T2 Biosystems, Inc.
Form 10-Q
May 09, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2016

OR

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

For the transition period from to

Commission file number: 001-36571

T2 Biosystems, Inc.

(Exact name of registrant as specified in its charter)

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

Registrant's telephone number, including area code: (781) 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 No

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

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

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

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

As of May 5, 2016, the registrant had 24,284,504 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)

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 59,519	$ 73,662
Accounts receivable	360	369
Prepaid expenses and other current assets	894	838
Inventories	1,259	683
Total current assets	62,032	75,552
Property and equipment, net	12,287	10,655
Restricted cash	260	260
Other assets	358	358
Total assets	$ 74,937	$ 86,825
Liabilities and stockholders’ equity		
Current liabilities:		
Accounts payable	$ 1,552	$ 1,228
Accrued expenses and other current liabilities	4,216	4,162
Current portion of notes payable	6,943	4,449
Deferred revenue	1,736	2,146
Current portion of lease incentives	276	268
Total current liabilities	14,723	12,253
Notes payable, net of current portion	23,572	26,121
Lease incentives, net of current portion	1,007	1,076
Other liabilities	546	436
Commitments and contingencies (Note 8)		

Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at March 31, 2016 and December 31, 2015; 24,283,115 and 24,175,381 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	24	24
Additional paid-in capital	197,376	195,800
Accumulated deficit	(162,311)	(148,885)
Total stockholders' equity	35,089	46,939
Total liabilities and stockholders' equity	$ 74,937	$ 86,825

See accompanying notes to condensed consolidated financial statements.

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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 March 31,	
	2016	2015
Revenue:		
Product revenue	$ 437	$ 10
Research revenue	659	178
Total revenue	1,096	188
Costs and expenses:		
Cost of product revenue	1,026	3
Research and development	6,589	5,868
Selling, general and administrative	6,204	4,468
Total costs and expenses	13,819	10,339
Loss from operations	(12,723)	(10,151)
Interest expense, net	(735)	(477)
Other income, net	32	9
Net loss and comprehensive loss	$ (13,426)	$ (10,619)
Net loss per share — basic and diluted	$ (0.55)	$ (0.53)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	24,218,767	20,080,515

See accompanying notes to condensed consolidated financial statements.

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T2 Biosystems, Inc.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Three months ended March 31,	
	2016	2015
Operating activities		
Net loss	$ (13,426)	$ (10,619)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	529	253
Stock-based compensation expense	1,290	722
Noncash interest expense	148	24
Deferred rent	(60)	(18)
Changes in operating assets and liabilities:		
Accounts receivable	9	113
Prepaid expenses and other assets	(56)	390
Inventory	(576)	(137)
Accounts payable	679	438
Accrued expenses and other liabilities	36	(509)
Deferred revenue	(409)	1,949
Net cash used in operating activities	(11,836)	(7,394)
Investing activities		
Purchases and manufacture of property and equipment	(2,158)	(1,460)
Net cash used in investing activities	(2,158)	(1,460)
Financing activities		
Payment of offering costs from issuance of common stock in public offering	(370)	—
Proceeds from issuance of common stock and stock options exercises, net	301	375
Repayments of note payable	(80)	(75)
Net cash (used in) provided by financing activities	(149)	300
Net decrease in cash and cash equivalents	(14,143)	(8,554)
Cash and cash equivalents at beginning of period	73,662	73,849
Cash and cash equivalents at end of period	$ 59,519	$ 65,295

Supplemental disclosures of cash flow information

Cash paid for interest	$ 517	$ 321
Supplemental disclosures of noncash investing and financing activities		
Accrued property and equipment	$ 132	$ 332
Leasehold improvements paid by landlord	$ —	$ 1,033

See accompanying notes to condensed consolidated financial statements.

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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 March 31, 2016, the Company has cash and cash equivalents of $59.5 million and an accumulated deficit of $162.3 million. The future success of the Company is dependent on its ability to successfully commercialize its FDA approved products, obtain regulatory clearance for and successfully launch its future product candidates, obtain additional capital and ultimately attain profitable operations. Historically, the Company has funded its operations primarily through its August 2014 initial public offering, its December 2015 secondary public offering, private placements of redeemable convertible preferred stock and through debt financing arrangements. Management believes that its existing cash and cash equivalents at March 31, 2016, together with the additional remaining liquidity of up to $10.0 million available under an Equipment Lease Credit Facility (the "Credit Facility") entered into in October 2015 to help the Company meet its capital equipment needs, 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.

