

T2 Biosystems, Inc.
Form 10-Q
November 03, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2017

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	02421

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

(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 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company) Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant of Section 13(a) of the Exchange Act

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 October 30, 2017, the registrant had 35,824,960 shares of common stock outstanding.

T2 BIOSYSTEMS, INC.

TABLE OF CONTENTS

	Page
<u>PART I FINANCIAL INFORMATION</u>	
Item 1. <u>Financial Statements (unaudited)</u>	1
<u>Condensed Consolidated Balance Sheets as of September 30, 2017 and December 31, 2016</u>	1
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for three and nine months ended September 30, 2017 and September 30, 2016</u>	2
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2017 and September 30, 2016</u>	3
<u>Notes to Condensed Consolidated Financial Statements</u>	4
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	16
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	30
Item 4. <u>Controls and Procedures</u>	30
<u>PART II OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings</u>	31
Item 1A. <u>Risk Factors</u>	31
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	31
Item 3. <u>Defaults Upon Senior Securities</u>	31
Item 4. <u>Mine Safety Disclosures</u>	31
Item 5. <u>Other Information</u>	31
Item 6. <u>Exhibits, Financial Statement Schedules</u>	32
<u>SIGNATURES</u>	33

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, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 52,897	\$ 73,488
Accounts receivable	442	327
Prepaid expenses and other current assets	754	820
Inventories, net	1,254	803
Total current assets	55,347	75,438
Property and equipment, net	13,854	13,589
Restricted cash	260	260
Other assets	218	281
Total assets	\$ 69,679	\$ 89,568
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 993	\$ 962
Accrued expenses and other current liabilities	5,513	4,908
Current portion of notes payable	1,416	1,269
Deferred revenue	2,076	2,445
Current portion of lease incentives	247	301
Total current liabilities	10,245	9,885
Notes payable, net of current portion	40,089	39,504
Lease incentives, net of current portion	751	792
Other liabilities	467	49
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2016 and December 31, 2016	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized; 35,796,722 and 30,482,712 shares issued and outstanding at September 30, 2017 and December 31,	36	30

30,482,712 shares issued and outstanding at September 30, 2017 and December 31,

2016, respectively		
Additional paid-in capital	266,014	242,997
Accumulated deficit	(247,923)	(203,689)
Total stockholders' equity	18,127	39,338
Total liabilities and stockholders' equity	\$ 69,679	\$ 89,568

See accompanying notes to condensed consolidated financial statements.

T2 BIOSYSTEMS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Revenue:				
Product revenue	\$739	\$580	\$2,105	\$1,168
Research revenue	369	504	900	2,003
Total revenue	1,108	1,084	3,005	3,171
Costs and expenses:				
Cost of product revenue	2,106	1,894	5,722	4,701
Research and development	5,880	5,200	19,577	18,160
Selling, general and administrative	5,559	5,935	17,192	18,282
Total costs and expenses	13,545	13,029	42,491	41,143
Loss from operations	(12,437)	(11,945)	(39,486)	(37,972)
Interest expense, net	(1,718)	(876)	(5,008)	(2,416)
Other income, net	79	38	260	133
Net loss and comprehensive loss	\$(14,076)	\$(12,783)	\$(44,234)	\$(40,255)
Net loss per share — basic and diluted	\$(0.45)	\$(0.51)	\$(1.43)	\$(1.64)
Weighted-average number of common shares used in computing				
net loss per share — basic and diluted	31,420,726	25,027,751	30,873,930	24,524,508

See accompanying notes to condensed consolidated financial statements.

T2 BIOSYSTEMS, INC.

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended	
	September 30, 2017	2016
Cash flows from operating activities		
Net loss	\$ (44,234)	\$ (40,255)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,194	1,626
Stock-based compensation expense	3,806	3,659
Loss on sale of T2 owned equipment	134	—
Non-cash interest expense	1,968	459
Deferred rent	(95)	(187)
Changes in operating assets and liabilities:		
Accounts receivable	(115)	(10)
Prepaid expenses and other assets	129	(118)
Inventories, net	(451)	(654)
Accounts payable	31	(132)
Accrued expenses and other liabilities	361	797
Deferred revenue	(369)	(1,328)
Net cash used in operating activities	(36,641)	(36,143)
Cash flows from investing activities		
Purchases of property and equipment	(843)	—
Purchases of T2-owned equipment	(1,758)	(4,594)
	(2,601)	(4,594)

Net cash used in investing activities		
Cash flows from financing activities		
Payment of offering costs for issuance of common stock in public offering	(37)	(385)
Proceeds from issuance of common stock and stock options exercises, net	717	736
Proceeds from issuance of common stock in connection with private offering, net of offering costs	37	—
Proceeds from private investment in public entity	—	39,723
Proceeds from confidentially marketed public offering	18,832	—
Proceeds from notes payable, net of issuance costs	—	4,593
Repayments of note payable	(898)	(2,481)
Net cash provided by financing activities	18,651	42,186
Net decrease in cash and cash equivalents	(20,591)	1,449
Cash and cash equivalents at beginning of period	73,488	73,662
Cash and cash equivalents at end of period	\$ 52,897	\$ 75,111
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ 2,967	\$ 1,881
Supplemental disclosures of noncash investing and financing activities		
Accrued property and equipment	\$ 90	\$ 133

See accompanying notes to condensed consolidated financial statements.

3

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 diagnostics company that has developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. The Company is using its T2 Magnetic Resonance technology (“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. T2MR enables rapid detection of pathogens, biomarkers and other abnormalities in a variety of unpurified patient sample types, including whole blood, plasma, serum, saliva, sputum and urine, and can detect cellular targets at limits of detection as low as one colony forming unit per milliliter (“CFU/mL”). The Company’s initial development efforts target sepsis and lyme disease, which are 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 clearance from the U.S. Food and Drug Administration (“FDA”) for its first two products, the T2Dx Instrument (the “T2Dx”) and T2Candida Panel (“T2Candida”). On June 30, 2017 the Company received a CE Mark for its T2Bacteria Panel (“T2Bacteria”). On September 8, 2017 the Company filed a 510(k) premarket submission for the T2Bacteria Panel with the U.S. Food and Drug Administration (FDA).

Liquidity

At September 30, 2017, the Company had cash and cash equivalents of \$52.9 million and an accumulated deficit of \$247.9 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, including T2Bacteria, obtain additional capital and ultimately attain profitable operations. Historically, the Company has funded its operations primarily through its August 2014 initial public offering, its December 2015 confidentially marketed public offering (“CMPO”), its September 2016 private investment in public equity (“PIPE”) financing, its September 2017 CMPO, private placements of redeemable convertible preferred stock and through debt financing arrangements.

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

Having obtained authorization from the FDA to market T2Dx and T2Candida, the Company has incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution. The Company will continue the research and development of other product candidates and maintain, expand and protect its intellectual property portfolio. The Company may seek to fund its operations through public equity or private equity or debt financings, as well as other sources. However, the Company may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. The Company’s failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on the Company’s business, results of operations and financial condition and the Company’s ability to develop and commercialize T2Dx, T2Candida, T2Bacteria and other product candidates.

Management believes that its existing cash and cash equivalents at September 30, 2017, together with the additional remaining liquidity on the Company's Term Loan Agreement of up to an additional \$10.0 million, will be sufficient to allow the Company to fund its current operating plan through early 2019. The borrowing on the Term Loan Agreement is available at any time through July 27, 2018, and is subject to certain conditions including that the Company receive 510(k) clearance for the marketing of T2Bacteria by the FDA by April 30, 2018 (see Note 5). Should the Company's current operating plan not materialize as expected, including the Company's ability to draw additional borrowings on the Term Loan Agreement on a timely basis, the Company would delay certain research projects and capital expenditures and reduce or eliminate certain future operating expenses in order to fund operations at reduced levels for the Company to continue as a going concern for a period of 12 months from the date the financial statements are issued.

For more information, refer to the section titled "Liquidity and Capital Resources" in Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations and the section entitled "Risk Factors" in the Annual Report on Form 10-K for the year ended December 31, 2016, for additional risks associated with our capital needs.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

We have evaluated subsequent events from September 30, 2017 through the date of the issuance of these condensed consolidated financial statements and have determined that no material subsequent events have occurred that would have a material effect on the information presented in these consolidated financial statements.

Unaudited Interim Financial Information

Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2016.

The accompanying interim condensed consolidated balance sheet as of September 30, 2017, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2017 and 2016, the condensed consolidated statements of cash flows for the nine months ended September 30, 2017 and 2016 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, 2017, and the results of its operations and its cash flows for the three and nine months ended September 30, 2017 and 2016. The results for the three and nine months ended September 30, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017, 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 lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier.

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting the weighted-average number of shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net

loss per share calculation, stock options and unvested restricted stock are considered to be common stock equivalents, but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share applicable to common stockholders was the same for all periods presented.

Guarantees

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

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

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

As of September 30, 2017 and December 31, 2016, 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 instruments, 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 instruments and consumable diagnostic tests predominantly through the Company's direct sales force in the United States and distributors in geographic regions outside the United States. The Company does not offer product return or exchange rights (other than those relating to defective goods under warranty) or price protection allowances to its customers, including its distributors. Payment terms granted to distributors are the same as those granted to end-user customers and payments are not dependent upon the distributors' receipt of payment from their end-user customers. The Company either sells instruments to customers and international distributors, or retains title and places the instrument at the customer site pursuant to a reagent rental agreement. When the instrument is directly purchased by a customer, the Company recognizes revenue when all applicable revenue recognition criteria are met. When the instrument is placed under a reagent rental agreement, the Company's customers generally agree to fixed term agreements, which can be extended, certain of which may include minimum purchase commitments and/or incremental charges on each consumable diagnostic test purchased, which varies based on the volume of test cartridges purchased. Revenue from the sale of consumable diagnostic tests, which includes the incremental charge, is recognized upon delivery or shipment as a component of product revenue in the Company's consolidated statements of operations and comprehensive loss.

Direct sales of instruments include warranty, maintenance and technical support services typically for one year following the installation of the purchased instrument ("Maintenance Services"). After the completion of the initial Maintenance Services period, customers have the option to renew the Maintenance Services typically 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 the instrument equal to the relative fair value of the one year of Maintenance Services and training and recognizes the amounts ratably over the service delivery period.

