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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

OR

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

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

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 x No o

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 x No o

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 o	Accelerated filer o
Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of November 3, 2015, the registrant had 20,384,532 shares of common stock outstanding.

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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, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 40,117	$ 73,849
Accounts receivable	378	201
Prepaid expenses and other current assets	1,104	1,076
Inventories	1,057	115
Restricted cash	—	80
Total current assets	42,656	75,321
Property and equipment, net	9,448	2,760
Restricted cash, net of current portion	260	260
Deferred tax assets	313	313
Other assets	447	480
Total assets	$ 53,124	$ 79,134
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 993	$ 735
Accrued expenses and other current liabilities	4,291	3,662
Notes payable	1,417	295
Deferred revenue	1,199	80
Deferred tax liabilities	313	313
Lease incentives	241	87
Total current liabilities	8,454	5,172

Notes payable, net of current portion	19,344	20,660
Lease incentives, net of current portion	1,136	106
Other liabilities	380	195
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized; 20,339,261 and 20,041,645 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	20	20
Additional paid-in capital	160,643	156,576
Accumulated deficit	(136,853)	(103,595)
Total stockholders' equity	23,810	53,001
Total liabilities and stockholders' equity	$ 53,124	$ 79,134

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T2 Biosystems, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue				
Product revenue	$ 245	$ —	$ 255	$ —
Research revenue	804	—	1,547	—
Total revenue	1,049	—	1,802	—
Costs and expenses:				
Cost of product revenue	829	—	832	—
Research and development	6,204	4,803	18,724	14,572
Selling, general and administrative	5,181	2,984	14,086	7,271
Total costs and expenses	12,214	7,787	33,642	21,843
Loss from operations	(11,165)	(7,787)	(31,840)	(21,843)
Interest expense, net	(501)	(304)	(1,455)	(471)
Other income (expense), net	22	—	37	(1)
Net loss	$ (11,644)	$ (8,091)	$ (33,258)	$ (22,315)
Comprehensive loss	$ (11,644)	$ (8,091)	$ (33,258)	$ (22,315)
Reconciliation of net loss to net loss applicable to common stockholders:				
Net loss	$ (11,644)	$ (8,091)	$ (33,258)	$ (22,315)
Accretion of redeemable convertible preferred stock to redemption value	$ —	$ (758)	$ —	$ (4,570)
Net loss applicable to common stockholders	$ (11,644)	$ (8,849)	$ (33,258)	$ (26,885)
Net loss per share applicable to common stockholders — basic and diluted	$ (0.57)	$ (0.71)	$ (1.64)	$ (5.25)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders — basic and diluted	20,331,274	12,379,337	20,225,056	5,120,977

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T2 Biosystems, Inc.

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

	Nine Months Ended September 30,	
	2015	2014
Operating activities		
Net loss	$ (33,258)	$ (22,315)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	979	459
Stock-based compensation expense	2,899	1,057
Noncash interest expense	288	102
Change in fair value of warrants	—	1

Deferred rent	(86)	15
Changes in operating assets and liabilities:		
Accounts receivable	(177)	—
Prepaid expenses and other current assets	(28)	(901)
Inventories	(942)	—
Accounts payable	258	(227)
Accrued expenses and other liabilities	303	2,110
Deferred revenue	1,119	—
Net cash used in operating activities	(28,645)	(19,699)
Investing activities		
Purchases of property and equipment	(6,100)	(1,039)
Decrease in restricted cash	80	—
Net cash used in investing activities	(6,020)	(1,039)
Financing activities		
Proceeds from issuance of common stock in initial public offering, net of offering costs	—	60,145
Proceeds from issuance of common stock and stock option exercises	1,168	150
Proceeds from notes payable, net of issuance costs	—	9,800
Repayment of notes payable	(235)	(3,966)
Net cash provided by financing activities	933	66,129
Net (decrease) increase in cash and cash equivalents	(33,732)	45,391
Cash and cash equivalents at beginning of period	73,849	30,198
Cash and cash equivalents at end of period	$ 40,117	$ 75,589
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 1,110	$ 294
Supplemental disclosures of noncash activities		
Accrued cost of property and equipment	$ 1,567	$ —
Accretion of Series A-1, A-2, B, C, D and E redeemable convertible preferred stock to redemption value	$ —	$ 4,570
Issuance costs incurred but unpaid at period end	$ —	$ 80
Initial public offering costs incurred but unpaid at period end	$ —	$ 2,104
Conversion of redeemable convertible preferred stock to common stock	$ —	$ 117,383
Conversion of preferred stock warrants to common stock	$ —	$ 1,226

