

T2 Biosystems, Inc.
Form 10-Q
August 05, 2015
[Table of Contents](#)

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 June 30, 2015

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

Smaller reporting company

(Do not check if a 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 August 3, 2015, the registrant had 20,324,741 shares of common stock outstanding.

Table of Contents

T2 BIOSYSTEMS, INC.

TABLE OF CONTENTS

	Page
<u>PART I FINANCIAL INFORMATION</u>	
<u>Item 1. Financial Statements (unaudited)</u>	1
<u>Condensed Consolidated Balance Sheets as of June 30, 2015 and December 31, 2014</u>	1
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2015 and 2014</u>	2
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2015 and 2014</u>	3
<u>Notes to Condensed Consolidated Financial Statements</u>	4
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	26
<u>Item 4. Controls and Procedures</u>	27
<u>PART II OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	28
<u>Item 1A. Risk Factors</u>	28
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	28
<u>Item 3. Defaults Upon Senior Securities</u>	29
<u>Item 4. Mine Safety Disclosures</u>	29
<u>Item 5. Other Information</u>	29
<u>Item 6. Exhibits, Financial Statement Schedules</u>	30
<u>SIGNATURES</u>	31

Table of Contents

PART I.

FINANCIAL INFORMATION

Item 1. Financial Statements

T2 Biosystems, Inc.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)

(Unaudited)

	June 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 53,289	\$ 73,849
Accounts receivable	389	201
Prepaid expenses and other current assets	628	1,076
Inventories	569	115
Restricted cash		80
Total current assets	54,875	75,321
Property and equipment, net	7,809	2,760
Restricted cash, net of current portion	260	260
Deferred tax assets	313	313
Other assets	456	480
Total assets	\$ 63,713	\$ 79,134
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,562	\$ 735
Accrued expenses	3,475	3,662
Notes payable	305	295
Deferred revenue	1,776	80
Deferred tax liabilities	313	313
Lease incentives	259	87
Total current liabilities	7,690	5,172
Notes payable, net of current portion	20,522	20,660
Lease incentives, net of current portion	1,136	106
Other liabilities	313	195
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued	20	20

Edgar Filing: T2 Biosystems, Inc. - Form 10-Q

Common stock, \$0.001 par value; 200,000,000 shares authorized; 20,312,980 and 20,041,645 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively		
Additional paid-in capital	159,241	156,576
Accumulated deficit	(125,209)	(103,595)
Total stockholders' equity	34,052	53,001
Total liabilities and stockholders' equity	\$ 63,713	\$ 79,134

See Notes to Condensed Consolidated Financial Statements

Table of Contents

T2 Biosystems, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenue:				
Product revenue	\$	\$	\$ 10	\$
Research revenue		564	743	
Total revenue		564	753	
Costs and expenses:				
Cost of product revenue			3	
Research and development		6,651	12,520	9,768
Selling, general and administrative		4,437	8,905	4,288
Total costs and expenses		11,088	21,428	14,056
Loss from operations		(10,524)	(20,675)	(14,056)
Interest expense, net		(477)	(954)	(166)
Other income (expense), net		6	15	(1)
Net loss	\$	(10,995)	\$ (21,614)	\$ (14,223)
Comprehensive loss	\$	(10,995)	\$ (21,614)	\$ (14,223)
Reconciliation of net loss to net loss applicable to common stockholders:				
Net loss	\$	(10,995)	\$ (21,614)	\$ (14,223)
Accretion of redeemable convertible preferred stock to redemption value			(1,906)	(3,812)
Net loss applicable to common stockholders	\$	(10,995)	\$ (21,614)	\$ (18,035)
Net loss per share applicable to common stockholders basic and diluted	\$	(0.54)	\$ (1.07)	\$ (12.60)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders basic and diluted		20,260,591	20,171,051	1,431,542