The Company warrants that consumable diagnostic tests will be free from defects, when handled according to product specifications, for the stated life of the product. To fulfill valid warranty claims, the Company either provides a credit to its customers on future orders or provides a replacement product. 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 instruments or consumable diagnostic tests.

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

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

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

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

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

Product Recall

In July 2016, the Company initiated a voluntary recall and replacement of its T2Candida cartridges at certain customer sites because T2Candida was experiencing higher than normal invalid test rates as the T2Candida cartridges aged. As of September 30, 2016, as a result of this voluntary recall, the Company deferred revenue totaling \$149,000 and recorded additional costs of product revenue of \$41,000 related to returned products, which are no longer usable. As of September 30, 2017, the Company had \$20,000 of deferred revenue and \$2,000 of warranty reserve remaining, both related to this voluntary recall. The impact of the voluntary recall on T2Candida cartridges in inventory was not material to the condensed consolidated financial statements.

Cost of Product Revenue

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

Research and Development Costs

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

Recent Accounting Standards

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.

7

Accounting Standards Adopted

In August 2014, the Financial Accounting Standards Board (“FASB”) issued ASU No. 2014-15, “Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern” which is intended to define management’s responsibility to evaluate whether there is substantial doubt about an organization’s ability to continue as a going concern and to provide related footnote disclosures. Substantial doubt about an entity’s ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its financial obligations as they become due within one year after the date that the financial statements are issued (or are available to be issued). ASU No. 2014-15 provides guidance to an organization’s management, with principles and definitions intended to reduce diversity in the timing and content of disclosures commonly provided by organizations in the footnotes of their financial statements. ASU No. 2014-15 was effective for annual reporting periods ending after December 15, 2016, and for annual and interim periods thereafter. This standard has been adopted and reflected in the Company’s disclosures regarding liquidity.

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’s adoption of this standard did not have a material effect on its condensed consolidated financial statements.

In March 2016, the FASB released ASU No. 2016-09 Improvements to Employee Share-Based Payment Accounting (“ASU 2016-09”) which is intended to simplify income tax accounting for excess tax benefits, accounting for forfeitures, and employer statutory withholding. Under the current guidance, excess tax benefits that result from an award vesting or settling are recognized in additional paid-in capital in the period that they reduce cash taxes payable. This requires the provision to be computed on a with and without option basis and may result in net operating loss and credit carryforwards on the balance sheet being less than what is available on the tax return. Under the new guidance, the income tax effects of awards will be recognized as a component of income tax expense when the awards vest or are settled (regardless if cash taxes are reduced). For interim reporting purposes, companies will account for excess tax benefits and tax deficiencies as discrete items in the period during which they occurred. The guidance is effective for public entities for fiscal years beginning after December 15, 2016, and interim periods within those years. Early adoption is permitted, however all of the guidance included in the update must be applied when adopted. The Company must use a modified retrospective transition method for adopting and record the cumulative effect of all unrecognized benefits and any change in valuation allowances at the end of the prior tax period as an adjustment to retained earnings. The Company’s adoption of this standard did not have a material effect on its condensed consolidated financial statements and prior periods have not been adjusted. As a result, the Company established a net operating loss deferred tax asset of \$1.2 million to account for prior period excess tax benefits through retained earnings, however an offsetting valuation allowance of \$1.2 million will also be established through retained earnings because it is not more likely than not that the deferred tax asset will be realized due to historical and expected future losses, such that there is no impact on the Company’s condensed consolidated financial statements. The Company also elected to maintain the use of estimated forfeitures in the calculation of stock based compensation.

In March 2016, the FASB issued ASU No. 2016-06, Derivatives and Hedging (Topic 815): Contingent Put and Call Options in Debt Instruments (“ASU 2016-06”), which applies to all issuers of or investors in debt instruments with embedded call or put options. ASU 2016-06 clarifies the requirements for assessing whether contingent call or put options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts. Entities performing the assessment under the guidance of ASU 2016-06 are required to assess the embedded call or put options solely in accordance with the four-step decision process. In addition, ASU 2016-06 clarifies what

steps are required when assessing whether the economic characteristics and risks of call or put options are clearly and closely related to the economic characteristics and risks of their debt hosts. ASU 2016-06 is effective for financial statements issued for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years using the modified retrospective method for existing debt instruments. The Company's adoption of this standard did not have a material effect on its condensed consolidated financial statements.

Accounting Standards Issued, Not Adopted

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments ("ASC 2016-15"), which provides guidance on the classification of certain specific cash flow issues including debt prepayment or extinguishment costs, settlement of certain debt instruments, contingent consideration payments made after a business combination, proceeds from the settlement of certain insurance claims and distributions received from equity method investees. The standard requires the use of a retrospective approach to all periods presented, but may be applied prospectively if retrospective application would be impracticable. The guidance is effective for public entities for fiscal years beginning after

December 15, 2017, and interim periods within those years, and early application is permitted. The Company is currently evaluating the impact of its pending adoption of ASU 2016-15 on the Company’s consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (“ASU 2016-02”), which applies to all leases. Under ASU 2016-02, a right-of-use asset and lease obligation will be recorded for all leases, whether operating or financing leases, while the statement of operations will reflect lease expense for operating leases and amortization and interest expense for financing leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 and interim periods within those years, which is the year ended December 31, 2019 for the Company. Entities are required to use a modified retrospective approach of adoption for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. Full retrospective application is prohibited. The Company is evaluating the new guidance and the expected effect on the Company’s 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 currently anticipates adoption of the new standard effective January 1, 2018 under the modified retrospective method. The Company is analyzing the potential impact that ASU 2014-09 may have on its financial position and results of operations; however, the Company anticipates significant changes to its financial statement disclosures. As of September 30, 2017, the Company has completed its revenue stream analysis and advanced its assessment of the impact of ASU 2014-09 on its revenue-generating arrangements, including its product sales made as direct sales, sales to distributors, reagent rental agreements and its research arrangements. The Company is in the process of finalizing the quantitative impact the ASUs will have on the financial statements, as well as its plan for implementation. In addition, the Company continues to monitor additional changes, modifications, clarifications or interpretations undertaken by the FASB, which may impact its conclusions.

3. Fair Value Measurements

The Company measures the following financial assets at fair value on a recurring basis. There were no transfers between levels of the fair value hierarchy during any of the periods presented. The following tables set forth the Company’s financial assets carried at fair value categorized using the lowest level of input applicable to each financial instrument as of September 30, 2017 and December 31, 2016 (in thousands):

Balance at	Quoted	Significant	Significant
September 30,	Prices	Other	Unobservable
2017	in	Observable	Inputs
	Active	Inputs	(Level 3)
	Markets	(Level 2)	
	for	Identical	
	Assets	Assets	

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

		(Level 1)		
Assets:				
Cash	\$ 19,644	\$19,644	\$ —	\$ —
Money market funds	33,253	33,253	—	—
Restricted cash	260	260	—	—
Total	\$ 53,157	\$53,157	\$ —	\$ —

		Quoted Prices in Active Markets for	Significant Other	Significant Unobservable Inputs
	Balance at December 31, 2016	Identical Assets (Level 1)	Observable Inputs (Level 2)	(Level 3)
Assets:				
Cash	\$ 16,887	\$16,887	\$ —	\$ —
Money market funds	56,601	56,601	—	—
Restricted cash	260	260	—	—
Total	\$ 73,748	\$73,748	\$ —	\$ —

For certain financial instruments, including accounts payable and accrued expenses, the carrying amounts approximate their fair values as of September 30, 2017 and December 31, 2016 because of their short-term nature. At September 30, 2017 and December 31, 2016, the carrying value of the Company's debt approximated fair value, which was determined using Level 3 inputs, using market quotes from brokers and is based on current rates offered for similar debt (Note 5).

4. Supplemental Balance Sheet Information

Inventories

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

	September 30,	December 31,
	2017	2016
Raw materials	\$ 500	\$ 389
Work-in-process	476	351
Finished goods	278	63
Total inventories, net	\$ 1,254	\$ 803

Property and Equipment

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

	September 30,	December 31,
	2017	2016
Office and computer equipment	\$ 409	\$ 409
Software	743	708
Laboratory equipment	4,094	4,516
Furniture	200	200
Manufacturing equipment	910	897
Manufacturing tooling and molds	160	154
T2-owned instruments and components	10,878	9,119
Leasehold improvements	3,378	3,353
Construction in progress	1,557	1,299
	22,329	20,655
Less accumulated depreciation and amortization	(8,475)	(7,066)
Property and equipment, net	\$ 13,854	\$ 13,589

Construction in progress is primarily comprised of equipment and leasehold improvement projects that have not been placed in service. T2-owned instruments and components is comprised of raw materials and work-in-process inventory that are expected to be used or used to produce T2-owned instruments, based on our business model and forecast, and completed instruments that will be used for internal research and development, clinical studies or reagent rental agreements with customers. Completed T2-owned instruments are placed in service once installation procedures are completed and are depreciated over five years. The Company has approximately \$7.9 million and \$5.7 million of T2-owned instruments installed and depreciating as of September 30, 2017 and December 31, 2016, respectively. Depreciation expense for T2-owned instruments placed at customer sites pursuant to reagent rental

agreements is recorded as a component of cost of product revenue and totaled approximately \$0.2 million and \$0.2 million for the three months ended September 30, 2017 and 2016, respectively, and \$0.7 million and \$0.4 million for the nine months ended September 30, 2017 and 2016, respectively. Depreciation expense for T2-owned instruments used for internal research and development and clinical studies is recorded as a component of research and development expense.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, December 31,	
	2017	2016
Accrued payroll and compensation	\$ 2,875	\$ 2,479
Accrued research and development expenses	1,038	846
Accrued professional services	987	884
Other accrued expenses	613	699
Total accrued expenses	\$ 5,513	\$ 4,908

5. Notes Payable

Future principal payments on the notes payable are as follows (in thousands):

	September 30,	December 31,
	2017	2016
Term loan agreement, net of deferred issuance costs of \$2.5 million and \$3.0 million, respectively	\$ 38,695	\$ 37,031
Equipment lease credit facility, net of deferred issuance cost of \$29 thousand and \$45 thousand, respectively	2,810	3,742
Total notes payable	41,505	40,773
Less: current portion of notes payable	(1,416)	(1,269)
Notes payable, net of current portion	\$ 40,089	\$ 39,504

Term Loan Agreement

In December 2016, the Company entered into a Term Loan Agreement (the “Term Loan Agreement”) with CRG Servicing LLC (“CRG”). The Company initially borrowed \$40.0 million pursuant to the Term Loan Agreement and may borrow up to an additional \$10.0 million at any time through and including July 27, 2018, provided that, among other conditions, the Company receives 510(k) clearance for the marketing of T2Bacteria by the FDA on or before April 30, 2018 (the “Approval Milestone”). The Term Loan Agreement has a six-year term with three years (through December 30, 2019) of interest-only payments, which period shall be extended to four years (through December 30, 2020) if the Company achieves the Approval Milestone, after which quarterly principal and interest payments will be due through the December 30, 2022 maturity date. Interest on the amounts borrowed under the Term Loan Agreement accrues at an annual fixed rate of (a) prior to the Approval Milestone, 12.5%, 4.0% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount and (b) following the Approval Milestone, 11.5%, 3.5% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount. In addition, if the Company achieves certain financial performance metrics, the loan will convert to interest-only until the December 30, 2022 maturity, at which time all unpaid principal and accrued unpaid interest will be due and payable. The Company is required to pay CRG a financing fee based on the loan principal amount drawn. The Company is also required to pay a final payment fee of 8.0% of the principal outstanding upon repayment, which is being accreted over the term of the debt as additional interest expenses.