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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, 2015 the Company has cash and cash equivalents of $40.1 million and an accumulated deficit of $136.9 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 and ultimately attain profitable operations, and obtain additional capital. Historically, the Company has funded its operations primarily through its August 2014 initial public offering, private placements of redeemable convertible preferred stock and through debt financing arrangements. Management believes that its existing cash resources at September 30, 2015 together with the additional remaining liquidity of up to $10.0 million of available borrowings from existing debt facilities (Note 5) and $10.0 million available under an Equipment Lease Facility (the “Facility”) entered into in October 2015 (Note 8) to help the Company meet its capital equipment needs, will be sufficient to allow the Company to fund its current operating plan through at least the next 12 months.

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.

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.

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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 financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

The accompanying interim condensed consolidated balance sheet as of September 30, 2015, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2015 and 2014, the condensed consolidated statements of cash flows for the nine months ended September 30, 2015 and 2014 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, 2015, and the results of its operations and its cash flows for the three and nine months ended September 30, 2015 and 2014. The results for the three and nine months ended September 30, 2015 are not necessarily indicative of the results to be expected for the year ending December 31, 2015, 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 applicable to common stockholders, which is net loss plus accretion of redeemable convertible preferred stock to redemption value in the period, 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 and warrants. For purposes of the diluted net loss per share calculation, redeemable convertible preferred stock and warrants to purchase redeemable convertible preferred stock outstanding prior to the August 2014 initial public offering and 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, including the related impact to the numerator of the fair value adjustment of the warrant and the impact to the denominator of the warrant shares, 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.

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Guarantees

From time to time, the Company enters into indemnification agreements in the ordinary course of business, including, but not limited to, indemnification agreements with directors and officers, within its lease agreements for office, laboratory and manufacturing space, and with certain suppliers and business partners. As of September 30, 2015 and December 31, 2014, 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 directly sells the T2Dx to customers, or retains title and places the T2Dx at the customer site pursuant to a reagent rental agreement. When a T2Dx is directly purchased by a customer, the Company generally recognizes revenue upon completion of the installation of the T2Dx at the customer location. When a T2Dx is placed under a reagent rental agreement, the Company's customers generally agree to longer-term agreements, minimum purchase commitments and/or pay an incremental charge 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 shipment 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 the 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 T2Dx equal to the relative fair value of the 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 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 the 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 its 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 we compete, and, as such, we 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.

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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, and is recognized 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.

Cost of Revenues

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 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, warranty and repair and maintenance expense on T2Dx that have been placed with customers under reagent rental agreements.

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.

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 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 has not adopted the guidance prescribed by ASU 2015-05 and does not expect the new guidance to have a material effect on its condensed consolidated financial statements.

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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 has not adopted the guidance prescribed by ASU 2015-03 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.

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, 2015 and December 31, 2014 (in thousands):

	Balance at September 30, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash	$ 2,114	$ 2,114	$ —	$ —
Money market funds	38,003	38,003	—	—
Restricted cash	260	260	—	—
	$ 40,377	$ 40,377	$ —	$ —

	Balance at December 31, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash	$ 10,348	$ 10,348	$ —	$ —
Money market funds	63,501	63,501	—	—
Restricted cash	340	340	—	—
	$ 74,189	$ 74,189	$ —	$ —

For certain financial instruments, including accounts payable and accrued expenses, the carrying amounts approximate their fair values as of September 30, 2015 and December 31, 2014 because of their short-term nature. At September 30, 2015 and December 31, 2014, the carrying value of the Company's debt approximated fair value, which was determined using Level 3 inputs, including a market interest rate.

