there were no other material changes to our contractual obligations and commitments from those described under Management's Discussion and Analysis of Financial Condition and Results of Operations in the Annual Report on Form 10-K for the year ended December 31, 2015.

In October 2015, we signed the $10.0 million Credit Facility with Essex Capital Corporation (the "Lessor") to fund capital equipment needs. Under the Credit Facility, the Lessor will fund capital equipment purchases presented. We will repay the amounts borrowed in 36 equal monthly installments from the date of the amount funded. At the end of the 36 month lease term, we have the option to (a) repurchase the leased equipment at the lesser of fair market value or 10% of the original equipment value, (b) extend the applicable lease for a specified period of time, which will not be less than one year, or (c) return the leased equipment to the Lessor. Through September 2016, we borrowed $4.6 million under the Credit Facility and commenced repayment.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under U.S. Securities and Exchange Commission ("SEC") rules.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk related to changes in interest rates. As of September 30, 2016, we had cash and cash equivalents of $75.1 million held primarily in money market funds consisting of U.S. government agency securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate one percent change in interest rates would not have a material effect on the fair market value of our portfolio. We are also subject to interest rate risk from the loans under our credit facility with Solar Capital, Ltd., which has an outstanding principal balance of $28.3 million as of September 30, 2016 and bears interest at an annual rate equal to the one-month LIBOR plus 7.05%.

A 10% increase in the one-month LIBOR annual rate would result in an immaterial increase in our annual interest expense under our credit facility with Solar Capital, Ltd., as a result of the current low interest rate environment.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

Management of the Company, with the participation of the Chief Executive Officer and the Chief Financial Officer, evaluated the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of September 30, 2016. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported on a timely basis and that such information is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding disclosure. Based upon this evaluation, the Chief Executive Officer and the Chief Financial Officer have concluded that the Company's disclosure controls and procedures were effective as of September 30, 2016.

(b) Changes in Internal Control over Financial Reporting

There have been no material changes to the Company's internal control over financial reporting during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II.
OTHER INFORMATION

Item 1. Legal Proceedings

We may be from time to time subject to various claims and legal actions during the ordinary course of our business. There are currently no claims or legal actions, individually or in the aggregate, that would have a material adverse effect on our results of operations or financial condition.

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2015, which could materially affect our business, financial condition or future results. There have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits, Financial Statement Schedules

Exhibit Number	Exhibit Description
3.1	Restated Certificate of Incorporation of the Company, as amended (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36571) filed on August 12, 2014)
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 of the Company's Form 8-K (File No. 001-36571) filed on August 12, 2014)
10.1*	Employment Letter Agreement, dated June 30, 2016, by and between the Company and Dr. Joanne Spadoro, Ph. D.
10.2*	Change of Control Severance Agreement, dated July 7, 2016, by and between the Company and Dr. Joanne Spadoro, Ph. D.
10.3	Stock Purchase Agreement, dated September 21, 2016, by and among Canon U.S.A., Inc. and the Company (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on September 22, 2016)
10.4	Voting and Standstill Agreement, dated September 21, 2016, by and among Canon U.S.A., Inc. and the Company (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K (File No. 001-36571) filed on September 22, 2016)
10.5	Registration Rights Agreement, dated September 21, 2016, by and among Canon U.S.A., Inc. and the Company (incorporated by reference to Exhibit 10.3 of the Company's Form 8-K (File No. 001-36571) filed on September 22, 2016)
31.1*	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.1*	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, formatted in XBRL: (i) Condensed Consolidated Balance Sheets (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited), (iii) Condensed Consolidated Statements of Cash Flows (unaudited), and (v) Notes of Condensed Consolidated Financial Statements.

* Filed herewith
** Furnished herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

	T2 Biosystems, Inc.
Date: November 8, 2016	By: /s/ John McDonough John McDonough President and Chief Executive Officer
	T2 Biosystems, Inc.
Date: November 8, 2016	By: /s/ Shawn Lynch Shawn Lynch Chief Financial Officer

T2 Biosystems

June 15, 2016

Joanne Spadoro
15 Stony Brook Road
Long Valley, NJ 07853

Dear Joanne:

On behalf of T2 Biosystems, Inc., (the "Company") I am delighted to make this offer of employment to you to join us in the role of Chief Operations Officer for the Company beginning no later than September 6, 2016.