The Company may prepay all or a portion of the outstanding principal and accrued unpaid interest under the Term Loan Agreement at any time upon prior notice subject to a prepayment fee during the first five years of the term and no prepayment fee thereafter. As security for its obligations under the Term Loan Agreement the Company entered into a security agreement with CRG whereby the Company granted a lien on substantially all of its assets, including intellectual property. The Term Loan Agreement also contains customary affirmative and negative covenants for a credit facility of this size and type. The Term Loan Agreement also requires the Company to achieve certain annual revenue targets, whereby the Company is required to pay double the amount of any shortfall as an acceleration of principal payments. The revenue target for fiscal 2017 is \$5.0 million on this provision. The Term Loan Agreement includes a subjective acceleration clause whereby an event of default, including a material adverse change in the business, operations, or conditions (financial or otherwise), could result in the acceleration of the obligations under the

Term Loan Agreement. Under certain circumstances, a default interest rate of an additional 4.0% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default. CRG has not exercised its right under this clause, as there have been no such events. The Company believes the likelihood of CRG exercising this right is remote.

The Company assessed the terms and features of the Term Loan 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 Term Loan Agreement, including put and call features. The Company determined that the features of the Term Loan Agreement are either 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. Included in these features are principal payment acceleration clauses triggered by a developmental milestone. Should the Company's assessment of this milestone change, there could be a non-cash charge in operations. The Company will continue to reassess the features to determine if they require separate accounting on a quarterly basis.

In December 2016, pursuant to the Term Loan Agreement, the Company made an initial draw of \$39.2 million, net of financing fees. The Company used approximately \$28.0 million of the initial proceeds to repay approximately \$27.5 million of outstanding debt pursuant to the Loan and Security Agreement and to repay approximately \$0.5 million of outstanding debt pursuant to the Promissory Note. Upon the repayment of all amounts owed by the Company under these agreements, all commitments were terminated and all security interests granted by the Company were released.

In connection with the Term Loan Agreement entered into in December 2016, the Company issued to CRG four separate warrants to purchase a total of 528,958 shares of the Company's common stock. The warrants are exercisable any time prior to December 30, 2026 at a price of \$8.06 per share, with typical provisions for termination upon a change of control or a sale of all or substantially all of the assets of the Company. The warrants are classified within shareholders' equity, and the proceeds were allocated between the debt and warrants based on their relative fair value. The fair value of the warrants was determined by the Black Scholes Merton option pricing model. The fair value of the warrants at issuance on December 30, 2016 was \$1.8 million.

Equipment Lease Credit Facility

In October 2015, the Company signed a \$10.0 million Credit Facility with Essex Capital Corporation (the "Lessor") to fund capital equipment needs. As one of the conditions of the Term Loan Agreement, the Credit Facility is capped at a maximum of \$5.0 million. Under the Credit Facility, Essex will fund capital equipment purchases presented by the Company. The Company will repay the amounts borrowed in 36 equal monthly installments from the date of the amount funded. At the end of the 36 month lease term, the Company has the option to (a) repurchase the leased equipment at the lesser of fair market value or 10% of the original equipment value, (b) extend the applicable lease for a specified period of time, which will not be less than one year, or (c) return the leased equipment to the Lessor.

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

6. Stockholders' Equity

Private Investment in Public Equity Financing

On September 21, 2016, Canon U.S.A., Inc. ("Canon") became a related party when the Company sold 6,055,341 shares of its common stock (the "Canon Shares") to Canon at \$6.56 per share, the closing price on this date, for an aggregate cash purchase price of \$39.7 million. As of September 21, 2016, the Canon Shares represented 19.9% of the outstanding shares of common stock of the Company. In connection with the sale of the Canon Shares, the Company agreed to grant Canon certain board designation rights, including the right to initially appoint a Class I director to the Company's board of directors. On March 20, 2017, the Company filed with the Securities and Exchange Commission (the "SEC") a registration statement on Form S-3 for purposes of registering the resale of the Canon Shares with the SEC.

On September 15, 2017, the company sold 5,031,250 shares of its common stock in a CMPO at \$4.00 per share, for an aggregate gross cash purchase price of \$20.1 million, or proceeds of \$18.8 million after underwriters discount and expenses.

7. Stock-Based Compensation

Stock Incentive Plans

2006 Stock Incentive Plan

The Company's 2006 Employee, Director and Consultant 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 Incentive Award Plan ("2014 Plan", and together with the 2006 Plan, the "Stock Incentive 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 and restricted stock units. 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) 4% of the shares outstanding (on an as-converted basis) on the final day of the immediately preceding calendar year, and (B) such smaller number of shares determined by the Company's Board of Directors. As of September 30, 2017 there were 979,124 shares available for future grant under the 2014 Plan.

Stock Options

During the nine months ended September 30, 2017 and 2016, the Company granted stock options with an aggregate fair value of \$2.5 million and \$6.6 million, respectively, which are being amortized into compensation expense over the vesting period of the stock options as the services are being provided.

The following is a summary of stock option activity under the Plans (in thousands, except share and per share amounts):

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average	
			Remaining Contractual Term (In years)	Aggregate Intrinsic Value
Outstanding at December 31, 2016	4,042,627	\$ 8.20	7.05	\$ 4,091
Granted	807,450	5.18	6.00	
Exercised	(194,783)	2.34		502
Forfeited	(554,867)	9.17		
Cancelled	(267,127)	12.56		
Outstanding at September 30, 2017	3,833,300	7.42	6.67	1,040
Exercisable at September 30, 2017	2,440,070	7.24	5.57	976
Vested or expected to vest at September 30,				
2017	3,600,971	7.35	5.77	1,024

Included in the stock options outstanding as of December 31, 2016 are 166,066 options to purchase common stock granted to certain executive officers of the Company that vest upon the achievement of certain performance conditions, which include the attainment of specified operating result and regulatory targets, by December 31, 2017, of which 20,000 options to purchase common stock upon the achievement of certain performance conditions were forfeited during the year ended December 31, 2016. There are 146,066 performance based stock options outstanding at September 30, 2017 and December 31, 2016. The Company will continually evaluate the probability of achievement of each performance condition and will commence recognition of stock-based compensation expense on these awards in the period the achievement of each performance condition is deemed probable, including a catch-up adjustment from the grant date.

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

The weighted-average grant date fair values of stock options granted in the nine month periods ended September 30, 2017 and 2016 were \$3.04 per share and \$4.76 per share, respectively, and were calculated using the following estimated assumptions:

	Nine Months Ended September 30,	
	2017	2016
Weighted-average risk-free interest rate	1.98 %	1.42 %
Expected dividend yield	— %	— %
Expected volatility	63 %	61 %
Expected terms	6.0 years	6.0 years

The total fair values of stock options that vested during the nine months ended September 30, 2017 and 2016 were \$3.5 million and \$3.7 million, respectively.

As of September 30, 2017, there was \$5.2 million of total unrecognized compensation cost related to unvested stock options granted under the Stock Incentive Plans, including the unrecognized compensation expense of stock options with performance conditions deemed probable of vesting. Total unrecognized compensation cost will be adjusted for future changes in the estimated forfeiture rate. The Company expects to recognize that cost over a remaining weighted-average period of 2.24 years as of September 30, 2017.

Restricted Stock Units

During the nine months ended September 30, 2017, the Company awarded shares of restricted stock units to certain employees and directors at no cost to them, which cannot be sold, assigned, transferred or pledged during the restriction period. The restricted stock and restricted stock units vest through the passage of time, assuming continued employment. Restricted stock units are not included in issued and outstanding common stock until the shares are vested and released. The fair value of the award at the time of the grant is expensed on a straight line basis. The granted restricted stock units had an aggregate fair value of \$2.9 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 restricted stock unit activity under the 2014 Plan (in thousands, except share and per share amounts):

	Number of Shares	Weighted-Average Grant Date Fair Value
Nonvested at December 31, 2016	272,195	5.83
Granted	552,925	5.17
Vested	—	—
Forfeited	(74,800)	5.87
Canceled	—	—
Nonvested at September 30, 2017	750,320	5.34

There was no vesting of restricted stock units during the nine months ended September 30, 2017. As of September 30, 2017, there was \$2.6 million of total unrecognized compensation cost related to unvested restricted stock units granted under the Stock Incentive Plans. Total unrecognized compensation cost will be adjusted for future forfeitures. The Company expects to recognize that cost over a remaining weighted-average period of 1.7 years as of September 30, 2017.

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		Nine Months Ended	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Cost of product revenue	\$18	\$27	\$87	\$86
Research and development	340	292	1,047	902

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

Selling, general and administrative	862	779	2,555	2,572
Total stock-based compensation expense	\$1,220	\$1,098	\$3,689	\$3,560

For the three months ended September 30, 2017 and 2016, \$33,000 and \$32,000 of stock-based compensation expenses were capitalized as part of inventory or T2Dx instruments and components, respectively. For the nine months ended September 30, 2017 and 2016, \$117,000 and \$99,000 of stock-based compensation expenses were capitalized as part of inventory or T2Dx instruments and components, respectively.