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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, 2015	December 31, 2014
Raw materials	$ 545	$ 71
Work-in-process	451	44
Finished goods	61	—
Total inventories	$ 1,057	$ 115

Property and Equipment

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

	September 30, 2015	December 31, 2014
Office and computer equipment	$ 395	$ 383

Software	623	480
Laboratory equipment	3,842	3,312
Furniture	187	187
Manufacturing tooling and molds	71	26
Leasehold improvements	3,158	764
T2Dx and components	4,026	563
Construction in progress	1,467	387
	13,769	6,102
Less accumulated depreciation and amortization	(4,321)	(3,342)
Property and equipment, net	$ 9,448	$ 2,760

Construction in progress is primarily comprised of equipment and leasehold improvement construction projects that have not been placed in service. T2Dx and components is comprised of raw materials and work-in-process inventory 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 T2Dx are placed in service once installation procedures are completed and are depreciated over five years. Depreciation expense for Company-owned T2Dx placed at customer sites pursuant to reagent rental agreements is recorded as a component of cost of product revenue and totaled approximately $28,000 for the three and nine months ended September 30, 2015. Depreciation expense for T2Dx 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, 2015	December 31, 2014
Accrued payroll and compensation	$ 2,524	$ 1,846
Accrued research and development expenses	365	733
Accrued professional services	403	374
Other accrued expenses	999	709
Total accrued expenses	$ 4,291	$ 3,662

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5. Debt

On July 11, 2014, the Company entered into a loan and security agreement ("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 $20.0 million available under tranche A by December 31, 2014. Under the Note Agreement, borrowings under tranche B are only available to the Company if both of the following conditions are met by June 30, 2015: (a) the Company receives Section 510(k) clearance from the FDA on the Company's T2Dx and T2Candida products and (b) the Company completes a public or private stock offering, equity raise or strategic partner arrangement resulting in the receipt of at least $30.0 million in net proceeds by the Company. As the Company received FDA approval in September 2014 and the Company closed its initial public offering in August 2014, the borrowings under tranche B are now available as both of the required conditions have been met.

In May 2015, the Company entered into the First Amendment to the Note Agreement whereby the availability to draw up to $10.0 million for tranche B was extended from June 30, 2015 to December 31, 2015. Commencing July 1, 2015, the Company incurs a fee equal to 1.0% per annum of any undrawn amounts under tranche B. This fee is payable on the date tranche B is drawn or upon the expiration of the draw period. All other terms of the Note Agreement remain in effect.

In October 2015, the Company entered into the Second Amendment to the Note Agreement to enable the Company to enter into the Equipment Lease Facility (Note 8).

Through September 30, 2015, the Company received proceeds of $19.7 million under tranche A, net of issuance costs. To date, the Company has not drawn the remaining tranche B available borrowings of $10.0 million.

The amounts borrowed under the Note Agreement are collateralized by substantially all of the assets of the Company and bear interest at the one-month LIBOR plus 7.05%, which was 7.25% on September 30, 2015. The Company will pay interest only payments on the amounts borrowed under the Note Agreement through July 31, 2016. After the interest only period, the Company will 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 9.5%.

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.

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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 ("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 2006 Plan which are forfeited, lapsed unexercised or are settled in cash subsequent to the effective date of the 2014 Plan 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) 823,529 shares, (B) 4% of the shares outstanding (on an as-converted basis) on the final day of the immediately preceding calendar year, and (C) such smaller number of shares determined by the Company's board of directors. As of September 30, 2015 there were 524,330 shares available for future grant under the 2014 Plan.

Stock Options

During the nine months ended September 30, 2015, the Company granted options with an aggregate fair value of $8.6 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 (In thousands)
Outstanding at December 31, 2014	2,911,146	$ 5.30	7.87	$ 40,586
Granted	972,133	16.96		
Exercised	(264,393)	2.89		3,588
Cancelled	(147,950)	6.52		
Outstanding at September 30, 2015	3,470,936	8.69	7.64	11,396
Exercisable at September 30, 2015	1,649,062	4.36	6.16	8,850
Vested or expected to vest at September 30, 2015	3,238,718	8.34	7.53	11,181

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The weighted-average fair values of options granted in the nine-month periods ended September 30, 2015 and 2014 were $8.91 per share and $5.71 per share, respectively, and were calculated using the following estimated assumptions:

	Nine Months Ended September 30,	
	2015	2014
Weighted-average risk-free interest rate	1.70%	1.93%
Expected dividend yield	0.00%	0.00%
Expected volatility	55%	61%
Expected terms	5.9 years	6.0 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 of such shares of common stock, as

determined by the market value per share of common stock at the beginning of the offering period. The Company issued 33,224 shares of common stock for total proceeds of $404,000 upon completion of the offering period ended April 30, 2015. The current offering period commenced on May 1, 2015 and ends November 15, 2015. Stock-based compensation expense from the 2014 ESPP for the three and nine-months ended September 30, 2015 was $66,000 and $192,000, respectively.