At T2 Biosystems, our mission is to lower mortality rates, improve patient outcomes and reduce the cost of healthcare by empowering medical professionals to make targeted therapeutic treatment decisions earlier. As we proceed with the commercial launch of our first products, you are joining us at a very exciting time! In September 2014, we received FDA clearance to sell our first two products, the T2Dx Instrument and T2Candida Panel, which provide sensitive detection of specific sepsis-causing pathogens directly from a whole blood specimen in 3-5 hours versus 2-5 days for competitive detection methods. Published data has demonstrated that this improvement in time to detection may reduce the current mortality rate of 40% for those infections to 11%. We are truly excited to bring this product to market.

This speed and detection capability is made possible by our proprietary magnetic resonance-based diagnostic technology platform, called T2MR, which has been in development since our inception in 2006. Our next clinical applications for our T2MR technology will target bacterial sepsis, lyme disease and hemostasis, areas of significant unmet medical need where existing therapies could be more effective with improved diagnostics.

Joanne, we are excited to extend this offer of employment to you. We think you can help us fulfill our mission and we believe you will be a great fit with our team. To kick things off, you will find all of the pertinent information related to our offer of employment in the attached pages. Please read the offer carefully and, if it is acceptable, sign and return one copy to my attention (PDF copy is fine).

If you have any questions, please do not hesitate to contact me at (781) 457-1220 or email atjmcdonough@t2biosystems.com. We are looking forward to having you on our team!

Sincerely,

John McDonough
CEO & President

OFFER OF EMPLOYMENT

Date of employment: Should you accept the terms of this offer, your employment with the Company will commence by September 6, 2016 (“Hire Date”).

Background check: Your employment is contingent upon your successful completion of a background check, which is required for all employees of the Company. The Company will forward you the appropriate documents, and such documents shall be required to be submitted to the Company by no later than one week prior to your start date.

Position: You have been offered the position of Chief Operations Officer. In this capacity, you will report to John McDonough, Chief Executive Officer. Your duties and responsibilities will include all those customarily attendant to such a position, and any other such duties or responsibilities that John McDonough or the Company may, from time to time, assign to you. You agree that you shall not enter into any employment endeavors which may conflict with your ability to devote the necessary time and energies to the Company’s business interest while engaged by the Company. You further agree to comply with all applicable laws and with all Company rules and policies established by the Company from time to time.

Compensation and Tax Matters: Your base salary shall be $14,583.34, payable semi-monthly (the equivalent of $350,000 when annualized) (your “Base Salary”) and subject to pro-ration for any partial initial or terminal week during which you are employed, in accordance with the normal payroll practices and schedule of the Company.

You will be eligible to receive an annual bonus (the "Annual Bonus") based upon the achievement of specific company and individual milestones as determined by the Board of Directors. The target amount of your Annual Bonus will be 45% of your Base Salary, subject to adjustment by the Board of Directors. Payment of the Annual Bonus will be pro-rated for 2016 and will in all events be subject to your continued employment with the Company through the date of payment.

Additionally, the Company will provide you with relocation assistance in the amount of $115,000, which can be used at any time between now and June 30, 2017. The items eligible for reimbursement are attached to this letter. This financial assistance may be provided in the form of cash compensation and/or by the reimbursement of actual expenses incurred, however the total amount paid by the company will not exceed the $115,000 allowance limit. Should you voluntarily leave the Company prior to twelve (12) months from your Hire Date, or should the Company terminate your employment for cause, you agree you must refund to the Company the entire amount of relocation assistance received by you. If you voluntarily leave the Company more than twelve (12) months from your Hire Date, but prior to twenty-four (24) months from your Hire Date, you agree you must refund 50% of the relocation assistance that was paid to you. You further agree that the Company may deduct any such amounts remaining at the time of termination from amounts the Company owes you.

All compensation amounts stated are before any deductions for FICA taxes, state and federal withholding taxes and other payroll deductions required to be made by the Company under applicable law.

Stock Options: Subject to the approval of the Board of Directors and your execution of the Company's Stock Option Agreement, you will be offered options to purchase 146,600 shares of T2 Biosystems common stock under the Company's 2014 Incentive Award Plan (the "2014 Plan"). The exercise price of the options will be equal to their fair market value on the date of grant (determined in accordance with the 2014 Plan). The stock options will have a 4-year vesting schedule with 25% of the options vesting one year from the vesting commencement date (your start date) and the remaining options vesting in equal monthly installments over the following 36 months. The terms and conditions of such stock option grant are more fully described in the 2014 Plan.