8. Warrants

In connection with the Term Loan Agreement entered into in December 2016, the Company issued to CRG four separate warrants to purchase a total of 528,958 shares of the Company's common stock. The warrants are exercisable any time prior to December 30, 2026 at a price of \$8.06 per share, with typical provisions for termination upon a change of control or a sale of all or substantially all of the assets of the Company. The warrants are classified within shareholders' equity, and the proceeds were allocated between the debt and warrants based on their relative fair value. The fair value of the warrants was determined by the Black-Scholes-Merton option pricing model. The fair value of the warrants at issuance on December 30, 2016 was \$1.8 million.

9. 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 their effect would have been anti-dilutive for the periods presented:

	Three Months Ended		Nine Months Ended	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Options to purchase common shares	3,833,300	4,263,094	3,833,300	4,263,094
Restricted stock units	750,320	—	750,320	—
Warrants to purchase common stock	528,958	—	528,958	—
Total	5,112,578	4,263,094	5,112,578	4,263,094

10. Co-Development Agreements

Canon US Life Sciences

On September 21, 2016, Canon became a related party when the Company sold the Canon Shares for an aggregate cash purchase price of \$39.7 million, which represented 19.9% of the outstanding shares of common stock of the Company. On February 3, 2015, the Company entered into a Co-Development Partnership Agreement (the “Co-Development Agreement”) with Canon U.S. Life Sciences, Inc. (“Canon US Life Sciences”) to develop a diagnostic test panel to rapidly detect Lyme disease. Under the terms of the Co-Development Agreement, the Company received an upfront payment of \$2.0 million from Canon US Life Sciences, and the agreement includes an additional \$6.5 million of consideration upon achieving certain development and regulatory milestones for total aggregate payments of up to \$8.5 million. In October 2015, the Company achieved a specified technical requirement and received \$1.5 million related to the achievement of the milestone. The Company is eligible to receive an additional \$5.0 million under the arrangement, in two milestone payments of \$2.0 million and \$3.0 million, related to the achievement of additional development and regulatory milestones. All payments under the Co-Development Agreement are non-refundable once received. The Company will retain exclusive worldwide commercialization rights of any products developed under the Co-Development Agreement, including sales, marketing and distribution and Canon US Life Sciences will not receive any commercial rights and will be entitled to only receive royalty payments on the sales of all products developed under the Co-Development Agreement. Either party may terminate the Co-Development Agreement upon the occurrence of a material breach by the other party (subject to a cure period).

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

The Company recorded revenue of \$0.0 and \$0.4 million during the three months ended September 30, 2017 and September 30, 2016, respectively, and recorded revenue of \$0.3 million and \$1.5 million during the nine months

ended September 30, 2017 and 2016, under the Co-Development Agreement, and expects to record revenue over the next two years, provided development milestones are achieved.

Allergan Sales, LLC

On November 1, 2016, the Company entered into a Co-Development, Collaboration and Co-Marketing Agreement (the “Allergan Agreement”) with Allergan Sales, LLC (“Allergan Sales”) to develop (1) a direct detection diagnostic test panel that adds one additional bacteria species to the existing T2Bacteria product candidate (the “T2Bacteria II Panel”), and (2) a direct detection diagnostic test panel for testing drug resistance directly in whole blood (the “T2GNR Panel” and, together with the T2Bacteria II Panel, the “Developed Products”). In addition, both the Company and Allergan Sales will participate in a joint research and development committee and Allergan Sales will receive the right to cooperatively market the T2Candida, T2Bacteria, and the Developed Products under the Allergan Agreement to certain agreed-upon customers. On June 1, 2017 the Company and Allergan Sales entered into an Amendment to the Allergan Agreement which primarily modified the project plan to combine the T2Bacteria II Panel and T2GNR Panel into one test panel.

Under the terms of the Allergan Agreement, the Company received an upfront payment of \$2.0 million from Allergan Sales and will receive additional milestone payments upon achieving certain developmental milestones for total aggregate payments of up to \$4.0 million. All payments under the Allergan Agreement are non-refundable once received. The Company will retain exclusive

worldwide commercialization rights of any products developed under the Allergan Agreement, including distribution, subject to Allergan Sales' right to co-market the Developed Products. Allergan Sales, at its election, may co-market T2Candida, T2Bacteria and the Developed Products worldwide to certain agreed-upon customers and will receive royalty based on its sales for a period of time.

The Company evaluated the deliverables under the Allergan Agreement and determined that the Allergan Agreement included two units of accounting, the research and development services for the T2Bacteria II Panel and the research and development services for the T2GNR Panel, as the joint research and development committee and right to cooperatively market deliverables were deemed to be de minimus. The Company is recognizing revenue for research and development services as a component of research revenue in the 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 Allergan Agreement are recorded as research and development expense in the consolidated financial statements.

The Company recorded revenue of \$0.4 million and \$0.6 million for the three and nine months ended September 30, 2017, respectively, under the Allergan Agreement and expects to record revenue over the next two years, provided development and regulatory milestones are achieved.

11. Subsequent Events.

None

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, and Section 21E of the Securities and 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 clearance from the U.S. Food and Drug Administration ("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, availability of funding for such 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 of these terms or other similar expressions. The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described under the sections in this Quarterly Report on Form 10-Q entitled "Item 1A.—Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Quarterly Report on Form 10-Q. These forward looking statements are subject to numerous risks, including, without limitation, the following:

- our expectation to incur losses in the future;
- the market acceptance of our T2MR technology;
- our ability to timely and successfully develop and commercialize our existing products and future product candidates;
- the length of our anticipated sales cycle;
- our ability to gain the support of leading hospitals and key thought leaders and publish the results of our clinical trials in peer-reviewed journals;
- our ability to successfully manage our growth;
- our future capital needs and our need to raise additional funds;
- the performance of our diagnostics;
- our ability to compete in the highly competitive diagnostics market;

16

our ability to obtain marketing clearance from the FDA or regulatory clearance for new product candidates in the United States or any other jurisdiction;
federal, state, and foreign regulatory requirements, including FDA regulation of our product candidates; and
our ability to protect and enforce our intellectual property rights, including our trade secret-protected proprietary rights in T2MR.

These forward-looking statements represent our estimates and assumptions only as of the date of this Quarterly Report on Form 10-Q. Unless required by U.S. federal securities laws, we do not intend to update any of these forward-looking statements to reflect circumstances or events that occur after the statement is made or to conform these statements to actual results. The following discussion should be read in conjunction with the financial statements and notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2016, as supplemented or amended from time to time under “Item 1A.—Risk Factors” in our Quarterly Reports on Form 10-Q, and elsewhere in this Quarterly Report on Form 10-Q.

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

Business Overview

We are an in vitro diagnostics company that has developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. We are using our T2 Magnetic Resonance technology (“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. T2MR enables rapid detection of pathogens, biomarkers and other abnormalities in a variety of unpurified patient sample types, including whole blood, plasma, serum, saliva, sputum and urine, and can detect cellular targets at limits of detection as low as one colony forming unit per milliliter (“CFU/mL”). Our initial development efforts target sepsis and Lyme disease, which are areas of significant unmet medical need in which existing therapies could be more effective with improved diagnostics. On September 22, 2014, we received market clearance from the FDA for our first two products, the T2Dx Instrument (the “T2Dx”) and the T2Candida Panel (“T2Candida”), which have the ability to rapidly identify the five clinically relevant species of Candida, a fungal pathogen known to cause sepsis. In the United States, we have built a direct sales force that is primarily targeting the top 450 hospitals with the highest concentration of patients at risk for Candida infections. This target number of hospitals may be increased to an estimated over 1,200 with the introduction of T2Bacteria in the United States upon approval by the FDA. Outside of the United States, we have partnered with distributors that target large hospitals in their respective markets. Four additional diagnostic applications in various stages of development are called T2Bacteria, T2Candida auris, T2GNR and T2Lyme, which are focused on bacterial and fungal infections and Lyme disease, respectively. In late 2015, we initiated the collection of patient blood samples to support the clinical trial in the United States for T2Bacteria, and in early 2017, we initiated a multi-site clinical trial for T2Bacteria. The T2Bacteria Panel received authorization to affix a CE mark in July 2017 and is being commercially launched in Europe and other countries that accept the CE mark. The multi-site clinical study was completed in the United States in August 2017. On September 8, 2017, we filed a 510(k) premarket notification with the FDA requesting market clearance to enable commercial launch of T2Bacteria for clinical use in the United States. T2 Bacteria is currently

available in the United States for Research Use Only (RUO). We believe that we may receive a determination from the FDA on our application for the T2Bacteria possibly as early as the end of 2017, although it may take longer for the FDA to reach a decision and there can be no assurance of such a determination within this timeframe or at all. We believe that T2Bacteria, if approved, may expand the number of high risk patients who could be candidates for testing with T2Candida and/or T2Bacteria. We expect that existing reimbursement codes will support our sepsis and Lyme disease products and product candidates, and that the anticipated economic savings associated with testing of hospital inpatients in the United States with our sepsis products will be realized directly by hospitals.

We believe our sepsis products, which include T2Candida and our product candidate, T2Bacteria, will redefine the standard of care in sepsis management while lowering healthcare costs by improving both the precision and the speed of detection of sepsis-causing pathogens. According to a study published in the Journal of Clinical Microbiology in 2010, targeted therapy for patients with bloodstream infections can be delayed up to 72 hours due to the wait time for blood culture results. In another study published in Clinical Infectious Diseases in 2012, the delayed administration of appropriate antifungal therapy was associated with higher mortality among patients with septic shock attributed to Candida infection and, on that basis, the study concluded that more rapid and accurate

diagnostic techniques are needed. Due to the high mortality rate associated with Candida infections, physicians often will place patients on antifungal drugs while they await blood culture diagnostic results which generally take at least five days to generate a negative test result. Antifungal drugs are toxic and may result in side effects and can cost over \$50 per day. T2Candida's speed to result coupled with its superior sensitivity as compared to blood culture may help reduce the overuse of ineffective, or even unnecessary, antimicrobial therapy which may reduce side effects for patients, lower hospital costs and potentially counteract the growing resistance to antifungal therapy. The administration of inappropriate therapy is a driving force behind the spread of antimicrobial-resistant pathogens, which the United States Centers for Disease Control and Prevention ("CDC") recently called "one of our most serious health threats." The T2Sepsis Solution refers to the approach of combining the standard of care for the management of sepsis patients with our products, including the T2Dx Instrument, or the T2Dx, T2Candida, and T2Bacteria, which is commercially available in Europe and other countries that accept the CE mark and available for research use only in the United States. The T2Sepsis Solution is designed to enable clinicians to potentially treat 95% of septic patients within the first twelve hours of developing the symptoms of disease. Currently, high risk patients are typically initially treated with broad spectrum antibiotic drugs that typically cover approximately 60% of patients with infections. Of the remaining 40% of patients, approximately 30% of the patients have a bacterial infection and 10% have Candida infections. T2Candida and our product candidate, T2Bacteria are designed to identify pathogens commonly not covered by broad spectrum antibiotic drugs, which we believe may enable physicians to effectively treat an additional 35% of septic patients beyond the 60% of patients covered by broad spectrum antibiotic drugs.