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,	
	2015	2014	2015	2014
Research and development	$ 440	$ 127	$ 1,017	$ 250
Selling, general and administrative	882	425	1,882	807
Total stock-based compensation expense	$ 1,322	$ 552	$ 2,899	$ 1,057

As of September 30, 2015, there was $12.1 million of total unrecognized compensation cost related to unvested stock options granted under the Plans. 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 3.0 years as of September 30, 2015.

7. Net Loss Per Share

Excluded from the calculation of diluted net loss per share applicable to common stockholders, prior to the application of the treasury stock method, were 3,470,936 and 2,791,317 shares, for the three and nine month periods ended September 30, 2015 and 2014, respectively, related to options to purchase common shares. The shares are excluded because their effect would have been anti-dilutive for the periods presented.

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8. Commitments and Contingencies

Lease Amendments

In May 2015, the Company entered into an amendment to a lease to expand existing manufacturing facilities. The lease amendment term is June 1, 2015 to December 31, 2017, and the annual rent for the expansion space is $66,000.

In May 2015, the Company entered into an amendment to a lease to extend the term of the lease for office and laboratory space at the Company's headquarters in Lexington, MA. The lease term will now extend from December 31, 2015 to December 31, 2017. The annual rent for the extension period is $1.1 million for 2016 and $1.2 million for 2017.

In April 2015, the Company entered into an amendment to extend the term of an office space lease. The lease amendment extends the lease term from December 31, 2016 to December 31, 2017 and the annual rent for the additional year is approximately $300,000.

Equipment Lease Facility

In October 2015, the Company signed a $10.0 million Facility to fund capital equipment needs. Under the 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.

9. 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 may receive 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 is eligible to receive $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 right 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 minimus. 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 $469,000 and $846,000 during the three and nine months ended September 30, 2015, respectively, under the Co-Development Agreement.

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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, or 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, or 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;*
- *our ability to obtain marketing authorization from the FDA or regulatory clearance for new product candidates in the United States or any other jurisdiction;*
- *the market acceptance of our T2MR technology;*
- *our ability to timely and successfully develop and commercialize our existing products and future product candidates;*
- *our future capital needs and our need to raise additional funds;*
- *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;*
- *the performance of our diagnostics;*
- *our ability to compete in the highly competitive diagnostics market;*
- *our ability to protect and enforce our intellectual property rights, including our trade secret-protected proprietary rights in T2MR; and*
- *our ability to successfully manage our growth;*
- *federal, state, and foreign regulatory requirements, including FDA regulation of our product candidates.*

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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, 2014, 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 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.

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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, or T2MR, to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. 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, or T2DX and the T2Candida Panel or 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 the T2Dx and T2Candida in the United States and we are building a direct sales force that is 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 late 2015, we plan to initiate the collection of samples to support clinical trials for T2Bacteria beginning in 2016 and we plan to initiate clinical trials in the middle of 2016 for T2HemoStat. We expect that existing reimbursement codes will support our T2Bacteria and T2HemoStat product candidates, 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 compete with traditional blood culture-based diagnostic companies, including Becton Dickinson & Co. and bioMerieux, Inc., as well as companies offering post-culture species identification using both molecular and non-molecular methods, including bioMerieux, Inc., Bruker Corporation, Cepheid and Siemens AG, as well as other diagnostic companies such as Abbott, Accelerate Diagnostics, BioFire and Nanosphere.

We have never been profitable and have incurred net losses in each year since inception. Our accumulated deficit at September 30, 2015 was $136.9 million. Substantially all our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. Having obtained authorization from the FDA to market the 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 the T2Dx, T2Candida and our other product candidates.

Our Commercial Products and the Unmet Clinical Need

Our initial FDA-authorized products, the T2Dx and T2Candida utilize T2MR to detect species-specific *Candida* directly from whole blood in three to five hours versus the two 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 forty-eight hours for blood culture. The T2Candida runs on the T2Dx and provides high sensitivity with a limit of detection as low as 1 CFU/mL, even in the presence of antimicrobial therapy.