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

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in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

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

Segment Information

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

Net Loss Per Share

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

Guarantees

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

Revenue Recognition

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

i.Persuasive evidence of an arrangement exists

ii.Delivery has occurred or services have been rendered

iii.The seller's price to the buyer is fixed or determinable

iv.Collectability is reasonably assured

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

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

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

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

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

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

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

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

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

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

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Cost of Product Revenue

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

Research and Development Costs

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

Recent Accounting Pronouncements

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

Standards Adopted

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

March 31, 2016 and 2015.

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

Standards Issued, Not Adopted

In March 2016, the FASB released ASU No. 2016-09 Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09") which is intended to simplify income tax accounting for excess tax benefits, accounting for forfeitures, and employer statutory withholding. Under the current guidance, excess tax benefits that result from an award vesting or settling are recognized in additional paid-in capital in the period that they reduce cash taxes payable. This requires the provision to be computed on a with and without option basis and may result in net operating loss and credit carryforwards on the balance sheet being less than what is available on the tax return. Under the new guidance, the income tax effects of awards will be recognized as a component of income tax expense when the awards vest or are settled (regardless if cash taxes are reduced). For interim reporting purposes, companies will account for excess tax benefits and tax deficiencies as discrete items in the period of which they occurred. The guidance is effective for public

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entities for fiscal years beginning after December 15, 2016, and interim periods within those years. Early adoption is permitted, however all of the guidance included in the update must be applied when adopted. The Company must use a modified retrospective transition method for adopting and record the cumulative effect of all unrecognized benefits and any change in valuation allowances at the end of the prior tax period as an adjustment to retained earnings. The Company has not elected to early adopt ASU 2016-09 and is evaluating the new guidance and the expected effect on the Company's condensed consolidated financial statements.

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

In February 2016, the FASB issued ASU No. 2016-02, Leases ("ASU 2016-02"), which applies to all leases and will require lessees to put most leases on the balance sheet, but recognize expense in a manner similar to the current standard. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 and interim periods within those years, which is the year ended December 31, 2019 for the Company. Entities are required to use a modified retrospective approach of adoption for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. Full retrospective application is prohibited. The Company is evaluating the new guidance and the expected effect on the Company's condensed consolidated financial statements.

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

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

guidance and the expected effect on the Company's condensed consolidated financial statements.

In 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements – Going Concern ("ASU 2014-15"), which is effective for annual periods ending after December 15, 2016. Early adoption is permitted. ASU 2014-15 provides new guidance on (1) management's responsibility in evaluating whether or not there is substantial doubt about a company's ability to continue as a going concern within one year from the date the financial statements are issued each reporting period and (2) related financial statement disclosures. The Company has not adopted the guidance prescribed by ASU 2014-15. If this standard had been adopted as of March 31, 2016, the Company believes that it would have concluded there was not substantial doubt about its ability to continue as a going concern. However, the Company faces certain risks and uncertainties, as further described in Note 1, "Nature of Business", that could affect this analysis.

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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 March 31, 2016 and December 31, 2015 (in thousands):

	Balance at March 31, 2016	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash	$ 3,356	$ 3,356	$ —	$ —
Money market funds	56,163	56,163	—	—
Restricted cash	260	260	—	—
	$ 59,779	$ 59,779	$ —	$ —

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

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

4. Supplemental Balance Sheet Information

Inventories

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

	March 31, 2016	December 31, 2015
Raw materials	$ 523	$ 203
Work-in-process	534	287
Finished goods	202	193
Total inventories	$ 1,259	$ 683

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Property and Equipment

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

	March 31, 2016	December 31, 2015
Office and computer equipment	$ 395	$ 395
Software	691	632
Laboratory equipment	4,329	4,112
Furniture	187	187
Manufacturing equipment	811	577
Manufacturing tooling and molds	71	71
T2 instruments and components	6,726	4,960
Leasehold improvements	3,353	3,332
Construction in progress	1,041	1,196
	17,604	15,462
Less accumulated depreciation and amortization	(5,317)	(4,807)
Property and equipment, net	$ 12,287	$ 10,655