We compete with traditional blood culture-based diagnostic companies, including Becton Dickinson & Co. and bioMerieux, Inc., as well as companies offering post-culture species identification using both molecular and non-molecular methods, including bioMerieux, Inc. (and its affiliate, BioFire Diagnostics, Inc.), Bruker Corporation, Accelerate Diagnostics, Luminex, Genmark, Cepheid and Beckman Coulter, a Danaher company.

We have never been profitable and have incurred net losses in each year since inception. Our accumulated deficit at September 30, 2017 was \$247.9 million. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations. We have incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution of our FDA-cleared T2Dx and T2Candida. In addition, we expect that costs and expenses may increase as we continue to develop other product candidates, improve existing products and maintain, expand and protect our intellectual property portfolio. 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 if and when needed would have a negative impact on our business, results of operations and financial condition and our ability to develop, commercialize and drive adoption of the T2Dx, T2Candida, our product candidate, T2Bacteria, and future T2MR-based diagnostics.

Management believes that its existing cash and cash equivalents at September 30, 2017, together with the additional remaining liquidity on the Company's Term Loan Agreement of up to an additional \$10.0 million (which is available at any time through July 27, 2018, subject to certain conditions including that the Company receives 510(k) clearance for the marketing of T2Bacteria by the FDA by April 30, 2018, see Note 5 for details) will be sufficient to allow the Company to fund its current operating plan to the first half of 2019. Should the Company's current operating plans not materialize as expected, or it is unable to obtain additional capital on a timely basis, or on acceptable terms, the Company will be required to change its current operating plans to reduce its future expenses in order to fund operations at reduced levels.

Our Commercial Products and the Unmet Clinical Need

Our initial FDA-cleared products, the T2Dx instrument and T2Candida, utilize T2MR to detect species-specific Candida directly from whole blood in as few as three hours versus the one to six or more days typically required by blood culture-based diagnostics. This allows the patient to potentially receive the correct treatment in four to six hours versus 24 to 144 hours for blood culture. The T2Candida runs on the T2Dx and provides high sensitivity with a limit of detection as low as 1 CFU/mL, even in the presence of antimicrobial therapy.

Our T2Candida Panel

Our directT2 pivotal clinical trial was designed to evaluate the sensitivity and specificity of T2Candida on the T2Dx. The directT2 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 the 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 greater than 120 hours with blood culture. The data and other information from the directT2 pivotal clinical trial was published in January 2015 in *Clinical Infectious Diseases*.

Sepsis is one of the leading causes of death in the United States, claiming more lives annually than breast cancer, prostate cancer and AIDS combined, and it is the most expensive hospital-treated condition. Most commonly afflicting immunocompromised, critical care and elderly patients, sepsis is a severe inflammatory response to a bacterial or fungal infection with a mortality rate of approximately 30%. According to data published by the U.S. Department of Health and Human Services for 2016, the cost of sepsis was over \$23 billion in the United States, or approximately 5% of the total aggregate costs associated with domestic hospital stays. Sepsis is typically caused by one or more of five *Candida* species or over 25 bacterial pathogens, and effective treatment requires the early detection and identification of these specific target pathogens in a patient's bloodstream. Today, sepsis is typically diagnosed through a series of blood cultures followed by post-blood culture species identification. These methods have substantial diagnostic limitations that lead to a high rate of false negative test results, a delay of up to several days in administration of targeted treatment and the incurrence of unnecessary hospital expense. In addition, the Survey of Physicians' Perspectives and Knowledge About Diagnostic Tests for Bloodstream Infections in 2015 reported that negative blood culture results are only trusted by 36% of those physicians. Without the ability to rapidly identify pathogens, physicians typically start treatment of at-risk patients with broad-spectrum antibiotics, which can be ineffective and unnecessary and have contributed to the spread of antimicrobial resistance. According to a study published by Critical Care Medicine in 2006, in sepsis patients with documented hypotension, administration of effective antimicrobial therapy within the first hour of detection was associated with a survival rate of 79.9% and, over the ensuing six hours, each hour of delay in initiation of treatment was associated with an average decrease in survival of 7.6%.

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

Candida is the fourth leading hospital-acquired bloodstream infection, afflicting more than 135,000 patients per year in the United States, and the most lethal form of common bloodstream infections that cause sepsis, with an average mortality rate of approximately 40%. This high mortality rate is largely due to a delay in providing targeted therapy to the patient due to the elapsed time from *Candida* infection to positive diagnosis. 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 an economic study regarding the use of T2Candida conducted by IMS Health, a healthcare economics agency. In that economic study, IMS demonstrated that an average hospital admitting 5,100 patients at risk for *Candida* infections could save approximately \$5.8 million annually due to decreased hospital stays for patients, reduction in use of antifungal drugs, and other associated savings. The economic study further showed T2Candida can potentially reduce the costs of care by \$26,887 per

Candida patient and that rapid detection of Candida reduces patient deaths by 60.6%. Results from a data analysis of T2Candida for the detection and monitoring of Candida infection and sepsis were published comparing aggregated results from the use of T2Candida to blood culture-based diagnostics for the detection of invasive candidiasis and candidemia. The analysis included samples acquired from more than 1,900 patients. Out of 55 prospective patient cases that were tested with T2Candida and blood culture and determined to be positive or likely to be positive for a Candida infection, T2Candida detected 96.4% of the patients (53 cases) compared to detection of 60% of the patients (33 cases) with blood culture. During 2016, a number of T2Candida users presented data on their experiences with the T2Candida Panel which demonstrated both the clinical and economic benefits of use of the T2Candida Panel in the diagnostic regimen. The Henry Ford Health System in Detroit, Michigan reported data on a pre- and post-T2Candida implementation analysis that covered 6 months of clinical experience. The data showed a statistically significant ($p = 0.009$) seven day reduction in median Intensive Care Unit (“ICU”) length of stay per positive patient that was identified as positive for Candida after implementation of the T2Candida test panel and a trend ($p = 0.164$) of total hospital length of stay reduction of four days. The data also showed significant reductions in use of antifungal drugs for negative patients tested with T2Candida. The overall economic savings resulting from these clinical benefits was projected to be approximately \$2.3 million on an annualized basis. The Lee Health System in Fort Myers, Florida compared patient and economic experience before and after T2Candida implementation. The data demonstrated that in the post-T2Candida cohort, median length of stay for patients with Candida infections was reduced by 7 days when detected by T2Candida while unnecessary antifungal therapy was avoided in 41% of patients

tested and was discontinued after one dose in another 15% of patients tested. The average economic savings derived solely from reduction in antifungal drug use was \$195 per patient tested, net of the cost of the T2Candida test panel. Huntsville Hospital in Huntsville, Alabama, reported that the use of the T2Candida test panel resulted in a reduction in the duration of therapy and time to de-escalation in patients that tested negative for Candida on the T2Candida test panel, yielding net pharmacy savings of approximately \$280 per patient tested. T2Candida also detected 56% more positive patients than blood culture. Finally, Riverside Community Hospital in Riverside, California, demonstrated improvements in time to appropriate therapy, increased sensitivity, and rapid discontinuation of antifungal therapy when using T2Candida. Specifically, 83% of patients who tested positive with T2Candida received appropriate therapy within six hours of the blood draw and 100% of patients received appropriate therapy in under nine hours. None of the patients who tested positive had been identified to have been treated with antifungals prior to T2Candida testing. In addition, antifungal therapy was discontinued for 100% of the patients who tested negative with T2Candida.

Due to the high mortality rate associated with Candida infections, physicians often will place patients on antifungal drugs while they await blood culture diagnostic results which generally take at least five days to generate a negative test result. Antifungal drugs are toxic and may result in side effects and can cost over \$50 per day. T2Candida's speed to result coupled with its superior sensitivity as compared to blood culture may help reduce the overuse of ineffective, or even unnecessary, antimicrobial therapy which may reduce side effects for patients, hospital costs and potentially, the growing resistance to antifungal therapy. This inappropriate therapy is a driving force behind the spread of antimicrobial-resistant pathogens, which the CDC recently called "one of our most serious health threats."

Our T2Candida auris Panel

On September 6, 2017, we announced that the Centers for Disease Control and Prevention (CDC) has agreed to utilize the T2Dx Instrument and the T2Candida auris investigational use only panel in their laboratory for testing and monitoring the emergence and outbreaks of the superbug Candida auris in hospitals around the country. Candida auris is a multi-drug resistant pathogen recognized by the CDC as a "serious global health threat" because it can be resistant to "all three major classes of antifungal drugs" and difficult to identify. The CDC has also reported that more than one in three patients with Candida auris infections have died. Unlike most other species of Candida, Candida auris can spread quickly in a hospital making rapid identification and hospital environment surveillance a critical component of containing these outbreaks. Existing laboratory methods that detect Candida auris, including blood culture, suffer from prolonged detection times and low accuracy, which exacerbates the challenge in the fight to contain the superbug. Recently, reported cases have surged internationally, and the CDC has reported a significant increase in infected patients in the United States. According to the European Centre for Disease Prevention and Control, hospital outbreaks have occurred in the United Kingdom and Spain. Because Candida auris can be resistant to most treatment options and can spread so quickly, these hospital outbreaks have been difficult to contain by even the most enhanced control measures. We are also conducting a study in Europe that has demonstrated the ability to detect Candida auris directly in patient blood specimens.