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Our T2Candida Panel

Our direcT2 pivotal clinical trial was designed to evaluate the sensitivity and specificity of T2Candida on the 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 Infectious* 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 anti-fungal 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 two to five 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 forty-eight to one hundred and twenty 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, the *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 IMS Health's T2Candida economic study demonstrating that an average hospital admitting 5,100 patients at risk for *Candida* infections could save $1,148 per patient tested with T2Candida, resulting in annual potential savings of approximately $5.8 million due to decreased hospital stays, anti-fungal utilization and mortality rates. The economic study further showed T2Candida can potentially reduce the costs of care by $26,887 for a *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 total cases, T2Candida demonstrated 96.4% sensitivity (53 cases) compared to 60% (33 cases) with blood culture.

Additionally, the speed to result of the T2Candida, run on the 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 the 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, the 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. The T2Dx incorporates a simple user interface and is designed to efficiently process up to seven specimens simultaneously.

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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 the Company's 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 nanoparticles to the sample that are coated with target-specific binding agents. If the target is present, the nanoparticles 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.

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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 upon completion of installation and as soon as all applicable revenue recognition criteria have been met. In the majority of cases, we expect to place instruments, under reagent rental agreements, in hospitals in exchange for longer-term agreements, 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 expected to be 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 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 T2Dx Instruments sold to customers; and other costs such as customer support costs, warranty and repair and maintenance expense on T2Dx Instruments that have been placed with our customers under reagent rental agreements. We manufacture our 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.

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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 will 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 issuance costs, partially offset by interest earned on our cash and cash equivalents.

Other income (expense), net

Other income (expense), net, consists of government grant income and the gain or loss associated with the change in the fair value of our liability for warrants to purchase redeemable securities.

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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, 2014 remain materially consistent, except for the critical accounting policies and estimates described below. 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, 2014.

Revenue Recognition

We generate revenue from product sales, which includes the sale of T2Dx, consumable diagnostic tests and related services, and research and development agreements with third parties. Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collection is reasonably assured. If any of the revenue recognition criteria described have not been met, we defer revenue until such time each of the revenue recognition criteria have been satisfied.

Product revenue is generated by the sale of T2Dx and consumable diagnostic tests. We either directly sell the T2Dx to customers or retain title and places the T2Dx at the customer site pursuant to a reagent rental agreement. When a T2Dx is directly purchased by a customer, we generally recognize revenue upon completion of the installation of the T2Dx at the customer location. When a T2Dx is placed under a reagent rental agreement, our customers generally agree to longer-term agreements, minimum purchase commitments and/or pay an incremental charge 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 shipment as a component of product revenue in our consolidated statements of operations and comprehensive loss.

Direct sales of T2Dx sales 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, we may provide training to customers. We defer revenue from the initial sale of T2Dx equal to the relative fair value of the Maintenance Services and training and recognize the amounts ratably over the service delivery period.

We warrant that consumable diagnostic tests will be free from defects, when handled according product specifications, for the stated life of the product. To fulfill valid warranty claims, we provide a credit to our customers on future orders. Accordingly, we defer revenue associated with the estimated defect rates of the consumable diagnostic tests.

We do not offer rights of return for T2Dx or consumable diagnostic tests.

For multiple-element arrangements,we identify 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 us to exercise our judgment. We account 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. We generally expects that we will not be able to establish selling price using third-party evidence due to the nature of our products and the markets in which we compete, and, as such, we typically will determine selling price using VSOE or BESP.

When we establish 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.

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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, and is recognized 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 our research and development agreements generally differs from when revenue is recognized.

Results of Operations for the Three Months Ended September 30, 2015 and September 30, 2014

	Three Months Ended September 30,		
	2015	2014	Change
	(in thousands)		
Revenue:			
Product revenue	$ 245	$ —	$ 245
Research revenue	804	—	804
Total revenue	1,049	—	1,049
Costs and expenses:			
Cost of product revenue	829	—	829
Research and development	6,204	4,803	1,401
Selling, general and administrative	5,181	2,984	2,197
Total operating expenses	12,214	7,787	4,427
Loss from operations	(11,165)	(7,787)	(3,378)
Interest expense, net	(501)	(304)	(197)
Other income (expense), net	22	—	22
Net loss	$ (11,644)	$ (8,091)	$ (3,553)

Product revenue

During the three months ended September 30, 2015, we recorded product revenue totaling $245,000 from the sales of our T2Candida Panels and T2Dx Instruments to customers. We did not record any product revenue in the three months ended September 30, 2014.

