

T2 Biosystems, Inc.
Form 10-Q
November 01, 2018

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, 2018

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 every Interactive Data File required to be submitted 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 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

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, 2018, the registrant had 44,038,754 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, 2018 and December 31, 2017</u>	1
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for three and nine months ended September 30, 2018 and 2017</u>	2
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2018 and 2017</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>	18
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	33
Item 4. <u>Controls and Procedures</u>	33
 <u>PART II OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings</u>	34
Item 1A. <u>Risk Factors</u>	34
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	34
Item 3. <u>Defaults Upon Senior Securities</u>	34
Item 4. <u>Mine Safety Disclosures</u>	34
Item 5. <u>Other Information</u>	34
Item 6. <u>Exhibits, Financial Statement Schedules</u>	35
<u>SIGNATURES</u>	36

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,	December 31,
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 60,225	\$ 41,799
Accounts receivable	1,734	467
Prepaid expenses and other current assets	2,024	708
Inventories	3,337	1,344
Total current assets	67,320	44,318
Property and equipment, net	8,190	10,015
Restricted cash	180	260
Other assets	206	268
Total assets	\$ 75,896	\$ 54,861
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 551	\$ 648
Accrued expenses and other current liabilities	4,427	6,218
Derivative liability	—	2,238
Notes payable	3,399	40,696
Deferred revenue	762	1,736
Current portion of lease incentives	262	246
Total current liabilities	9,401	51,782
Notes payable, net of current portion	38,869	1,008
Lease incentives, net of current portion	553	731
Deferred revenue, net of current portion	91	—
Derivative liability	2,063	—
Other liabilities	1,157	—
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued and		
outstanding at September 30, 2018 and December 31, 2017	—	—

Common stock, \$0.001 par value; 200,000,000 shares authorized; 44,038,754 and 35,948,900 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	44	36
Additional paid-in capital	325,740	267,421
Accumulated deficit	(302,022)	(266,117)
Total stockholders' equity	23,762	1,340
Total liabilities and stockholders' equity	\$ 75,896	\$ 54,861

See accompanying notes to condensed consolidated financial statements.

1

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, 2018	2017	September 30, 2018	2017
Revenue:				
Product revenue	\$ 1,218	\$ 739	\$ 3,486	\$ 2,105
Research revenue	1,248	369	5,222	900
Total revenue	2,466	1,108	8,708	3,005
Costs and expenses:				
Cost of product revenue	3,042	2,106	9,773	5,722
Research and development	2,725	5,880	11,193	19,577
Selling, general and administrative	5,873	5,559	19,238	17,192
Total costs and expenses	11,640	13,545	40,204	42,491
Loss from operations	(9,174)	(12,437)	(31,496)	(39,486)
Interest expense, net	(1,836)	(1,718)	(4,910)	(5,008)
Other income, net	243	79	402	260
Net loss and comprehensive loss	\$(10,767)	\$(14,076)	\$(36,004)	\$(44,234)
Net loss per share — basic and diluted	\$(0.25)	\$(0.45)	\$(0.91)	\$(1.43)
Weighted-average number of common shares used in computing				
net loss per share — basic and diluted	43,762,551	31,420,726	39,363,294	30,873,930

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, 2018	2017
Cash flows from operating activities		
Net loss	\$(36,004)	\$(44,234)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,862	2,194
Stock-based compensation expense	7,487	3,806
Change in fair value of derivative instrument	(175)	—
Loss on sale of T2 owned equipment	—	134
Loss on disposal of property and equipment	18	—
Impairment of property and equipment	173	—
Non-cash interest expense	1,658	1,968
Deferred rent	(162)	(95)
Changes in operating assets and liabilities:		
Accounts receivable	(1,267)	(115)
Prepaid expenses and other assets	(1,254)	129
Inventories	(1,191)	(451)
Accounts payable	(40)	31
Accrued expenses and other liabilities	(771)	361
Deferred revenue	(784)	(369)
Net cash used in operating activities	(30,450)	(36,641)
Cash flows from investing activities		
Purchases and manufacture of property and equipment	(950)	(2,601)
Net cash used in investing activities	(950)	(2,601)
Cash flows from financing activities		
Proceeds from issuance of common stock and stock option exercises, net	1,604	717
Proceeds from issuance of common stock in public offering, net of offering costs	49,236	18,795
Proceeds from issuance of common stock in connection with private offering, net of offering costs	—	37
Principal repayments of note payable	(1,094)	(898)
Net cash provided by financing activities	49,746	18,651
Net increase (decrease) in cash, cash equivalents and restricted cash	18,346	(20,591)
Cash, cash equivalents and restricted cash at beginning of period	42,059	73,748
Cash, cash equivalents and restricted cash at end of period	\$60,405	\$53,157
Supplemental disclosures of cash flow information		
Cash paid for interest	\$2,859	\$2,967
Supplemental disclosures of noncash activities		

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

Transfer of T2 owned instruments and components to inventory	\$802	\$—
Purchases of property and equipment included in accounts payable and accrued expenses	\$109	\$90

See accompanying notes to condensed consolidated financial statements.