Our T2Bacteria Panel

We have also developed a product candidate named T2Bacteria, a multiplex diagnostic panel that detects six major bacterial pathogens associated with sepsis and, in conjunction with T2Candida and standard empiric therapy regimens, may enable the early, appropriate treatment of 95% of sepsis patients. T2Bacteria, which will also run on the T2Dx, is expected to address the same approximately 6.75 million symptomatic high-risk patients as T2Candida and also a new population of patients who are at increased risk for bacterial infections, including an additional two million patients presenting with symptoms of infection in the emergency room setting. The T2Bacteria Panel received authorization to affix a CE mark in July 2017 and is being commercially launched in Europe and other countries that accept the CE mark.

On August 4, 2017 we completed a pivotal clinical study of the T2Bacteria® Panel, run on the T2Dx® Instrument (T2Dx), which is a qualitative T2 Magnetic Resonance (T2MR®) assay designed for the direct detection of bacterial species in EDTA human whole blood specimens from patients with suspected bacteremia. The T2Bacteria Panel is designed to identify six species of bacteria directly from human whole blood specimens: *Acinetobacter baumannii*, *Enterococcus faecium*, *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Staphylococcus aureus*.

The performance characteristics of the T2Bacteria Panel were evaluated through a series of analytical studies as well as a multi-center clinical study. The clinical study evaluated the performance of the T2Bacteria Panel in comparison to the current standard of care, blood culture. All of the data generated in the analytical studies and the clinical study were submitted to the United States Food and Drug Administration, or FDA, in a 510(k) premarket notification on September 8, 2017.

The clinical study consisted of two arms, a prospective arm and a seeded arm. In the prospective arm, a total of 1,427 subjects were tested at eleven geographically dispersed and demographically diverse sites in the United States. In the seeded arm, 300 specimens of known bacterial composition were evaluated at three sites. Seeded specimens were prepared by spiking whole blood

with multiple strains of the bacterial species detected by the T2Bacteria Panel at defined concentrations (CFU/mL). Fifty negative blood samples also were evaluated as part of the seeded arm of the study. In total, 1,777 (1,427 prospective specimens and 350 seeded and negative) clinical samples were tested to evaluate the clinical performance of T2Bacteria Panel.

T2Bacteria is currently available in the United States for Research Use Only (RUO).

Our Sepsis Solution

We believe our T2 Magnetic Resonance technology, or T2MR, delivers what no conventional technology currently available can: a rapid, sensitive and simple diagnostic platform to enable sepsis applications that can identify specific sepsis pathogens directly from an unpurified blood sample in hours instead of days at a level of accuracy equal to or better than blood culture-based diagnostics. The T2Sepsis Solution refers to the approach of combining the standard of care for the management of sepsis patients with our products, including the T2Dx Instrument, or the T2Dx, T2Candida, and T2Bacteria, which is commercially available in Europe and other countries that accept the CE mark and available for research use only in the United States. The T2Sepsis Solution is designed to enable clinicians to potentially treat 95% of septic patients within the first twelve hours of developing the symptoms of disease. Currently, high risk patients are typically initially treated with broad spectrum antibiotic drugs that typically cover approximately 60% of patients with infections. Of the remaining 40% of patients, approximately 30% of the patients have a bacterial infection and 10% have Candida infections. T2Candida and product candidate, T2Bacteria are designed to identify pathogens commonly not covered by broad spectrum antibiotic drugs, which we believe may enable physicians to effectively treat an additional 35% of septic patients beyond the 60% of patients covered by broad spectrum antibiotic drugs.

We believe the T2Sepsis Solution provides a pathway for more rapid and targeted treatment of infections, potentially reducing the mortality rate by as much as 75% if a patient is treated within 12 hours of suspicion of infection and significantly reducing the cost burden of sepsis. Each year, approximately 500,000 patients in the United States die from sepsis. According to a study published by Critical Care Medicine in 2006, in sepsis patients with documented hypotension, administration of effective antimicrobial therapy within the first hour of detection was associated with a survival rate of 79.9% and, over the ensuing six hours, each hour of delay in initiation of treatment was associated with an average decrease in survival of 7.6%. According to such study, the survival rate for septic patients who remained untreated for greater than 36 hours was approximately 5%. The toll of sepsis on a patient's health can be severe: more than one-in-five patients die within two years as a consequence of sepsis. Sepsis is also the most prevalent and costly cause of hospital readmissions.

We believe the T2Sepsis Solution addresses a significant unmet need in in vitro diagnostics by providing:

- **Limits of Detection as Low as 1 CFU/mL.** T2MR is the only technology currently available that can enable identification of sepsis pathogens directly from a patient's blood sample at limits of detection as low as 1 CFU/mL.
- **Rapid and Specific Results in as Few as Three Hours.** T2MR is the only technology that can enable species-specific results for pathogens associated with sepsis, directly from a patient's blood sample, without the need for blood culture, to deliver an actionable result in three hours.
- **Accurate Results Even in the Presence of Antimicrobial Therapy.** T2MR is the only technology that can reliably detect pathogens associated with sepsis, including slow-growing pathogens, such as *C. glabrata*, directly from a patient's blood sample, even in the presence of an antimicrobial therapy.
- **Easy-to-Use Platform.** T2MR eliminates the need for sample purification or extraction of target pathogens, enabling sample- to-result instruments that can be operated on-site by hospital staff, without the need for highly skilled technicians.

Our T2Dx Instrument

Our FDA-cleared T2Dx instrument 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 instrument, which automatically processes the sample and then delivers a diagnostic test result. Test results are displayed on screen or directly through the lab information system.

By utilizing our proprietary T2MR technology 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.

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 utilizes advances in the field of magnetic resonance by deploying particles with magnetic properties that enhance the magnetic resonance signals of specific targets. When particles coated with target-specific binding agents are added to a sample containing the target, the particles bind to and cluster around the target. This clustering changes the microscopic environment of water in that sample, which in turn alters the magnetic resonance signal, or the T2 relaxation signal that we measure, indicating the presence of the target.

We believe that T2MR can also address the significant unmet need associated with Lyme disease, a tick-borne illness that can cause prolonged neurological disease and musculoskeletal disease. For patients with Lyme disease, early diagnosis and appropriate treatment significantly reduces both the likelihood of developing neurological and musculoskeletal disorders, as well as the significant costs associated with treating these complications. Our product candidate, T2Lyme, will identify the bacteria that cause Lyme disease directly from the patient's blood, without the need for blood culture which, for the bacteria associated with Lyme disease, can take several weeks. Our Lyme product candidate is currently in pre-clinical development and we expect to initiate a T2Lyme clinical trial in 2018.

Another significant unmet clinical need is the diagnosis and management of impaired hemostasis, which is a life-threatening condition in which a patient is unable to promote the formation of blood clots to stabilize excessive bleeding. Within the broader population of patients with symptoms of impaired hemostasis, there are over ten million trauma patients in the United States annually. These trauma patients typically face life-threatening injuries or invasive surgical procedures. Approximately 25% of trauma patients have impaired hemostasis, which frequently goes undetected during the initial hospitalization. According to a study in the Journal of the American College of Surgeons, for trauma patients with symptoms of impaired hemostasis, mortality rates were reduced from 45% to 19% with more rapid delivery of therapy. The T2Plex and T2HemoStat are being designed to utilize T2MR and are designed to provide hemostasis measurements in less than 45 minutes. Our product candidate, T2HemoStat, is a comprehensive panel of diagnostic tests that can provide data across the hemostasis spectrum, including measurements of fibrinogen, platelet activity, and clot lysis. We believe that T2HemoStat may be the first panel capable of rapidly identifying key coagulation, platelet and other hematologic factors directly from whole blood on a single, easy-to-operate, compact instrument. We are exploring partnership opportunities to complete the development and commercialization of these products.

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

Financial Overview

Revenue

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

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

Product revenue is derived from the sale of our instruments and related consumable diagnostic tests, predominantly through our direct sales force in the United States, and distributors in geographic regions outside the United States. We do not offer product return or exchange rights (other than those relating to defective goods under warranty) or price protection allowances to our customers, including our distributors. Payment terms granted to distributors are the same as those granted to end-user customers and payments are not dependent upon the distributors' receipt of payment from their end-user customers. We recognize product revenue from the sale of our instruments as soon as all applicable revenue recognition criteria have been met. In the majority of cases, we expect to place our instruments, under reagent rental agreements, in hospitals, certain of which may include minimum commitments and/or an incremental charge on the purchase of our consumable diagnostic tests. Under this business model, we believe we will recover the cost of placing our instruments in hospitals through the margins realized from our consumable diagnostic tests. Our consumable diagnostic tests can only be used with our instruments, and accordingly, as the installed base of our instruments grows, we expect the following to occur:

- recurring revenue from our consumable diagnostic tests will increase and become subject to less period-to-period fluctuation;
- consumable revenue will become an increasingly predictable and important contributor to our total revenue; and
- we will gain economies of scale through the growth in our sales, resulting in improving gross margins and operating margins.

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

Cost of Product Revenue

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

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

Research and development expenses

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

We anticipate our overall research and development expenses to continue to be flat to down over the next several quarters in part due to the completion of our T2Bacteria clinical trial. Research and development costs include costs to support research partnerships, clinical trials and new product development. We have committed, and expect to

commit, significant resources toward developing additional product candidates, improving existing products, conducting ongoing and new clinical trials and expanding our laboratory capabilities.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of costs for our sales and marketing, finance, legal, human resources, business development and general management functions, as well as professional services, such as legal, consulting and accounting services. We expect selling, general and administrative expenses to increase in future periods as we commercialize products and future product candidates 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 expense all selling, general and administrative expenses as incurred.

Interest expense, net

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

Other income, net

Other income, net, consists of dividend and other investment income, 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.

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, 2016 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, 2016.