Change of Control Severance Agreement: Subject to the approval of the Board of Directors and your execution of the attached Change of Control Severance Agreement (the "Change in Control Agreement"), you will be offered certain benefits in the event of a change in control of the Company, as set forth in more detail and defined in the Change in Control Agreement, including severance compensation and the acceleration of certain stock options, each such benefit to be subject to the terms of the Change in Control Agreement.

Fringe Benefits: You will have the opportunity to participate in the Company's fringe benefits program. Currently, these fringe benefits are as follows:

- The Company currently provides contributions toward a medical and dental plan for yourself and immediate family members

- Three (3) weeks paid vacation, Company designated holidays, personal holidays and sick days (see Benefits Summary for more information).

- The Company provides 100% contribution towards Term Life Insurance, Accidental Death and Dismemberment Insurance, and Short and Long-Term Disability Insurance;

- The opportunity to enroll in the Company's 401(k) Investment and Section 125 Plans based on plan eligibility requirements; and

- The Company shall pay or reimburse you in accordance with the Company's reimbursement policies from time to time in connection with the performance of your duties for the Company subject to your submission of satisfactory documentation with respect thereto.

The Company reserves the right to amend, delete or change any of its employment policies and/or benefits at any time in its sole discretion.

Non Competition/Non-Disclosure/Invention Assignment Agreement: No later than on the first day of your employment with the Company you will be required to sign the enclosed Non-Competition/Non-Disclosure/Inventions Assignment Agreement ("Obligations Agreement") which includes nondisclosure, inventions ownership, and other provisions that are necessary to protect the Company's confidential information, intellectual; property, trade secrets, and customer relationships. As you may be given access to such protectable interests, your employment is contingent upon your signing the Obligations Agreement. The terms of the Obligations Agreement will survive termination, for whatever reason, of the employment relationship.

Prior Agreements: You acknowledge and confirm that you have provided/disclosed to the Company all restrictive covenants and agreements, including nondisclosure and confidentiality agreements, to which you are a party. You agree that you shall not disclose to the Company or use while an employee of the Company any confidential or trade secret information obtained by you from other persons or employers and shall not bring any property upon the Company premises which has been misappropriated by others. You also acknowledge that the Company expects you to honor any prior obligations to former employers to which you remain bound.

Employment At Will: Although you are being hired as an employee commencing on September 1, 2016, your employment with the Company shall be at will. This means that your employment is not guaranteed for any definite period of time, and you or the Company may terminate your employment relationship with or without notice at any time and for any or no reason or cause. Other than as required by applicable laws, the Company is not bound to follow any policy, procedure, or process in connection with employee discipline, employment termination or otherwise.

Entire Agreement: This letter (together with the attached Obligations Agreement and Change in Control Agreement) sets forth the entire understanding between the Company and yourself with respect to your employment by the Company. All prior discussions, negotiations, correspondence and other understandings between you and the Company are superseded, and there are no representations, warranties or undertakings by the Company or you with respect to your employment by the Company, which are not set forth in this letter.

If you agree with the terms of this offer, please acknowledge your understanding and acceptance of this offer by signing where indicated below and return to me by 5:00 p.m. ET on June 23, 2016. We look forward to working with you.

Sincerely,

T2 Biosystems, Inc.

By: ______________________________

John McDonough Date
CEO & President

I have read agree with and accept the items contained in this letter.

By: ______________________________

Joanne Spadoro Date

The Immigration Control and Reform Act of 1986 requires that all new employees complete the I-9 form and submit proof of employment eligibility to work in the United States within the first three days of their start date. If accepting employment the Company will provide you the I-9 form and requests that you present appropriate documents when you report to the Company and a representative of the Company will complete the I-9 form with you. Accordingly, you will have three days from your start date to submit proof of your eligibility to work in the United States.

Exhibit 10.2

T2 BIOSYSTEMS, INC.

CHANGE OF CONTROL SEVERANCE AGREEMENT

July 7, 2016

Joanne Spadoro
15 Stony Brook Road
Long Valley, NJ 07853

Dear Joanne,

This letter sets forth the agreement between you and T2 Biosystems, Inc. (the "Company") regarding certain terms and conditions of your employment.