Research revenue

We recorded $804,000 of research revenue during the three months ended September 30, 2015 from research and development agreements with third parties utilizing T2MR for potential applications. We did not record any research revenue in the three months ended September 30, 2014.

Cost of product revenue

During the three months ended September 30, 2015, we recorded cost of product revenue associated with the sale of T2Candida Panels and T2Dx Instruments to customers. Cost of product revenue for the three months ended September 30, 2015 also included $391,000 of cost to provide technical support services to customers and $28,000 of depreciation related to T2Dx Instruments placed at customer locations pursuant to reagent rental agreements. We did not record cost of product revenue in the three months ended September 30, 2014.

Research and development expenses

Research and development expenses were $6.2 million for the three months ended September 30, 2015, compared to $4.8 million for the three months ended September 30, 2014, an increase of approximately $1.4 million. The increase was primarily due to increased payroll and payroll related expenses of approximately $1.2 million, including $313,000 of incremental stock compensation expense, as we increased full-time and temporary headcount, increased facilities costs of $381,000 related to expanded laboratory and office space, an increase in prototype development expenses of $316,000, and $165,000 of increased clinical expenses related to research and development projects. Partially offsetting these increases was a decrease in other research and development expenses of $409,000 and a decrease in license fees of $301,000 related to a milestone payment made to Massachusetts General Hospital (“MGH”) during the three months ended September 30, 2014.

Selling, general and administrative expenses

Selling, general and administrative expenses were $5.2 million for the three months ended September 30, 2015, compared to $3.0 million for the three months ended September 30, 2014. The increase of approximately $2.2 million was due primarily to increased payroll and related expenses of approximately $1.5 million, including $457,000 of increased stock compensation expense, as we hired additional executive, sales, marketing and administrative employees, increased public company expenditures of $294,000, increased facilities costs of $195,000 related to expanded office space, and an increase in other selling, general and administrative expenses of $172,000.

Interest expense, net

Interest expense, net, was $501,000 for the three months ended September 30, 2015, compared to $304,000 for the three months ended September 30, 2014. Interest expense, net, increased by $197,000 due to higher borrowing levels on our notes payable.

Other income (expense), net

Other income (expense), net, was $22,000 of net income for the three months ended September 30, 2015, and primarily resulted from the recognition of consideration from a government grant.

Results of Operations for the Nine Months Ended September 30, 2015 and 2014

	Nine Months Ended September 30,		
	2015	2014	Change
		(in thousands)	
Revenue:			
Product revenue	$ 255	$ —	$ 255
Research revenue	1,547	—	1,547
Total revenue	1,802	—	1,802
Costs and expenses:			
Cost of product revenue	832	—	832
Research and development	18,724	14,572	4,152
Selling, general and administrative	14,086	7,271	6,815
Total operating expenses	33,642	21,843	11,799
Loss from operations	(31,840)	(21,843)	(9,997)
Interest expense, net	(1,455)	(471)	(984)
Other income (expense), net	37	(1)	38
Net loss	$ (33,258)	$ (22,315)	$ (10,943)

Product revenue

During the nine months ended September 30, 2015, product revenue totaled $255,000 and was primarily comprised of revenue from the sales of our T2Candida Panels and T2Dx Instruments to customers. We did not record any product revenue in the nine months ended September 30, 2014.

Research revenue

We recorded $1.5 million of research revenue during the nine months ended September 30, 2015 from research and development agreements with third parties utilizing T2MR for potential applications. We did not record any research revenue in the nine months ended September 30, 2014.

Cost of product revenue

During the nine months ended September 30, 2015, we recorded cost of product revenue associated with the sale of T2Candida Panels and T2Dx Instruments to customers. Cost of product revenue for the three months ended September 30, 2015 also included $391,000 of cost to provide technical support services to customers and $28,000 of depreciation related to T2Dx Instruments placed at customer locations pursuant to reagent rental agreements. We did not record cost of product revenue in the three months ended September 30, 2014.