See Notes to Condensed Consolidated Financial Statements

Table of Contents

T2 Biosystems, Inc.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2015	2014
Operating activities		
Net loss	\$ (21,614)	\$ (14,223)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	600	299
Stock-based compensation expense	1,577	505
Noncash interest expense	180	21
Change in fair value of warrants		1
Loss on disposal of asset		(1)
Deferred rent	(67)	(13)
Changes in operating assets and liabilities:		
Accounts receivable	(188)	
Prepaid expenses and other current assets	447	(8)
Inventories	(453)	
Accounts payable	827	(281)
Accrued expenses and other liabilities	(396)	1,509
Deferred revenue	1,695	
Net cash used in operating activities	(17,392)	(12,191)
Investing activities		
Purchases of property and equipment	(4,184)	(508)
Decrease in restricted cash	80	
Net cash used in investing activities	(4,104)	(508)
Financing activities		
Proceeds from issuance of common stock and stock options exercises, net	1,088	96
Payment of deferred initial public offering costs		(777)
Payment of deferred financing costs		(50)
Repayments of notes payable	(152)	(892)
Net cash provided by (used in) financing activities	936	(1,623)
Net decrease in cash and cash equivalents	(20,560)	(14,322)
Cash and cash equivalents at beginning of period	73,849	30,198
Cash and cash equivalents at end of period	\$ 53,289	\$ 15,876
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ 716	\$ 125
Supplemental disclosures of noncash investing and financing activities		
Accrued costs of property and equipment	\$ 1,595	\$
Accretion of Series A-1, A-2, B, C, D and E redeemable convertible preferred stock to redemption value	\$	\$ 3,812
Deferred financing costs incurred but unpaid at period end	\$	\$ 85
Initial public offering costs incurred but unpaid at period end	\$	\$ 1,309

See Notes to Condensed Consolidated Financial Statements

Table of Contents

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, preparing of the commercialization of its products.

Liquidity

At June 30, 2015 the Company has cash and cash equivalents of \$53.3 million and an accumulated deficit of \$125.2 million. The future success of the Company is dependent on its ability to successfully commercialize its recently authorized 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 June 30, 2015 together with the additional remaining liquidity of up to \$10.0 million of available borrowings from existing debt facilities (Note 5) 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.

Table of Contents

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 June 30, 2015, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2015 and 2014, the condensed consolidated statements of cash flows for the six months ended June 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 June 30, 2015, and the results of its operations and its cash flows for the three and six months ended June 30, 2015 and 2014. The results for the three and six months ended June 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, upon regulatory clearance, 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, warrants to purchase redeemable convertible preferred stock 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.

Table of Contents

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 June 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 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

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue.

The Company offers customers the choice either to purchase a T2Dx outright or to allow the placement of a Company-owned T2Dx at the customer site pursuant to a reagent rental agreement.

Revenue earned from activities performed pursuant to research and development agreements is reported as research revenue in the 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.

For multiple-element arrangements, the Company identifies the deliverables included within each agreement and evaluates which deliverables represent separate units of accounting. 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 management's best estimate of selling price, and the applicable revenue recognition criteria are applied to each of the separate units. 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.

Table of Contents

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.

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.

Table of Contents**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 June 30, 2015 and December 31, 2014 (in thousands):

	Balance at June 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	\$ 1,287	\$ 1,287		\$
Money market funds	52,002	52,002		
Restricted cash	260	260		
	\$ 53,549	\$ 53,549		\$

	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 June 30, 2015 and December 31, 2014 because of their short-term nature. At June 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.

Table of Contents**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):

	June 30, 2015	December 31, 2014
Raw materials	\$ 265	\$ 71
Work-in-process	219	44
Finished goods	85	
Total inventories	\$ 569	\$ 115

Property and Equipment

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

	June 30, 2015	December 31, 2014
Office and computer equipment	\$ 384	\$ 383
Software	596	480
Laboratory equipment	3,768	3,312
Furniture	187	187
Manufacturing tooling and molds	32	26
Leasehold improvements	3,144	764
T2Dx Instruments and components	2,486	563
Construction in progress	1,154	387
	11,751	6,102
Less accumulated depreciation and amortization	(3,942)	(3,342)
Property and equipment, net	\$ 7,809	\$ 2,760

Construction in progress is primarily comprised of equipment and leasehold improvement construction projects that have not been placed in service. T2Dx Instruments 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 our business model and forecast, and completed instruments that will be used for internal research and development or reagent rental agreements with customers. Such completed instruments have not yet been placed in service.

Accrued Expenses

Edgar Filing: T2 Biosystems, Inc. - Form 10-Q

Accrued expenses consist of the following (in thousands):

	June 30, 2015		December 31, 2014
Accrued payroll and compensation	\$ 1,885	\$	1,846
Accrued research and development expenses	296		733
Accrued professional services	286		374
Other accrued expenses	1,008		709
Total accrued expenses	\$ 3,475	\$	3,662

Table of Contents

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) by December 31, 2014 for tranche A and up to \$10.0 million by June 30, 2015 for tranche B. 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.

On May 27, 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 will 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 the Note Agreement remain in effect.

Through June 30, 2015, the Company received proceeds of \$19.7 million under tranche A, net of deferred financing 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 7.24% on June 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 9.4%.

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.

Table of Contents

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 June 30, 2015 there were 725,086 shares available for future grant under the 2014 Plan.

