T2 Biosystems, Inc.
Form 10-Q
November 04, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

OR

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

For the transition period from to

Commission file number: 001-36571

T2 Biosystems, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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T2 BIOSYSTEMS, INC.

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PART I.

FINANCIAL INFORMATION

Item 1. Financial Statements

T2 Biosystems, Inc.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)

(Unaudited)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 40,117	$ 73,849
Accounts receivable	378	201
Prepaid expenses and other current assets	1,104	1,076
Inventories	1,057	115
Restricted cash		80
Total current assets	42,656	75,321
Property and equipment, net	9,448	2,760
Restricted cash, net of current portion	260	260
Deferred tax assets	313	313
Other assets	447	480
Total assets	$ 53,124	$ 79,134
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 993	$ 735
Accrued expenses and other current liabilities	4,291	3,662
Notes payable	1,417	295
Deferred revenue	1,199	80
Deferred tax liabilities	313	313
Lease incentives	241	87
Total current liabilities	8,454	5,172
Notes payable, net of current portion	19,344	20,660
Lease incentives, net of current portion	1,136	106
Other liabilities	380	195
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued		
	20	20

Common stock, $0.001 par value; 200,000,000 shares authorized; 20,339,261 and 20,041,645 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively				
Additional paid-in capital		160,643		156,576
Accumulated deficit		(136,853)		(103,595)
Total stockholders equity		23,810		53,001
Total liabilities and stockholders equity	$	53,124	$	79,134

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T2 Biosystems, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

(Unaudited)

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

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T2 Biosystems, Inc.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2015	2014
Operating activities		
Net loss	$ (33,258)	$ (22,315)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	979	459
Stock-based compensation expense	2,899	1,057
Noncash interest expense	288	102
Change in fair value of warrants		1
Deferred rent	(86)	15
Changes in operating assets and liabilities:		
Accounts receivable	(177)	
Prepaid expenses and other current assets	(28)	(901)
Inventories	(942)	
Accounts payable	258	(227)
Accrued expenses and other liabilities	303	2,110
Deferred revenue	1,119	
Net cash used in operating activities	(28,645)	(19,699)
Investing activities		
Purchases of property and equipment	(6,100)	(1,039)
Decrease in restricted cash	80	
Net cash used in investing activities	(6,020)	(1,039)
Financing activities		
Proceeds from issuance of common stock in initial public offering, net of offering costs		60,145
Proceeds from issuance of common stock and stock option exercises	1,168	150
Proceeds from notes payable, net of issuance costs		9,800
Repayment of notes payable	(235)	(3,966)
Net cash provided by financing activities	933	66,129
Net (decrease) increase in cash and cash equivalents	(33,732)	45,391
Cash and cash equivalents at beginning of period	73,849	30,198
Cash and cash equivalents at end of period	$ 40,117	$ 75,589
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 1,110	$ 294
Supplemental disclosures of noncash activities		
Accrued cost of property and equipment	$ 1,567	$
Accretion of Series A-1, A-2, B, C, D and E redeemable convertible preferred stock to redemption value	$	$ 4,570
Issuance costs incurred but unpaid at period end	$	$ 80
Initial public offering costs incurred but unpaid at period end	$	$ 2,104
Conversion of redeemable convertible preferred stock to common stock	$	$ 117,383

Conversion of preferred stock warrants to common stock	$	$ 1,226

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T2 Biosystems, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Nature of Business

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

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

Liquidity

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

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

2. Summary of Significant Accounting Policies

Basis of Presentation

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

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Unaudited Interim Financial Information

Certain information and footnote disclosures normally included in the Company s annual financial statements have been condensed or omitted. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2014.

The accompanying interim condensed consolidated balance sheet as of September 30, 2015, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2015 and 2014, the condensed consolidated statements of cash flows for the nine months ended September 30, 2015 and 2014 and the related financial data and other information disclosed in these notes are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements, and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company s financial position as of September 30, 2015, and the results of its operations and its cash flows for the three and nine months ended September 30, 2015 and 2014. The results for the three and nine months ended September 30, 2015 are not necessarily indicative of the results to be expected for the year ending December 31, 2015, any other interim periods, or any future year or period.

Segment Information

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

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss applicable to common stockholders, which is net loss plus accretion of redeemable convertible preferred stock to redemption value in the period, by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting the weighted-average number of shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method for outstanding stock options and warrants. For purposes of the diluted net loss per share calculation, redeemable convertible preferred stock and warrants to purchase redeemable convertible preferred stock outstanding prior to the August 2014 initial public offering and stock options are considered to be common stock equivalents, but have been excluded from the calculation of diluted net loss per share, as their effect, including the related impact to the numerator of the fair value adjustment of the warrant and the impact to the denominator of the warrant shares, would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share applicable to common stockholders was the same for all periods presented.

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Guarantees

From time to time, the Company enters into indemnification agreements in the ordinary course of business, including, but not limited to, indemnification agreements with directors and officers, within its lease agreements for office, laboratory and manufacturing space, and with certain suppliers and business partners. As of September 30, 2015 and December 31, 2014, the Company had not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

Revenue Recognition

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

i. Persuasive evidence of an arrangement exists

ii. Delivery has occurred or services have been rendered

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

iv. Collectability is reasonably assured

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

Product revenue is generated by the sale of T2Dx and consumable diagnostic tests. The Company either directly sells the T2Dx to customers, or retains title and places the T2Dx at the customer site pursuant to a reagent rental agreement. When a T2Dx is directly purchased by a customer, the Company generally recognizes revenue upon completion of the installation of the T2Dx at the customer location. When a T2Dx is placed under a reagent rental agreement, the Company s customers generally agree to longer-term agreements, minimum purchase commitments and/or pay an incremental charge on each consumable diagnostic test purchased, which varies based on the monthly volume of test cartridges purchased. Revenue from the sale of consumable diagnostic tests, which includes the incremental charge, is generally recognized upon shipment as a component of product revenue in the Company s consolidated statements of operations and comprehensive loss.

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

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

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

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

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

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

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

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

Cost of Revenues

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

Recent Accounting Pronouncements

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

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

In April 2015, the FASB issued ASU No. 2015-05, *Customer s Accounting for Fee*