1. Severance Compensation. If your employment is terminated either by you with Good Reason within 12 months following a Change of Control, or by the Company without Cause within 3 months preceding or within 12 months following a Change of Control, subject to your executing and delivering to the Company, and not revoking, a release of claims in a form acceptable to the Company (the "Release") within the 30-day period following your termination of employment:

(a) the Company will pay you severance in an amount equal to 12 months of your then current annual base salary, payable in equal installments over a period of 12 months (the "Severance Period") in accordance with the Company's payroll practices, commencing on your termination of employment;

(b) if you have been continuously employed by the Company for less than one year as of the date your employment terminates, the vesting schedule of any equity awards of the Company held by you shall automatically be amended to state that all of the options subject to such equity award(s) scheduled to vest within 12 months of the date of your termination shall immediately accelerate and become fully vested, provided that with respect to any such awards intended to constitute "qualified performance based compensation" under Section 162(m) of the Code, whether a Change of Control has occurred shall be determined without regard to clause (iv) of the definition of Change of Control below;

(c) if you have been continuously employed by the Company for at least one year as of the date your employment terminates, all of the outstanding unvested equity awards of the Company held by you shall become fully vested and, if applicable, exercisable as of the date of your termination, provided that with respect to any such awards intended to constitute "qualified performance based compensation" under Section 162(m) of the Code, whether a Change of Control has occurred shall be determined without regard to clause (iv) of the definition of Change of Control below; and

(d) If you timely elect continued group medical and dental insurance coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company will reimburse you for a portion of the applicable premiums, based on the then-current cost-sharing rates for active employees, for you and your eligible dependents during the period commencing on the date of your termination of employment and ending on the earliest to occur of (a) the final day of the Severance Period, (b) the date you and/or your eligible dependents are no longer eligible for COBRA, and (c) the date you become eligible to receive medical insurance coverage from a subsequent employer (and you agree to notify the Company of such eligibility). Notwithstanding the foregoing, if the Company determines that it cannot provide such reimbursement of premiums to you without potentially violating applicable law, the Company shall in lieu thereof provide to you a taxable monthly payment in an amount equal to a portion of the applicable premiums, based on then-current cost-sharing rates for active employees, which payment will be made regardless of whether you elect COBRA continuation coverage and will commence in the month following the month in which your termination of employment occurs and end on the earliest to occur of (x) the final day of the Severance Period, (y) the date you and/or your eligible dependents are no longer eligible for COBRA, and (z) the date you become eligible to receive medical insurance coverage from a subsequent employer (and you agree to notify the Company of such eligibility).

Notwithstanding anything herein to the contrary, in the event that any compensation or benefit that constitutes "nonqualified deferred compensation" within the meaning of Section 409A (as defined below) becomes payable upon the occurrence of a Change of Control, such compensation or benefit shall not be paid unless such Change of Control constitutes a "change in control event" within the meaning of Section 409A.

2. Definitions. For purposes of this letter, the terms "Change of Control," "Cause," and "Good Reason" shall have the following meanings.

(a) "Change of Control" means that any of the following events has occurred:

(i) Any person (as such term is used in Section 13(d) of the Securities Exchange Act of 1934 (the "Exchange Act")), other than the Company, any employee benefit plan of the Company, or any entity organized, appointed, or established by the Company for or pursuant to the terms of any such plan, together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Exchange Act) becomes the beneficial owner or owners (as defined in Rule 13d-3 and 13d-5 promulgated under the Exchange Act), directly or indirectly (the "Control Group"), of more than 50% of the outstanding equity securities of the Company, or otherwise becomes entitled, directly or indirectly, to vote more than 50% of the voting power entitled to be cast at elections for directors ("Voting Power") of the Company, provided that a Change of Control will not have occurred if such Control Group acquired securities or Voting Power solely by purchasing securities from the Company, including, without limitation, acquisition of securities by one or more third party investors;

(ii) A consolidation or merger (in one transaction or a series of related transactions) of the Company pursuant to which the holders of the Company's equity securities immediately prior to such transaction or series of related transactions cease to be the holders, directly or indirectly, immediately after such transaction or series of related transactions of more than 50% of the Voting Power of the entity surviving such transaction or series of related transactions;

(iii) The sale, lease, exchange, or other transfer (in one transaction or series of related transactions) of all or substantially all of the assets of the Company; or

(iv) The liquidation or dissolution of the Company or the Company ceasing to do business.

(b) "Cause" means:

(i) Your conviction of a felony, either in connection with the performance of your obligations to the Company or which otherwise materially and adversely affects your ability to perform such obligations;

(ii) Your willful disloyalty to the Company or deliberate material dishonesty to the Company;

(iii) The commission by you of an act of fraud or embezzlement against the Company;

(iv) Your willful, substantial failure to perform any of your duties hereunder or your deliberate failure to follow reasonable, lawful directions of the Company's Board of Directors or your direct supervisor, which failure, if capable of being cured, is not cured within 30 days after delivery to you by the Company of written notice of such failure; or

(v) A material breach by you of any material provision of this letter which breach is not cured within 30 days after delivery to you by the Company of written notice of such breach.