Stock Options

During the six months ended June 30, 2015, the Company granted options with an aggregate fair value of \$6.7 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:

Edgar Filing: T2 Biosystems, Inc. - Form 10-Q

	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	699,983	18.18		
Exercised	(241,053)	2.88		3,327
Cancelled	(75,057)	9.17		
Outstanding at June 30, 2015	3,295,019	8.12	7.94	28,833
Exercisable at June 30, 2015	1,439,321	3.20	6.56	18,846
Vested or expected to vest at June 30, 2015	3,069,705	7.76	7.85	27,851

The total grant date fair values of stock options that vested during the six months ended June 30, 2015 and 2014 was \$1.2 million and \$359,000, respectively.

Table of Contents

The weighted-average fair values of options granted in the six-month periods ended June 30, 2015 and 2014 were \$9.53 per share and \$6.00 per share, respectively, and were calculated using the following estimated assumptions:

	Six Months Ended June 30,	
	2015	2014
Weighted-average risk-free interest rate	1.69%	1.97%
Expected dividend yield	0.00%	0.00%
Expected volatility	55%	62%
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 six-months ended June 30, 2015 was \$68,000 and \$128,000, 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 June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Research and development	\$ 297	\$ 67	\$ 577	\$ 123
Selling, general and administrative	558	199	1,000	382
Total stock-based compensation expense	\$ 855	\$ 266	\$ 1,577	\$ 505

As of June 30, 2015, there was \$11.5 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 June 30, 2015.

Table of Contents**7. Net Loss Per Share**

The following shares were excluded from the calculation of diluted net loss per share applicable to common stockholders, prior to the application of the treasury stock method, because the effect of including such shares would have been anti-dilutive for the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Redeemable convertible preferred stock		12,516,298		12,516,298
Options to purchase common shares	3,295,019	2,348,206	3,295,019	2,348,206
Warrants to purchase redeemable convertible preferred stock		147,484		147,484
Total	3,295,019	15,011,988	3,295,019	15,011,988

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.

Table of Contents

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. The next payment the Company is eligible to receive is \$1.5 million related to the achievement of a specified technical requirement. 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 diminimus. The Company will recognize 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 \$324,000 and \$377,000 during the three and six months ended June 30, 2015, respectively, under this Agreement.

Table of Contents

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.*

Table of Contents

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.

Table of Contents

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. We plan to initiate clinical trials in late 2015 or the first part of 2016 for T2Bacteria and in 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 have never been profitable and have incurred net losses in each year since inception. Our accumulated deficit at June 30, 2015 was \$125.2 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 recently obtained authorization from the FDA to market the T2Dx and T2Candida, we now expect to incur 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. 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.

Table of Contents

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*.

Candida is the fourth leading hospital-acquired bloodstream infection 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 showing T2Candida can potentially reduce a sepsis patient length of stay at a cost savings of \$26,887 per patient and that rapid detection of *Candida* reduces patient deaths by 60.6%. Most recently, results from an investigational study presented at the American Society of Microbiology Conference demonstrated that in 15 pediatric cases of confirmed candidemia, the T2Candida Panel accurately identified the correct *Candida* species in each sample in three to five hours compared to two to six days for blood culture. In addition, the protocol was adapted to deliver results from just 2mL of blood compared to the 3mL that is currently required for testing.

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.

Edgar Filing: T2 Biosystems, Inc. - Form 10-Q

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.

Table of Contents

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 immunodiagnosics 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.

For hemostasis measurements, T2MR is highly sensitive to changes in viscosity in a blood sample (such as clot formation, stabilization or dissipation), which alter the magnetic resonance signal and enable identification of clinically relevant hemostasis changes.

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.

Table of Contents

Financial Overview

Revenue

To date, we have generated revenue primarily from research and development agreements. Revenue earned from activities performed pursuant to research and development agreements and grants 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 will be derived from the sale of our instruments and related consumable diagnostic tests. We expect product revenue from the sale of our instruments to occur as soon as all applicable revenue recognition criteria have been met. We expect product revenue from the sale of consumable diagnostic tests to occur three to six months after signing a contract with a customer, once the installation and verification of the performance of our instruments has been completed. In the majority of cases, we expect to place instruments in hospitals in exchange for longer-term agreements, minimum commitments and/or an up-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.

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 associated with manufacturing activities, incurred for 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. 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.

Table of Contents

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, 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.

Application of 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. 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.