Construction in progress is primarily comprised of equipment and leasehold improvement construction projects that have not been placed in service. T2 instruments and components is comprised of raw materials and work-in-process instruments that are expected to be used or used to produce Company-owned instruments, based on our business model and forecast, and completed instruments that will be used for internal research and development or reagent rental agreements with customers. Completed T2 instruments are placed in service once installation procedures are completed and are depreciated over five years. The Company has approximately $2.8 million and $1.9 million of Company-owned T2 instruments installed and depreciating as of March 31, 2016 and December 31, 2015, respectively. Depreciation expense for Company-owned T2 instruments placed at customer sites pursuant to reagent rental agreements is recorded as a component of cost of product revenue and totaled approximately $88,000 for the three months ended March 31, 2016. There was no depreciation expense during the three months ended March 31, 2015, as no T2 instruments were in service during that time period. Depreciation expense for T2 instruments used for internal research and development is recorded as a component of research and development expense.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	March 31, 2016	December 31, 2015
Accrued payroll and compensation	$ 2,002	$ 2,418
Accrued professional services	888	542
Accrued research and development expenses	493	458
Other accrued expenses	833	744
Total accrued expenses	$ 4,216	$ 4,162

5. Debt

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

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

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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 7.49% on March 31, 2016. 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 9.9%.

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.

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

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determined by the Company's board of directors. As of March 31, 2016 there were 708,415 shares available for future grant under the 2014 Plan.

Stock Options

During the three months ended March 31, 2016, the Company granted options with an aggregate fair value of $3.4 million, which are being amortized into compensation expense over the vesting period of the options as the services are being provided. The following is a summary of option activity under the Plans:

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value
Outstanding at December 31, 2015	3,484,298	$ 8.79	7.64	$ 14,620
Granted	679,576	8.86		
Exercised	(108,322)	2.79		630
Cancelled	(168,267)	12.46		
Outstanding at March 31, 2016	3,887,285	8.81	7.79	12,141
Exercisable at March 31, 2016	1,778,049	5.71	6.24	9,817
Vested or expected to vest at March 31, 2016	3,531,457	8.64	7.61	11,844

Included in the stock options granted during the three months ended March 31, 2016 are 166,066 options to purchase common stock granted to certain executive officers of the Company that vest upon the achievement of certain performance conditions, which include the attainment of specified operating result and regulatory targets, by December 31, 2017. The Company has determined the fair value of these awards on the date of grant, but has not recognized compensation expense, as the performance conditions were not deemed probable of achievement as of March 31, 2016. The Company will continually evaluate the probability of achievement of each performance condition and will commence recognition of stock-based compensation expense on these awards in the period the achievement of each performance condition is deemed probable, including a catch-up adjustment from the grant date.

The weighted average fair values of options granted in the three-month periods ended March 31, 2016 and 2015 were $4.95 per share and $9.75 per share, respectively, and were calculated using the following estimated assumptions:

	Three months ended March 31,

	2016	2015
Weighted-average risk-free interest rate	1.52%	1.70%
Expected dividend yield	0.00%	0.00%
Expected volatility	60 %	56 %
Expected terms	6.0 years	6.1 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. Stock-based compensation expense from the 2014 ESPP for the three months ended March 31, 2016 and 2015 was $53,000 and $60,000, respectively.

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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 March 31,	
	2016	2015
Cost of product revenue	$ 26	$ —
Research and development	270	280
Selling, general and administrative	968	442
Total stock-based compensation expense	$ 1,264	$ 722

For the three months ended March 31, 2016, $26,000 of stock-based compensation expenses was capitalized as part of inventory or T2 instruments and components.

As of March 31, 2016, there was $11.8 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 March 31, 2016.

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 3,887,285 and 3,224,052 shares, for the three-month periods ended March 31, 2016 and 2015, respectively, related to options to purchase common shares. The shares are excluded because their effect would have been anti-dilutive for the periods presented.

8. Commitments and Contingencies

Equipment Lease Credit Facility

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

In April 2016, the Company completed its initial draw of $2.1 million under the Credit Facility and commenced repayment in accordance with the Credit Facility terms.