Research and development expenses

Research and development expenses were $18.7 million for the nine months ended September 30, 2015, compared to $14.6 million for the nine months ended September 30, 2014, an increase of approximately $4.1 million. The increase was primarily due to increased payroll and payroll related expenses of approximately $3.9 million, including $767,000 of incremental stock compensation expense, as we increased full-time and temporary headcount, increased facilities costs of approximately $1.6 million related to expanded laboratory and office space, increased prototype development expenditures of $641,000, and an increase in lab expenses of $426,000. Partially offsetting these increases was a decrease in clinical expenditures of approximately $1.0 million as the Company was incurring expenses related to the T2Candida direcT2 pivotal clinical trial, which was completed during the nine months ended September 30, 2014, a $938,000 decrease in other research and development expenses, a decrease in license fees of $291,000 related to a milestone payment made to MGH during the nine months ended September 30, 2014, and a decrease in research and development consulting expenses of $162,000.

Selling, general and administrative expenses

Selling, general and administrative expenses were $14.1 million for the nine months ended September 30, 2015, compared to $7.3 million for the nine months ended September 30, 2014. The increase of approximately $6.8 million was due primarily to increased payroll and related expenses of approximately $4.2 million, including $1.1 million of increased stock compensation expense, as we hired additional executive, sales, marketing and administrative employees, increased public company expenditures of $892,000, increased facilities costs of $610,000 related to expanded office space, an increase in marketing expenditures of $539,000 related to increased marketing programs to support commercialization efforts, and increased other selling, general and administrative costs of $534,000.

Interest expense, net

Interest expense, net, was $1.5 million for the nine months ended September 30, 2015, compared to $471,000 for the nine months ended September 30, 2014. Interest expense, net, increased by $984,000 due to higher borrowing levels on our notes payable.

Other income (expense), net

Other income (expense), net, was $37,000 of net income for the nine months ended September 30, 2015, compared to $1,000 of net expense for the nine months ended September 30, 2014. Other income for the nine months ended September 30, 2015 primarily resulted from the recognition of consideration from a government grant.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception, and as of September 30, 2015, we had an accumulated deficit of $136.9 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our cost of product revenue, research and development and selling, general and administrative 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, 2015, we had cash and cash equivalents of approximately $40.1 million. We believe that our existing cash and cash equivalents, and additional liquidity of up to $10.0 million available from existing debt facilities, as well as $10.0 million available under an Equipment Lease Facility (the "Facility") that was entered into in October 2015, will be sufficient to meet our anticipated cash requirements for at least the next 12 months.

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Cash flows

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

	Nine Months Ended September 30,	
	2015	2014
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (28,645)	$ (19,699)
Investing activities	(6,020)	(1,039)
Financing activities	933	66,129
Net (decrease) increase in cash and cash equivalents	$ (33,732)	$ 45,391

Net cash used in operating activities

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 and a net change in operating assets and liabilities (source of cash) of $447,000, primarily related to an increase in deferred revenue of approximately $1.1 million primarily related to an up-front payment received from 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 $114,000.

Net cash used in operating activities was approximately $19.7 million for the nine months ended September 30, 2014, and consisted primarily of a net loss of $22.3 million adjusted for non-cash items including depreciation and amortization expense of $459,000, stock-based compensation expense of $1.1 million, non-cash interest expense of $102,000 and a net change in operating assets and liabilities (source) of $1.0 million.

Net cash used in investing activities

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 used in investing activities was approximately $1.0 million for the nine months ended September 30, 2014, and consisted of $1.0 million of purchases of laboratory equipment, leasehold improvements and computer software.

Net cash provided by financing activities

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 the sale of stock from the Company's 2014 Employee Stock Purchase Plan (the "ESPP"), partially offset by $235,000 of repayments of notes payable.

Net cash provided by financing activities was approximately $66.1 million for the nine months ended September 30, 2014, and consisted of $60.1 million of proceeds from the issuance of common stock from our IPO in August 2014, net of offering costs paid, $5.8 million of proceeds from notes payable, net of principal repayments and the payment of issuance costs, and $150,000 of proceeds from the exercise of stock options. At September 30, 2014, there were $2.1 million of offering costs from our IPO that were incurred, but were unpaid.

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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, 2014.

In October 2015, we signed a $10.0 million Facility with Essex Capital Corporation (the "Lessor") to fund capital equipment needs. Under the 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.