Table of Contents**Results of Operations for the Three Months Ended June 30, 2015 and June 30, 2014**

	2015	Three Months Ended June 30, 2014 (in thousands)	Change
Revenue:			
Product revenue	\$	\$	\$
Research revenue	564		564
Total revenue	564		564
Costs and expenses:			
Cost of product revenue			
Research and development	6,651	4,703	1,948
Selling, general and administrative	4,437	2,446	1,991
Total costs and expenses	11,088	7,149	3,939
Loss from operations	(10,524)	(7,149)	(3,375)
Interest expense, net	(477)	(80)	(397)
Other income (expense), net	6	(74)	80
Net loss	\$ (10,995)	\$ (7,303)	\$ (3,692)

Research revenue

We recorded \$564,000 of research revenue during the three months ended June 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 June 30, 2014.

Research and development expenses

Research and development expenses were \$6.7 million for the three months ended June 30, 2015, compared to \$4.7 million for the three months ended June 30, 2014, an increase of approximately \$2.0 million. The increase was primarily due to increased payroll and payroll related expenses of approximately \$1.5 million, including \$230,000 of incremental stock compensation expense, as we increased full-time and temporary headcount, increased facilities costs of \$572,000 related to expanded laboratory and office space, and increased lab-related expenses of \$441,000 related to headcount and facility expansion. Partially offsetting these increases was a decrease in other research and development expenses of \$332,000 and a \$237,000 decrease in clinical expenditures as the Company was incurring expenses related to the T2Candida direct pivotal clinical trial, which was completed during the three months ended June 30, 2014.

Selling, general and administrative expenses

Selling, general and administrative expenses were \$4.4 million for the three months ended June 30, 2015, compared to \$2.4 million for the three months ended June 30, 2014. The increase of approximately \$2.0 million was due primarily to increased payroll and related expenses of approximately \$1.3 million, including \$359,000 of increased stock compensation expense, as we hired additional executive, sales, marketing and administrative employees, increased public company expenditures of \$283,000, increased facilities costs of \$221,000 related to expanded office

space, and an increase in other selling, general and administrative expenses of \$204,000.

Table of Contents***Interest expense, net***

Interest expense, net, was \$477,000 for the three months ended June 30, 2015, compared to \$80,000 for the three months ended June 30, 2014. Interest expense, net, increased by \$397,000 due to higher borrowing levels on our notes payable.

Other income (expense), net

Other income (expense), net, was \$6,000 of net income for the three months ended June 30, 2015, compared to \$74,000 of net expense for the three months ended June 30, 2014. Other income (expense), net for the three months ended June 30, 2014 included a loss from the remeasurement of the liability for warrants to purchase redeemable convertible preferred stock. The liability for warrants to purchase redeemable convertible preferred stock was extinguished in connection with our August 2014 initial public offering, or IPO, as the warrants were net exercised into common stock.

Results of Operations for the Six Months Ended June 30, 2015 and 2014

	Six Months Ended June 30,		
	2015	2014	Change
	(in thousands)		
Revenue:			
Product revenue	\$ 10	\$	\$ 10
Research revenue	743		743
Total revenue	753		753
Costs and expenses:			
Cost of product revenue	3		3
Research and development	12,520	9,768	2,752
Selling, general and administrative	8,905	4,288	4,617
Total costs and expenses	21,428	14,056	7,372
Loss from operations	(20,675)	(14,056)	(6,619)
Interest expense, net	(954)	(166)	(788)
Other income (expense), net	15	(1)	16
Net loss	\$ (21,614)	\$ (14,223)	\$ (7,391)

Product revenue

During the six months ended June 30, 2015, we recorded our initial product revenue from the sale of T2Candida Panels to a customer.

Research revenue

We recorded \$743,000 of research revenue during the six months ended June 30, 2015 from research and development agreements with third parties utilizing T2MR for potential applications. We did not record any research revenue in the six months ended June 30, 2014.

Cost of product revenue

During the six months ended June 30, 2015, we recorded cost of revenue and gross profit associated with its initial sale of T2Candida Panels to a customer.

Table of Contents

Research and development expenses

Research and development expenses were \$12.5 million for the six months ended June 30, 2015, compared to \$9.8 million for the six months ended June 30, 2014, an increase of approximately \$2.8 million. The increase was primarily due to increased payroll and payroll related expenses of approximately \$2.7 million, including \$454,000 of incremental stock compensation expense, as we increased full-time and temporary headcount, increased facilities costs of approximately \$1.1 million related to expanded laboratory and office space, an increase in lab expenses of \$574,000, and increased subcontractor expenditures related to prototype development work of \$444,000. Partially offsetting these increases was a decrease in clinical expenditures of approximately \$1.3 million as the Company was incurring expenses related to the T2Candida direct pivotal clinical trial, which was completed during the six months ended June 30, 2014, as well as a \$491,000 decrease in other research and development expenses and a decrease in consulting expenses of \$257,000.