Results of Operations for the Three Months Ended September 30, 2017 and 2016

	Three Months Ended		
	September 30, 2017	2016	Change
	(in thousands)		
Revenue:			
Product revenue	\$739	\$580	\$159
Research revenue	369	504	(135)
Total revenue	1,108	1,084	24
Costs and expenses:			
Cost of product revenue	2,106	1,894	212
Research and development	5,880	5,200	680
Selling, general and administrative	5,559	5,935	(376)
Total costs and expenses	13,545	13,029	516
Loss from operations	(12,437)	(11,945)	492
Interest expense, net	(1,718)	(876)	(842)
Other income, net	79	38	41

Net loss	\$(14,076)	\$(12,783)	\$(1,293)
----------	------------	------------	-----------

Product revenue

Product revenue was \$0.7 million for the three months ended September 30, 2017 compared to \$0.6 million for the three months ended September 30, 2016, an increase of \$0.1 million or 27.4%. The increase was driven primarily by higher comparable sales of T2Candida consumables of \$0.2 million and slightly higher support contract revenue plus sales of the new T2Bacteria consumables product in Europe. The increases were partially offset by lower instrument sales of \$0.1 million.

Research revenue

Research revenue was \$0.4 million for the three months ended September 30, 2017, compared to \$0.5 million for the three months ended September 30, 2016, a decrease of \$0.1 million or 26.8%. The decrease was primarily the result of lower revenue recognized under our Co-Development Agreement with Canon US Life Sciences, which decreased \$0.4 million over the prior year

comparable period, as well as a decrease in revenue from research and development agreements utilizing T2MR technology with other third parties of \$0.1 million. These decreases were offset by an increase in revenue from services delivered under our Co-Development Agreement with Allergan Sales, LLC of \$0.4 million.

Cost of product revenue

Cost of product revenue was \$2.1 million for the three months ended September 30, 2017, compared to \$1.9 million for the three months ended September 30, 2016, an increase of \$0.2 million. The increase in cost primarily correlated to increased product revenue and continued expansion of manufacturing activities and certain manufacturing costs of \$0.4 million over the prior year comparable period. The increases were offset by lower costs for consumables and instruments of \$0.1 million and lower service related and miscellaneous costs of \$0.1 million.

Research and development expenses

Research and development expenses were \$5.9 million for the three months ended September 30, 2017, compared to \$5.2 million for the three months ended September 30, 2016, an increase of \$0.7 million over the prior year comparable period. Clinical trial and related expenses increased by \$0.3 million primarily from the T2Bacteria clinical trial. Facilities related and other research and development expenses increased by \$0.2 million which includes increased depreciation, lab related and engineering prototype expenses. Outside service and travel expenses increased by \$0.3 million, primarily from increased work on the T2Bacteria clinical trial. Payroll and related expenses increased by \$0.2 million. Partially offsetting these increases is a decrease in preclinical related expenses of \$0.3 million.

Selling, general and administrative expenses

Selling, general and administrative expenses were \$5.6 million for the three months ended September 30, 2017, compared to \$5.9 million for the three months ended September 30, 2016, a decrease of \$0.3 million over the prior year comparable period. The decrease was due primarily to decreased payroll and related expenses of approximately \$0.2 million, due to a reduction in headcount, decreased travel expenses of \$0.1 million and decreased outside services of \$0.1 million. The decreases were partially offset by increased legal expenses of \$0.1 million.

Interest expense, net

Interest expense, net, was \$1.7 million for the three months ended September 30, 2017, compared to \$0.9 million for the three months ended September 30, 2016. Interest expense, net, increased by \$0.8 million primarily from the refinancing of debt with CRG.

Other income, net

Other income, net, was \$79,000 of net income for the three months ended September 30, 2017, compared to \$38,000 for the three months ended September 30, 2016. Other income, net, increased by \$41,000 due primarily to increased dividend and other investment income earned on higher average levels of invested cash over the prior comparable period.

Results of Operations for the Nine Months Ended September 30, 2017 and 2016

	Nine Months Ended		
	September 30, 2017	2016	Change
	(in thousands)		
Revenue:			
Product revenue	\$2,105	\$1,168	\$937
Research revenue	900	2,003	(1,103)
Total revenue	3,005	3,171	(166)
Costs and expenses:			
Cost of product revenue	5,722	4,701	1,021
Research and development	19,577	18,160	1,417
Selling, general and administrative	17,192	18,282	(1,090)
Total costs and expenses	42,491	41,143	1,348
Loss from operations	(39,486)	(37,972)	(1,514)
Interest expense, net	(5,008)	(2,416)	2,592
Other income, net	260	133	127
Net loss	\$(44,234)	\$(40,255)	\$(3,979)

Product revenue

Product revenue was \$2.1 million for the nine months ended September 30, 2017 compared to \$1.2 million for the nine months ended September 30, 2016, an increase of \$0.9 million or 80.2%. The increase was driven by an increase in sales volume of our products, primarily the sale of T2Candida and T2Bacteria (in Europe) consumable diagnostic tests of \$0.6 million plus higher instrument sales of \$0.1 million and an increase in service contract revenue.

Research revenue

Research revenue was \$0.9 million for the nine months ended September 30, 2017, compared to \$2.0 million for the nine months ended September 30, 2016, a decrease of \$1.1 million or 55.0%. This decrease was primarily the result of lower revenue recognized under our Co-Development Agreement with Canon of \$1.2 million as well as a decrease in revenue from research and development agreements utilizing our T2MR technology with other third parties over the prior year comparable period. These decreases were offset by revenue recognized under our Co-Development Agreement with Allergan Sales, LLC.

Cost of product revenue

Cost of product revenue was \$5.7 million for the nine months ended September 30, 2017, compared to \$4.7 million for the nine months ended September 30, 2016, an increase of \$1.0 million. \$0.3 million of the increase in cost correlates to increased product revenue. In addition, other cost increases relate to continued expansion of manufacturing activities and certain manufacturing costs of \$0.2 million, depreciation of \$0.2 million and increase in reserves of \$0.3 million over the prior year comparable period.

Research and development expenses

Research and development expenses were \$19.6 million for the nine months ended September 30, 2017, compared to \$18.2 million for the nine months ended September 30, 2016, an increase of \$1.4 million over the prior year comparable period. Clinical trial and related expenses increased by \$1.1 million primarily from the T2Bacteria clinical trial. Facilities related and other expenses increased by \$0.4 million which includes higher depreciation, lab related and engineering prototype expenses. Outside service and travel expenses increased by \$0.4 million, primarily from increased work on the T2Bacteria clinical trial. Partially offsetting these increases is a decrease in preclinical related expenses of \$0.3 million, a decrease in payroll and related expenses of \$0.1 million.

Selling, general and administrative expenses

Selling, general and administrative expenses were \$17.2 million for the nine months ended September 30, 2017, compared to \$18.3 million for the nine months ended September 30, 2016, a decrease of \$1.1 million. The decrease was due primarily to decreased payroll and related expenses of approximately \$1.1 million, due to a reduction in headcount, decreased travel expenses of \$0.3 million related to headcount reduction, and decreased legal expenses of \$0.1 million. These decreases were partially offset by increased

outside services expenditures of \$0.2 million and increased facility and other selling, general and administrative expenses of \$0.2 million.

Interest expense, net

Interest expense, net, was \$5.0 million for the nine months ended September 30, 2017, compared to \$2.4 million for the nine months ended September 30, 2016. Interest expense, net, increased by \$2.6 million primarily from the refinancing of debt with CRG.

Other income, net

Other income, net, was \$260,000 for the nine months ended September 30, 2017, compared to \$133,000 for the nine months ended September 30, 2016. Other income, net, increased by \$127,000 due primarily to increased dividend and other investment income earned on higher average levels of invested cash over the prior comparable period.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception, and as of September 30, 2017, and December 31, 2016 we had an accumulated deficit of \$247.9 million and \$203.7 million respectively. We anticipate that we will continue to incur losses for at least the next few years. We expect that our operating 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 historically funded our operations principally from the sale of common stock and preferred stock, the incurrence of indebtedness, and revenue from research and development agreements. In September 2017 we raised net proceeds of \$18.8 million through our confidentially marketed public offering (“CMPO”).

Plan of operations and future funding requirements

As of September 30, 2017 and December 31, 2016 we had unrestricted cash and cash equivalents of approximately \$52.9 million and \$73.5 million respectively. Currently, our funds are primarily held in money market funds invested in U.S. government agency securities. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, costs related to our products, clinical trials, laboratory and related supplies, supplies and materials used in manufacturing, legal and other regulatory expenses and general overhead costs.

Management believes that the existing cash and cash equivalents at September 30, 2017, together with the additional remaining liquidity on our Term Loan Agreement of up to an additional \$10.0 million, will be sufficient to fund our current operating plan into the first half of 2019. The borrowing on the Term Loan Agreement is available at any time through July 27, 2018, and is subject to certain conditions including that we receive 510(k) clearance for the marketing of T2Bacteria™ by the FDA by April 30, 2018 (see Note 5 to our unaudited condensed consolidated financial statements for details). Should our current operating plan not materialize as expected, including our ability to draw additional borrowings on the Term Loan Agreement on a timely basis, we would delay certain research projects and capital expenditures and reduce or eliminate certain future operating expenses in order to fund operations at reduced levels to continue as a going concern for a period of 12 months from the date the financial statements are issued. The Term Loan Agreement also requires us to achieve certain annual revenue targets, whereby we are required to pay double the amount of any shortfall as an acceleration of principal payments. The revenue target for fiscal 2017 is \$5.0 million. Should we fall short of the revenue target we would seek a waiver of this provision. There can be no assurances that we would be successful in obtaining a waiver.

Until such time as we can generate substantial product revenue, we expect to finance our cash needs, beyond what is currently available or on hand, through a combination of equity offerings, debt financings and revenue from potential research and development and other collaboration agreements. If we raise additional funds in the future, we may need to relinquish valuable rights to our technologies, future revenue streams or grant licenses on terms that may not be favorable to us.

Cash flows

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

	Nine Months Ended	
	September 30, 2017	2016
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$(36,641)	\$(36,143)
Investing activities	(2,601)	(4,594)
Financing activities	18,651	42,186
Net decrease in cash and cash equivalents	\$(20,591)	\$1,449

Net cash used in operating activities

Net cash used in operating activities was approximately \$36.7 million for the nine months ended September 30, 2017, and consisted primarily of a net loss of \$44.2 million adjusted for non-cash items including stock-based compensation expense of \$3.8 million, depreciation and amortization expense of \$2.2 million, non-cash interest expense of \$2.0 million, loss on sale of T2 owned equipment of \$0.2 million, offset by deferred rent of \$0.1 million, and a net change in operating assets and liabilities of \$0.4 million, primarily related to an increase in accrued expenses and accounts payable of \$0.4 million, an increase in accounts receivable of \$0.1 million, an increase in inventory of \$0.5 million to support our commercial demand, an increase in deferred revenue of \$0.4 million, and a decrease in prepaid expenses and other assets of \$0.1 million.