In October 2015, we entered into the Second Amendment to our loan and security agreement with Solar Capital, Ltd. (the "Note Agreement") to enable us to enter into an Equipment Lease Facility.

In May 2015, we entered into the First Amendment to the Note Agreement, whereby the availability to draw up to $10.0 million for tranche B was extended from June 30, 2015 to December 31, 2015. Commencing July 1, 2015, we incur a fee equal to 1.0% per annum of any undrawn amounts under tranche B. This fee is payable on the date tranche B is drawn or upon the expiration of the draw period. All other terms of such Note Agreement remain in effect.

In May 2015, we entered into an amendment to a lease to expand existing manufacturing facilities. The lease amendment term is June 1, 2015 to December 31, 2017, and the annual rent for the expansion space is $66,000.

In May 2015, we entered into an amendment to a lease to extend the term of the lease for office and laboratory space at our headquarters in Lexington, MA. The lease term will now extend from December 31, 2015 to December 31, 2017. The annual rent for the extension period is $1.1 million for 2016 and $1.2 million for 2017.

In April 2015, we entered into an amendment to extend the term of an office space lease. The lease amendment extends the lease term from December 31, 2016 to December 31, 2017 and the annual rent for the additional year is approximately $300,000.

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 Securities and Exchange Commission, or 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, 2015, we had cash and cash equivalents of $40.1 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 $20.0 million as of September 30, 2015 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.

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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, 2015. 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, 2015.

(b) Changes in Internal Control over Financial Reporting

There have been no material changes to the Company's internal control over financial reporting, except for controls implemented related to the recognition and reporting of product revenue and cost of product revenue, 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.

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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, 2014, 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, 2014.

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

Use of Proceeds

Use of Proceeds from the Sale of Registered Securities

Proceeds of approximately $1.2 million received from the issuance of common stock upon the exercise of options and the purchase of shares under our ESPP were principally used to fund operations.

On August 6, 2014, the SEC declared effective our Registration Statement on Form S-1 (File No. 333-197920), as amended, or Registration Statement, filed in connection with our IPO. Pursuant to the Registration Statement, we registered the offer and sale of 5,200,000 shares of common stock with an aggregate offering price of approximately $57.2 million. Goldman Sachs & Co. and Morgan Stanley acted as joint book-running managers for the offering; Leerink Partners and Janney Montgomery Scott acted as co-managers. On August 8, 2014, the underwriters exercised in full their option to purchase additional shares of common stock pursuant to the underwriting agreement. On August 12, 2014, we closed our IPO, including 780,000 additional shares of common stock related to the option to purchase additional shares pursuant to the underwriting agreement, and sold a total of 5,980,000 shares at a price to the public of $11.00 per share for net proceeds of approximately $58.1 million, which is comprised of gross proceeds of approximately $65.8 million, offset by underwriting discounts and commissions of approximately $4.6 million and offering expenses of approximately $3.1 million. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

The net proceeds of approximately $58.1 million from our IPO have been invested in accordance with the Company's investment policy and the remaining net proceeds are included in cash and cash equivalents at September 30, 2015. The net proceeds from our IPO are being used as described in our final prospectus, dated August 6, 2014, filed with the SEC pursuant to Rule 424(b) relating to our Registration Statement.

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Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

On October 31, 2015, the Company signed a $10.0 million Equipment Lease Facility (the "Facility") with Essex Capital Corporation (the "Lessor") to fund capital equipment needs. Under the 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.

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Item 6. Exhibits, Financial Statement Schedules

Exhibit Number	Exhibit Description
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, 2015,

formatted in XBRL: (i) Balance Sheets (unaudited), (ii) Statements of Operations and Comprehensive Loss (unaudited), (iii) Statements of Cash Flows (unaudited), and (v) Notes of Consolidated Financial Statements.

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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 4, 2015

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

T2 Biosystems, Inc.

Date: November 4, 2015

By: /s/ Maurice Castonguay
Maurice Castonguay
Chief Financial Officer

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 4, 2015

Exhibit 31.2

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

I, Maurice Castonguay, 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/ Maurice Castonguay
Maurice Castonguay
Chief Financial Officer

Date: November 4, 2015

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, 2015 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 4, 2015

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, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Maurice Castonguay, 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/ Maurice Castonguay
Maurice Castonguay
Chief Financial Officer

Date: November 4, 2015

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.