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 May 24, 2018, the Company received market clearance from the FDA for its T2Bacteria Panel (“T2Bacteria”).

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

Liquidity and Going Concern

At September 30, 2018, the Company had cash and cash equivalents of \$60.2 million and an accumulated deficit of \$302.0 million. The future success of the Company is dependent on its ability to successfully commercialize its products, obtain regulatory clearance for and successfully launch its future product candidates, obtain additional capital and ultimately attain profitable operations. Historically, the Company has funded its operations primarily through its August 2014 initial public offering, its December 2015 public offering, its September 2016 private investment in public equity (“PIPE”) financing, its September 2017 public offering, its June 2018 public offering, 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 the T2Dx, T2Candida, and T2Bacteria, the Company has incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution. The Company may seek to fund its operations through public equity, 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, financial condition and the Company’s ability to develop and commercialize T2Dx, T2Candida, T2Bacteria and other product candidates.

Pursuant to the requirements of Accounting Standards Codification (“ASC”) 205-40, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management’s plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company’s ability to continue as a going concern. The mitigating effect of management’s plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued.

Management believes that its existing cash and cash equivalents at September 30, 2018 will be sufficient to allow the Company to fund its current operating plan through November 30, 2019. At December 31, 2017, management had concluded that substantial

doubt existed about the Company's ability to continue as a going concern for a period of at least twelve months from the date of issuance of those consolidated financial statements. However, management alleviated the substantial doubt during the nine months ended September 30, 2018. On June 4, 2018, the Company raised net proceeds of \$49.2 million through its June 2018 public offering. During the nine months ended September 30, 2018, the Company also received a \$2.0 million milestone payment from a co-development partner and received 510(k) clearance for the marketing of T2Bacteria.

At December 31, 2017, the conditions that raised substantial doubt regarding the Company's ability to continue as a going concern resulted from certain elements of the Company's operating plan being outside of the Company's control, including the approval of T2Bacteria and receipt of certain development and regulatory milestone payments under the Company's co-development agreements. Under ASC 205-40, the future receipt of potential funding from the Company's co-development partners and other resources cannot be considered probable if the plans are not entirely within the Company's control. The Term Loan Agreement with CRG 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, and maintain a minimum liquidity amount (Note 6). Should we have fallen short of the revenue target we would have sought a waiver of this provision. There can be no assurances that we would have been successful in obtaining a waiver.

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, 2018 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, 2017.

The accompanying interim condensed consolidated balance sheet as of September 30, 2018, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2018 and 2017, the condensed consolidated statements of cash flows for the nine months ended September 30, 2018 and 2017 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, 2018, and the results of its operations and its cash flows for the three and nine months ended September 30, 2018 and 2017. The results for the three and nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for the year ending

December 31, 2018, 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, commercializing 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.

5

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, 2018 and December 31, 2017, 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 adopted ASC 606, Revenue from Contracts with Customers ("ASC 606") on January 1, 2018 using the modified retrospective method for all contracts not completed as of the date of adoption. For contracts that were modified before the effective date, the Company reflected the aggregate effect of all modifications when identifying performance obligations and allocating transaction price in accordance with practical expedient ASC 606-10-65-1-(f)-4. The reported results for 2018 reflect the application of ASC 606 guidance while the reported results for 2017 were prepared under the guidance of ASC 605, Revenue Recognition ("ASC 605" or "legacy GAAP"). The impact of ASC 606 on the three and nine months ended September 30, 2018 was higher revenue of \$0.1 million and \$0.3 million, respectively. The higher revenue is the result of recognizing consideration allocated to the instrument, upon shipment. Under ASC 605, no revenue would be recognized until installation was completed.

The Company generates revenue from the sale of instruments, consumable diagnostic tests, related services, reagent rental agreements and research and development agreements with third parties. Pursuant to ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration the Company expects to be entitled to receive in exchange for these goods and services.