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 the agreement includes an additional $6.5 million of consideration upon achieving certain development and regulatory milestones for total aggregate payments of up to $8.5 million. In October 2015, the Company achieved a specified technical requirement and received $1.5 million related to the achievement of the milestone. The Company is eligible to receive an additional $5.0 million under the arrangement, in two milestone payments of $2.0 million and $3.0 million, related to the achievement of additional development and regulatory milestones. All payments under the Co-Development Agreement are non-refundable once received. The Company will retain exclusive worldwide commercialization rights of any products developed under the Co-Development Agreement, including sales, marketing and distribution and Canon US Life Sciences will not receive any

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commercial rights and will be entitled to only receive royalty payments on the sales of all products developed under the Co-Development Agreement.

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

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

The Company recorded revenue of $523,000 and $53,000 during the three months ended March 31, 2016 and 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 (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy, prospective products and product candidates, their expected performance and impact on healthcare costs, marketing authorization from the U.S. Food and Drug Administration (the "FDA"), regulatory clearance, reimbursement for our product candidates, research and development costs, timing of regulatory filings, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

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

- our expectation to incur losses in the future;
- the market acceptance of our T2MR technology;
- our ability to timely and successfully develop and commercialize our existing products and future product candidates;
- the length of our anticipated sales cycle;
- our ability to gain the support of leading hospitals and key thought leaders and publish the results of our clinical trials in peer-reviewed journals;

- our ability to successfully manage our growth;

- our future capital needs and our need to raise additional funds;

- the performance of our diagnostics;

- our ability to compete in the highly competitive diagnostics market;

- our ability to obtain marketing authorization from the FDA or regulatory clearance for new product candidates in the United States or any other jurisdiction;

- federal, state, and foreign regulatory requirements, including FDA regulation of our product candidates; and

- our ability to protect and enforce our intellectual property rights, including our trade secret-protected proprietary rights in T2MR.

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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, 2015, as supplemented or amended from time to time under “Item 1A.—Risk Factors” in our Quarterly Reports on Form 10-Q, and elsewhere in this Quarterly Report on Form 10-Q.

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

Business Overview

We are an in vitro diagnostics company that has developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. We are using our T2 Magnetic Resonance platform (“T2MR”), to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. Our initial development efforts utilizing T2MR target sepsis and hemostasis, which are areas of significant unmet medical need where existing therapies could be more effective with improved diagnostics. On September 22, 2014, we received market authorization from the FDA for our first two products, the T2Dx Instrument (“T2Dx”), and the T2Candida Panel (“T2Candida”), for the direct detection of Candida species in human whole blood specimens and independent of blood culture from patients with symptoms of, or medical conditions predisposing the patient to, invasive fungal infections. We have launched the commercialization of T2Dx and T2Candida in the United States, and we have built and continue to expand a direct sales force that is primarily targeting the top 450 hospitals in the United States that have the highest concentration of patients at risk for Candida infections. Our next three diagnostic applications are called T2Bacteria, T2HemoStat, and T2Lyme, which are focused on bacterial sepsis infections, hemostasis, and Lyme disease, respectively. In Q4 2015, we began collecting patient samples for our clinical trial for T2Bacteria. We hope to commercially launch the T2Bacteria Panel in the second quarter of 2017. We plan to initiate clinical trials in the second half 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 have never been profitable and have incurred net losses in each year since inception. Our accumulated deficit at March 31, 2016 was $162.3 million. Substantially all our net losses resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations. Having obtained authorization from the FDA to market T2Dx and T2Candida, we are incurring significant commercialization expenses related to product sales, marketing, manufacturing and distribution. In addition, we expect that our expenses will increase substantially as we continue the research and development of our other product candidates and maintain, expand and protect our intellectual property portfolio. Accordingly, we may seek to fund our operations through public equity or private equity or debt financings, as well as other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our

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failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop and commercialize T2Dx, T2Candida and our other product candidates.