(c) "Good Reason" means one or more of the following:

(i) A material change in the principal location at which you provide services to the Company, without your prior written consent;

(ii) A material and continuing diminution by the Company in the duties, authority or responsibilities of your position which causes such position to become of less responsibility or authority than immediately prior to such material and continuing diminution, provided that such change is not in connection with a termination of your employment hereunder by the Company (for purposes of clarity, if you are not the Chief Financial Officer of the combined public company following the Change of Control, you shall be deemed to have a material diminution of your duties);

(iii) A material reduction in your base salary or other benefits except if such a reduction is in connection with a general reduction in compensation or other benefits of all similarly situated employees of the Company;

(iv) Failure by the Company to obtain the assumption of this Agreement by any successor to the Company.

Notwithstanding the foregoing, Good Reason shall only exist if you have given written notice to the Company within 90 days of the initial existence of the Good Reason condition(s), and the Company has failed to cure such event(s) within 30 days of its receipt of said notice.

3. Section 409A.

(a) *Separation from Service*. Notwithstanding anything in this letter to the contrary, any compensation or benefit payable under this letter that is designated as payable upon your termination of employment shall be payable only upon your "separation from service" with the Company (a "Separation from Service") within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder (collectively, "Section 409A"), and except as provided below, any such compensation or benefits shall not be paid, or, in the case of installments, shall not commence payment, until the 30th day following your Separation from Service. Any installment payments that would have been made to you during the 30 day period immediately following your Separation from Service but for the preceding sentence shall be paid to you on the 30th day following your Separation from Service and the remaining payments shall be made as provided in this letter.

(b) *Specified Employee*. Notwithstanding anything in this letter to the contrary, if you are deemed by the Company at the time of your Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which you are entitled under this letter is required in order to avoid a prohibited distribution under Section 409A, such portion of your benefits shall not be provided to you prior to the earlier of (i) the expiration of the six-month period measured from the date of your Separation from Service with the Company or (ii) the date of your death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump-sum to you (or your estate or beneficiaries), and any remaining payments due to you under this letter shall be paid as otherwise provided herein.

(c) *Installments*. Your right to receive any installment payments under this letter shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

4. General

(a) No provision of this letter shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by you and by an authorized officer of the Company (other than you). No waiver by either party of any breach of, or of compliance with, any condition or provision of this letter by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time. The validity, interpretation, construction and performance of this letter shall be governed by the laws of the Commonwealth of Massachusetts without regard to conflicts of law. The invalidity or unenforceability of any provision or provisions of this letter shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect. This letter may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

(b) This letter contains the entire and exclusive agreement between the parties with respect to the subject matter hereof and is intended to supersede and replace all previous agreements, negotiations, and representations between the parties, whether written or oral, including any provision of the employment offer letter agreement between you and the Company, dated as of April 15, 2016, to the extent such letter addresses the subject matter hereof.

Sincerely,

T2 BIOSYSTEMS, INC.

By: ______________________________________
Name:
Title:

Acknowledged and Agreed

____
Joanne Spadoro

Exhibit 31.1

**CERTIFICATION
PURSUANT TO 17 CFR 240.13a-14
PROMULGATED UNDER
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, John McDonough, certify that:

1. I have reviewed this quarterly report on Form 10-Q of T2 Biosystems, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

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

Date: November 8, 2016

CERTIFICATION
PURSUANT TO 17 CFR 240.13a-14
PROMULGATED UNDER
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Shawn Lynch, certify that:

1. I have reviewed this quarterly report on Form 10-Q of T2 Biosystems, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Shawn Lynch
Shawn Lynch
Chief Financial Officer

Date: November 8, 2016

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of T2 Biosystems, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John McDonough, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

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

Date: November 8, 2016

This certification accompanies each Report pursuant to §906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of §18 of the Securities Exchange Act of 1934, as amended.

A signed original of this written statement required by §906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of T2 Biosystems, Inc. (the “Company”) on Form 10-Q for the period ending September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Shawn Lynch, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Shawn Lynch
Shawn Lynch
Chief Financial Officer

Date: November 8, 2016

This certification accompanies each Report pursuant to §906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of §18 of the Securities Exchange Act of 1934, as amended.

A signed original of this written statement required by §906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.