Net cash used in operating activities was approximately \$36.1 million for the nine months ended September 30, 2016, and consisted primarily of a net loss of \$40.3 million adjusted for non-cash items including depreciation and amortization expense of \$1.6 million, stock-based compensation expense of \$3.7 million, non-cash interest expense of \$0.5 million, deferred rent of \$0.2 million, and a net change in operating assets and liabilities (use of cash) of \$1.4 million, primarily related to an increase in inventory of \$0.7 million to support our commercial demand, prepaid expenses of \$0.1 million related to the amortization of insurance premiums and a decrease in deferred revenue of approximately \$1.3 million primarily related to the recognition of revenue from our Co-Development Agreement with Canon US Life Sciences, partially offset by an increase in accounts payable and accrued expenses of \$0.7 million related to increased audit, clinical study and payroll accruals.

Net cash used in investing activities

Net cash used in investing activities was approximately \$2.6 million for the nine months ended September 30, 2017 and consisted of costs to acquire property and equipment and purchases of T2-owned instruments of \$0.9 and \$1.8 million, respectively, which are classified as property and equipment, less \$0.1 million cash received from sale of T2-owned instruments.

Net cash used in investing activities was approximately \$4.6 million for the nine months ended September 30, 2016 and consisted of costs to acquire components of and manufacture Company-owned instruments of \$3.7 million, which are classified as property and equipment, \$0.7 million of purchases of laboratory and manufacturing equipment

incurred to support commercialization efforts and research and development programs and \$0.2 million of other equipment and software purchases to support internal functions.

Net cash provided by financing activities

Net cash provided by financing activities was approximately \$18.7 million for the nine months ended September 30, 2017, and consisted primarily of \$18.8 million in net proceeds from our September 2017 CMPO and by \$0.7 million of proceeds from the exercise of stock options and sale of common stock under our 2014 Employee Stock Purchase Plan partially offset by \$0.9 million of repayments of notes payable.

Net cash provided by financing activities was approximately \$42.2 million for the nine months ended September 30, 2016, and consisted primarily of proceeds from our September 21, 2016 PIPE financing with Canon of \$39.7 million, in which we sold 6,055,341 shares of common stock at the closing price of \$6.56 per share. Net cash provided by financing activities also consisted of \$0.7 million of proceeds from the exercise of stock options and sale of common stock under our 2014 Employee Stock Purchase Plan and \$4.6 million of proceeds from the Credit Facility. Partially offsetting these sources of cash were \$2.5 million of repayments of notes payable and \$0.3 million of payments of issuance costs from our December 2015 secondary offering.

Borrowing Arrangements

Term Loan Agreement

In December 2016, we entered into a Term Loan Agreement (the “Term Loan Agreement”) with CRG. We borrowed \$40.0 million pursuant to the Term Loan Agreement and may borrow up to an additional \$10.0 million at any time through and including July 27, 2018, provided that, among other conditions, we receive 510(k) clearance for the marketing of T2Bacteria by the FDA on or before April 30, 2018, or the Approval Milestone. The Term Loan Agreement has a six-year term with three years (through December 30, 2019) of interest-only payments, which period shall be extended to four years (through December 30, 2020) if we achieve the Approval Milestone, after which quarterly principal and interest payments will be due through the December 30, 2022 maturity date. Interest on the amounts borrowed under the Term Loan Agreement accrues at an annual fixed rate of (a) prior to the Approval Milestone, 12.5%, 4.0% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount and (b) following the Approval Milestone, 11.5%, 3.5% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount. In addition, if we achieve certain financial performance metrics, the loan will convert to interest-only until the December 30, 2022 maturity, at which time all unpaid principal and accrued unpaid interest will be due and payable. We are required to pay CRG a financing fee based on the loan principal amount drawn. We are also required to pay a final payment fee of 8.0% of the principal outstanding upon repayment.

We may prepay all or a portion of the outstanding principal and accrued unpaid interest under the Term Loan Agreement at any time upon prior notice subject to a prepayment fee during the first five years of the term and no prepayment fee thereafter. As security for our obligations under the Term Loan Agreement we entered into a security agreement with CRG whereby we granted a lien on substantially all of its assets, including intellectual property. The Term Loan Agreement also contains customary affirmative and negative covenants for a credit facility of this size and type. The Term Loan Agreement also requires us to achieve certain revenue targets, whereby we are required to pay double the amount of any shortfall as an acceleration of principal payments. The Term Loan Agreement includes a subjective acceleration clause whereby an event of default, including a material adverse change in the business, operations, or conditions (financial or otherwise), could result in the acceleration of the obligations under the Term Loan Agreement. Under certain circumstances, a default interest rate of an additional 4.0% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default. CRG has not exercised its right under this clause, as there have been no such events. We believe the likelihood of CRG exercising this right is remote.

We assessed the terms and features of the Term Loan Agreement in order to identify any potential embedded features that would require bifurcation or any beneficial conversion features. As part of this analysis, we assessed the economic characteristics and risks of the Term Loan Agreement, including put and call features. We determined that the features of the Term Loan Agreement are either 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. Included in these features are principal payment acceleration clauses triggered by a developmental milestone. Should our assessment of this milestone change, there could be a non-cash charge in operations. We will continue to reassess the features to determine if they require separate accounting on a quarterly basis.

In December 2016, pursuant to the Term Loan Agreement, we made an initial draw of \$39.2 million, net of financing fees. We used approximately \$28.0 million of the initial proceeds to repay approximately \$27.5 million of outstanding debt pursuant to the Loan and Security Agreement and to repay approximately \$0.5 million of outstanding debt pursuant to the Promissory Note. Upon the repayment of all amounts owed by us under these agreements, all commitments were terminated and all security interests granted by us were released.

Promissory Note

In May 2011, the Company entered into a promissory agreement (the “Promissory Note”) with a separate lender to borrow up to \$1.7 million for the purchase of laboratory equipment and office equipment through December 2013. The Company borrowed a total of \$1.4 million under the Promissory Note. The Company paid interest only on the borrowings through December 2013 and was required to make equal monthly payments of principal and interest through the maturity date. In December 2016, the Company used approximately \$0.5 million of the proceeds from the Term Loan agreement to repay the outstanding debt pursuant to the Promissory Note. Upon the repayment of all amounts owed by the Company under the Promissory Note, all commitments were terminated and all security interests granted by the Company were released.

The amounts borrowed were collateralized by the associated equipment and bear interest at 6.5%. The Promissory Note included financial covenants that required the Company to maintain a minimum cash balance of \$0.3 million. In addition, the Promissory Note contained a subjective acceleration clause whereby an event of default and immediate acceleration of the borrowing occurs if there was a material adverse change in the business, operations, or condition of the Company or a material impairment of the prospect of repayment of any portion of the obligations. In the event of default, the lender had first priority on the laboratory equipment and office equipment purchased with the proceeds.

Equipment Lease Credit Facility

In October 2015, we signed a \$10.0 million Equipment Lease Credit Facility, or the Credit Facility, with Essex Capital Corporation (the “Lessor”) to fund capital equipment needs. As one of the conditions of the Term Loan Agreement, the Credit Facility is capped at a maximum of \$5.0 million. Under the Credit Facility, Essex will fund capital equipment purchases presented by us. We will repay the amounts borrowed in 36 equal monthly installments from the date of the amount funded. At the end of the 36 month lease term, we have the option to (a) repurchase the leased equipment at the lesser of fair market value or 10% of the original equipment value, (b) extend the applicable lease for a specified period of time, which will not be less than one year, or (c) return the leased equipment to the Lessor.

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

Contractual Obligations and Commitments

There were no 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, 2016. During the quarter ended September 30, 2017 we entered into a new Lease Indenture Agreement (the “Lease”) relating to office space we currently lease at 91 Hartwell Ave, Lexington, MA, pursuant to which we reduced the square footage of leased space from 13,233 square feet to 10,900 square feet. Under the terms of the Lease, beginning on January 1, 2018 and ending on December 31, 2021, the Company is obligated to pay the landlord monthly rent of \$29,066.

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 SEC rules.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk related to changes in interest rates. As of September 30, 2017 and December 31, 2016, we had cash and cash equivalents of \$52.9 million and \$73.5 million, respectively, 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. As of September 30, 2017 and December 31, 2016, we had no outstanding debt exposed to variable market interest rates.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

Management of the Company, with the participation of the Chief Executive Officer and the Chief Financial Officer, evaluated the effectiveness of the design and operation of the Company’s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of September 30,

2017. 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 the Chief Financial Officer, as appropriate, to allow timely decisions regarding disclosure. Based upon this evaluation, the Chief Executive Officer and the Chief Financial Officer have concluded that the Company's disclosure controls and procedures were effective as of September 30, 2017.

(b) Changes in Internal Control over Financial Reporting

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

PART II.

OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2016, 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, 2016.

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

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None

Item 6. Exhibits, Financial Statement Schedules

Exhibit Number Exhibit Description

- 3.1 Restated Certificate of Incorporation of the Company, as amended (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36571) filed on August 12, 2014)
- 3.2 Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 of the Company's Form 8-K (File No. 001-36571) filed on August 12, 2014)
- 10.1 Lease Indenture Agreement, dated September 21, 2017, between 91 Hartwell Ave. Trust and the Company, relating to office space located for property at 91 Harwell Avenue, Lexington, MA, Massachusetts
- 31.1* Certification of principle 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 principal 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 pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2** Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 101.1* The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, formatted in XBRL: (i) Condensed Consolidated Balance Sheets (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited), (iii) Condensed Consolidated Statements of Cash Flows (unaudited), and (v) Notes of Condensed Consolidated Financial Statements.

* Filed herewith

**Furnished herewith

SIGNATURES

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

T2 BIOSYSTEMS, INC.

Date: November 3, 2017 By: /s/ JOHN MCDONOUGH
John McDonough
President, Chief Executive Officer and Director
(principal executive officer)

Date: November 3, 2017 By: /s/ DARLENE DEPTULA-HICKS
Darlene Deptula-Hicks
SVP and Chief Financial Officer
(principal financial officer)