Our Commercial Products and the Unmet Clinical Need

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

Our T2Candida Panel

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

Sepsis is one of the leading causes of death in the United States, claiming more lives annually than breast cancer, prostate cancer and AIDS combined, and it is the most expensive hospital-treated condition. Most commonly afflicting immunocompromised, critical care and elderly patients, sepsis is a severe inflammatory response to a bacterial or fungal infection with a mortality rate of approximately 30%. One out of approximately every two to three hospital deaths in the United States is attributable to sepsis. According to data published by the U.S. Department of Health and Human Services for 2011, the cost of treating sepsis is over $20 billion in the United States, or approximately 5% of the total aggregate costs associated with domestic hospital stays. Sepsis is typically caused by one or more of five Candida species or over 25 bacterial pathogens, and effective treatment requires the early detection and identification of these specific target pathogens in a patient's bloodstream. Today, sepsis is typically diagnosed through a series of blood cultures followed by post-blood culture species identification. This method has substantial diagnostic limitations that lead to a delay of up to several days in administration of targeted treatment and the incurrence of unnecessary hospital expense. In addition, the Survey of Physicians' Perspectives and Knowledge About Diagnostic Tests for Bloodstream 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 antifungal therapy was associated with higher mortality among patients with septic shock attributed to Candida infection and, on that basis, the study stated that more rapid and accurate diagnostic techniques appear to be needed. Our pivotal clinical trial demonstrated that T2Candida can deliver actionable results as fast as three hours, with an average time to result of 4.2 hours, compared to the average time to result of one to six or more days typically required for blood-culture-based diagnostics, which we believe will enable physicians to make treatment decisions and administer targeted treatment to patients in four to six hours versus 24 to 144 hours for blood culture. We believe that T2Bacteria will also deliver actionable results within these timeframes because this diagnostic panel operates similarly to T2Candida and is designed to run on the same instrument as T2Candida.

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

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

Our T2Dx Instrument

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

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

process up to seven specimens simultaneously.

Our T2Bacteria Panel

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

Our T2MR Platform

T2MR is a miniaturized, magnetic resonance-based approach that measures how water molecules react in the presence of magnetic fields. For molecular and immunodiagnostics targets, T2MR introduces particles to the sample that

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are coated with target-specific binding agents. If the target is present, the particles bind to and cluster around it, disrupting the surrounding water molecules and altering the magnetic resonance signal.

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

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

Financial Overview

Revenue

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

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

Product revenue is derived from the sale of our instruments and related consumable diagnostic tests. We recognize product revenue from the sale of our instruments as soon as all applicable revenue recognition criteria have been met. In the majority of cases, we expect to place our instruments, under reagent rental agreements, in hospitals in exchange for long-term agreements, certain of which may include minimum commitments and/or an incremental

charge on the purchase of our consumable diagnostic tests. Under this business model, we believe we will recover the cost of placing our instruments in hospitals through the margins realized from our consumable diagnostic tests. Our consumable diagnostic tests can only be used with our instruments, and accordingly, as the installed base of our instruments grows, we expect the following to occur:

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

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

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

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

Cost of Product Revenue

Cost of product revenue includes the cost of materials, direct labor and manufacturing overhead costs used in the manufacture of our consumable diagnostic tests sold to customers and related license and royalty fees. Cost of product revenue also includes depreciation on the revenue-generating T2Dx Instruments that have been placed with our customers under reagent rental agreements; costs of materials, direct labor and manufacturing overhead costs on the

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T2Dx Instruments sold to customers; and other costs such as customer support costs, warranty and repair and maintenance expense on the T2Dx Instruments that have been placed with our customers under reagent rental agreements. We manufacture the T2Dx Instruments and some of our consumable diagnostic tests in our facilities. We outsource the manufacturing of components of our consumable diagnostic tests to a contract manufacturer.

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

Research and development expenses

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

We expect that our overall research and development expenses 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 deferred financing costs, partially offset by interest earned on our cash and cash equivalents.

Other income (expense), net

Other income (expense), net, primarily consists of government grant income.

Critical Accounting Policies and Use of Estimates

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

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apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions.