Selling, general and administrative expenses

Selling, general and administrative expenses were \$8.9 million for the six months ended June 30, 2015, compared to \$4.3 million for the six months ended June 30, 2014. The increase of approximately \$4.6 million was due primarily to increased payroll and related expenses of approximately \$2.7 million, including \$618,000 of increased stock compensation expense, as we hired additional executive, sales, marketing and administrative employees, increased marketing program expenses of \$516,000, increased public company expenditures of \$597,000, an increase in facilities costs of \$428,000 related to expanded office space, and increased other selling, general and administrative costs of \$369,000.

Interest expense, net

Interest expense, net, was \$954,000 for the six months ended June 30, 2015, compared to \$166,000 for the six months ended June 30, 2014. Interest expense, net, increased by \$788,000 due to higher borrowing levels on our notes payable.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception, and as of June 30, 2015, we had an accumulated deficit of \$125.2 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our 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.

Edgar Filing: T2 Biosystems, Inc. - Form 10-Q

As of June 30, 2015, we had cash and cash equivalents of approximately \$53.3 million. We believe that our existing cash and cash equivalents, and additional liquidity of up to \$10.0 million available from existing debt facilities, will be sufficient to meet our anticipated cash requirements for at least the next 12 months.

Table of Contents***Cash flows***

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

	Six Months Ended		
	June 30,		
	2015		2014
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	\$	(17,392)	\$ (12,191)
Investing activities		(4,104)	(508)
Financing activities		936	(1,623)
Net decrease in cash and cash equivalents	\$	(20,560)	\$ (14,322)

Net cash used in operating activities

Net cash used in operating activities was approximately \$17.4 million for the six months ended June 30, 2015, and consisted primarily of a net loss of \$21.6 million adjusted for non-cash items including depreciation and amortization expense of \$600,000, stock-based compensation expense of \$1.6 million, non-cash interest expense of \$180,000 and a net change in operating assets and liabilities (source of cash) of \$1.9 million, primarily related to an increase in deferred revenue from an up-front payment received from our Co-Development Agreement with Canon US Life Sciences.

Net cash used in operating activities was approximately \$12.2 million for the six months ended June 30, 2014, and consisted primarily of a net loss of \$14.2 million adjusted for non-cash items including depreciation and amortization expense of \$0.3 million, stock-based compensation expense of \$0.5 million, and a net change in operating assets and liabilities of \$1.2 million.

Net cash used in investing activities

Net cash used in investing activities was approximately \$4.1 million for the six months ended June 30, 2015, and consisted of costs to develop Company-owned instruments and purchases of laboratory equipment and leasehold improvements of \$4.2 million, partially offset by proceeds of \$80,000 from the release of certain restricted cash balances.

Net cash used in investing activities was approximately \$0.5 million for the six months ended June 30, 2014, and consisted of \$0.5 million of purchases of laboratory equipment and computer software.

Net cash provided by (used in) financing activities

Net cash provided by financing activities was approximately \$936,000 for the six months ended June 30, 2015, and consisted of \$1.1 million of proceeds from the exercise of stock options and the sale of stock from the Company's 2014 employee stock purchase plan, partially offset by \$152,000 of repayments of notes payable.

Net cash used in financing activities was approximately \$1.6 million for the six months ended June 30, 2014, and consisted of \$0.9 million of repayments of notes payable and \$0.8 million of payments of deferred initial public offering costs, partially offset by proceeds from the exercise of stock options of \$0.1 million.

Table of Contents

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 May 2015, the Company entered into the First Amendment to our loan and security agreement with Solar Capital, Ltd. 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 will 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 the Note Agreement remain in effect.

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.

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 June 30, 2015, we had cash and cash equivalents of \$53.3 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 June 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.

Table of Contents

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 June 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 June 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 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.

Table of Contents

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 \$1.1 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

Edgar Filing: T2 Biosystems, Inc. - Form 10-Q

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 June 30, 2015. There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus, dated August 6, 2014, filed with the SEC pursuant to Rule 424(b) relating to our Registration Statement.

Table of Contents

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Table of Contents

Item 6. Exhibits, Financial Statement Schedules

Exhibit Number	Exhibit Description
10.1	Non-Employee Director Compensation Program (as amended)
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 June 30, 2015, 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 (iv) Notes to the Condensed Consolidated Financial Statements.

Table of Contents

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: August 5, 2015

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

T2 Bioystems, Inc.

Date: August 5, 2015

By: /s/ Marc R. Jones
Marc R. Jones
Chief Financial Officer