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

Results of Operations for the Three Months Ended March 31, 2016 and 2015

	Three months ended March 31,		
	2016	2015	Change
	(in thousands)		
Revenue:			
Product revenue	$ 437	$ 10	$ 427
Research revenue	659	178	481
Total revenue	1,096	188	908
Costs and expenses:			
Cost of product revenue	1,026	3	1,023
Research and development	6,589	5,868	721
Selling, general and administrative	6,204	4,468	1,736
Total costs and expenses	13,819	10,339	3,480
Loss from operations	(12,723)	(10,151)	(2,572)
Interest expense, net	(735)	(477)	(258)
Other income (expense), net	32	9	23
Net loss	$ (13,426)	$ (10,619)	$ (2,807)

Product revenue

Product revenue was $437,000 for the three months ended March 31, 2016, compared to $10,000 for the three months ended March 31, 2015, an increase of $427,000. The increase was the result of an increase in sales volume of our products, primarily the sale of T2Candida Panels, driven from growth in our installed based over the second half of 2015.

Research revenue

Research revenue was $659,000 for the three months ended March 31, 2016, compared to $178,000 for the three months ended March 31, 2015, an increase of $481,000. The increase was primarily the result of higher revenue from services delivered under our Co-Development Agreement with Canon US Life Sciences, which increased $470,000 over the prior year period, as well as increase in revenue from research and development agreements utilizing T2MR technology with other third parties.

Cost of product revenue

During the three months ended March 31, 2016, we recorded total cost of product revenue of $1.0 million, which included costs associated with the sale of T2Candida Panels and T2Dx Instruments to customers. Cost of product revenue for the three months ended March 31, 2016 also included approximately $638,000 of cost to provide technical support services to customers and $88,000 of depreciation related to T2Dx Instruments placed at customer locations pursuant to reagent rental agreements.

Research and development expenses

Research and development expenses were $6.6 million for the three months ended March 31, 2016, compared to $5.9 million for the three months ended March 31, 2015, an increase of $721,000. The increase was primarily due to increased payroll and payroll related expenses of $452,000, including $46,000 of incremental stock compensation expense, as we increased full-time and temporary headcount, increased clinical study costs of $242,000 primarily related

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to costs incurred in connection with our T2Bacteria clinical trial, and increased other research and development costs of $27,000.

Selling, general and administrative expenses

Selling, general and administrative expenses were $6.2 million for the three months ended March 31, 2016, compared to $4.5 million for the three months ended March 31, 2015. The increase of approximately $1.7 million was due primarily to increased payroll and related expenses of approximately $1.6 million, including $525,000 of increased stock compensation expense, as we expanded our sales personnel and hired additional executive, marketing and administrative employees, increased consulting and legal expenditures of $462,000, and increased travel expenses of $215,000 related to increased sales personnel. Partially offsetting these increases were lower marketing program expenditures of $482,000 and lower other selling, general and administrative expenses of $47,000.

Interest expense, net

Interest expense, net, was $735,000 for the three months ended March 31, 2016, compared to $477,000 for the three months ended March 31, 2015. Interest expense, net, increased by $258,000 due to higher borrowing levels on our notes payable.

Other income (expense), net

Other income (expense), net, was $32,000 of net income for the three months ended March 31, 2016, and 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 March 31, 2016, we had an accumulated deficit of $162.3 million. We anticipate that we will continue to incur losses for at least the next couple of 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 March 31, 2016, we had cash and cash equivalents of approximately $59.5 million. We believe that our existing cash and cash equivalents, and additional liquidity of up to $10.0 million available under an Equipment Lease Credit Facility (the "Credit Facility") that was entered into in October 2015, will be sufficient to meet our anticipated cash requirements for at least the next 12 months.

Cash flows

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

	Three months ended March 31,	
	2016	2015
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (11,836)	$ (7,394)
Investing activities	(2,158)	(1,460)
Financing activities	(149)	300
Net (decrease) increase in cash and cash equivalents	$ (14,143)	$ (8,554)

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Net cash used in operating activities

Net cash used in operating activities was approximately $11.8 million for the three months ended March 31, 2016, and consisted primarily of a net loss of $13.4 million adjusted for non-cash items including depreciation and amortization expense of $529,000, stock-based compensation expense of $1.3 million, non-cash interest expense of $148,000, deferred rent of $60,000, and a net change in operating assets and liabilities (use of cash) of $317,000, primarily related to an increase in inventory of $576,000 to support our commercial demand and a decrease in deferred revenue of approximately $409,000 primarily related to the recognition of revenue from our Co-Development Agreement with Canon US Life Sciences, partially offset by an increase accounts payable $679,000 related to growth in the business.

Net cash used in operating activities was approximately $7.4 million for the three months ended March 31, 2015, and consisted primarily of a net loss of $10.6 million adjusted for non-cash items including depreciation and amortization expense of $253,000, stock-based compensation expense of $723,000, non-cash interest expense of $24,000 and a net change in operating assets and liabilities (source) of $2.2 million.

Net cash used in investing activities

Net cash used in investing activities was approximately $2.2 million for the three months ended March 31, 2016 and consisted of costs to acquire components of and manufacture Company-owned instruments of $1.8 million, which are classified as property and equipment, and $376,000 of purchases of laboratory and manufacturing equipment incurred to support commercialization efforts and research and development programs.

Net cash used in investing activities was approximately $1.5 million for the three months ended March 31, 2015, and consisted of costs to develop Company-owned instruments and purchases of laboratory equipment and leasehold improvements.

Net cash (used in) provided by financing activities

Net cash used in financing activities was approximately $149,000 for the three months ended March 31, 2016, and consisted of $370,000 of payments of issuance costs from our December 2015 secondary offering and $80,000 of repayments of notes payable. Partially offsetting these uses of cash were $301,000 of proceeds from the exercise of stock options.

Net cash provided by financing activities was approximately $300,000 for the three months ended March 31, 2015, and consisted of $375,000 of proceeds from the exercise of stock options, partially offset by $75,000 of repayments of notes payable.

Contractual Obligations and Commitments

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

In October 2015, we signed the $10.0 million Credit Facility with Essex Capital Corporation (the "Lessor") to fund capital equipment needs. Under the Credit Facility, the Lessor will fund capital equipment purchases presented. We will repay the amounts borrowed in 36 equal monthly installments from the date of the amount funded. At the end of the 36 month lease term, we have the option to (a) repurchase the leased equipment at the lesser of fair market value or 10% of the original equipment value, (b) extend the applicable lease for a specified period of time, which will not be less than one year, or (c) return the leased equipment to the Lessor. In April 2016, the we completed our initial draw under the Credit Facility of $2.1 million and commenced repayment.

Off-Balance Sheet Arrangements

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

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Item 3.Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk related to changes in interest rates. As of March 31, 2016, we had cash and cash equivalents of $59.5 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 $30.0 million as of March 31, 2016 and bears interest at an annual rate equal to the one-month LIBOR plus 7.05%. A 10% increase in the one-month LIBOR annual rate would result in an immaterial increase in our annual interest expense under our credit facility with Solar Capital, Ltd., as a result of the current low interest rate environment.

Item 4.Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

Management of the Company, with the participation of the Chief Executive Officer and the Chief Financial Officer, evaluated the effectiveness of the design and operation of the Company’s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of March 31, 2016. The Company’s disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported on a timely basis and that such information is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding disclosure. Based upon this evaluation, the Chief Executive Officer and the Chief Financial Officer have concluded that the Company’s disclosure controls and procedures were effective as of March 31, 2016.

(b) Changes in Internal Control over Financial Reporting

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

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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, 2015, which could materially affect our business, financial condition or future results. There have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015.

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

None.

Item 3.Defaults Upon Senior Securities

Not applicable.

Item 4.Mine Safety Disclosures

Not applicable.

Item 5.Other Information

None.

Item 6.Exhibits, Financial Statement Schedules

Exhibit Number	Exhibit Description
3.1	Restated Certificate of Incorporation of the Company, as amended (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36571) filed on August 12, 2014)
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 of the Company's Form 8-K (File No. 001-36571) filed on August 12, 2014)
10.1	Change of Control Severance Agreement, dated August 3, 2015, by and between the Company and Maurice Castonguay
10.2	Change of Control Severance Agreement, dated October 14, 2015, by and between the Company and David Harding
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

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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 March 31, 2016, formatted in XBRL: (i) Condensed Consolidated Balance Sheets (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited), (iii) Condensed Consolidated Statements of Cash Flows (unaudited), and (v) Notes of Condensed Consolidated Financial Statements.

* Filed herewith
** Furnished herewith

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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: May 9, 2016 By: /s/ John McDonough
John McDonough
President and Chief Executive Officer

T2 Biosystems, Inc.

Date: May 9, 2016 By: /s/ Maurice Castonguay
Maurice Castonguay
Chief Financial Officer