Once a contract is determined to be within the scope of ASC 606 at contract inception, the Company reviews the contract to determine which performance obligations the Company must deliver and which of these performance obligations are distinct. The Company recognizes as revenues the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied or as it is satisfied. Generally, the Company's performance obligations are transferred to customers at a point in time, typically upon shipment, or over time, as services are performed.

Most of the Company's contracts with customers contain multiple performance obligations. For these contracts, the Company accounts for individual performance obligations separately if they are distinct. The transaction price is allocated to the separate performance obligations on a relative standalone selling price basis.

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 an instrument is purchased by a customer, the Company recognizes revenue when the related performance obligation is satisfied (i.e. when the control of an instrument has passed to the customer; typically, at shipping point). When the instrument is placed under a reagent rental agreement, the Company's customers generally agree to fixed term agreements, which can be extended, and incremental charges on each consumable diagnostic test purchased. Revenue from the sale of consumable diagnostic tests (under a reagent rental agreement) is recognized upon shipment. The transaction price from consumables purchases is allocated between the lease of the instrument (under a contingent rent methodology as provided for in ASC 840, Leases), and the consumables when related performance obligations are satisfied, as a component of lease and product revenue, and is included as Instrument Rentals in the below table. Revenue associated with reagent rental consumables purchases is currently classified as variable consideration and constrained until a purchase order is received and related performance obligations have been satisfied. Shipping and handling costs billed to customers in connection with a product sale are recorded as a component of the transaction price and allocated to product revenue in the consolidated statements of operations and comprehensive loss as they are incurred by the Company in fulfilling its performance obligations.

Direct sales of instruments include warranty, maintenance and technical support services typically for one year following the installation of the purchased instrument ("Maintenance Services"). Maintenance Services are separate performance obligations as they are service based warranties and are recognized on a straight-line basis over the service delivery period. After the completion of the initial Maintenance Services period, customers have the option to renew or extend the Maintenance Services typically for additional one-year periods in exchange for additional consideration. The extended Maintenance Services are also service based warranties that represent separate purchasing decisions. The Company recognizes revenue allocated to the extended Maintenance Services performance obligation on a straight-line basis over the service delivery period.

The Company warrants that consumable diagnostic tests will be free from defects, when handled according to product specifications, for the stated life of the product. To fulfill valid warranty claims, the Company provides replacement product free of charge. Accordingly, the Company accrues warranty expense associated with the estimated defect rates of the consumable diagnostic tests.

Revenue earned from activities performed pursuant to research and development agreements is reported as research revenue in the condensed consolidated statements of operations and comprehensive loss, and is recognized over time using an input method as the work is completed. 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. Milestones are contingent on the occurrence of future events and are considered variable consideration being constrained until the Company believes a significant revenue reversal will not occur. Refer to Note 11 for further details regarding the Company's research and development arrangements.

Disaggregation of Revenue

The Company disaggregates revenue from contracts with customers by type of products and services, as it best depicts how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors. The following table disaggregates our revenue by major source (in thousands):

	Three months ended,	Nine months ended,
	September 30, 2018	September 30, 2018
Product Revenue		
Instruments	\$ 504	\$ 1,213
Consumables	608	1,929
Instrument Rentals	106	344
Total Product Revenue	1,218	3,486
Research Revenue	1,248	5,222
Total Revenue	\$ 2,466	\$ 8,708

Remaining Performance Obligations

Remaining performance obligations represent the transaction price of firm orders for which work has not been performed or goods and services have not been delivered. As of September 30, 2018, the aggregate amount of transaction price allocated to

remaining performance obligations for contracts with an original duration greater than one year was \$3.8 million. We do not disclose the value of unsatisfied performance obligations for (i) contracts with an original expected length of one year or less and (ii) contracts for which we recognize revenue at the amount to which we have the right to invoice for services performed. The Company expects to recognize revenue on the remaining performance obligations over the next 2 years.

Significant Judgments

Our contracts with customers often include promises to transfer multiple products and services to a customer. Determining whether products and services are considered distinct performance obligations that should be accounted for separately versus together may require significant judgment. Once we determine the performance obligations, the Company determines the transaction price, which includes estimating the amount of variable consideration, based on the most likely amount, to be included in the transaction price, if any. We then allocate the transaction price to each performance obligation in the contract based on a relative stand-alone selling price method. The corresponding revenue is recognized as the related performance obligations are satisfied as discussed in the revenue categories above.

Judgment is required to determine the standalone selling price for each distinct performance obligation. We determine standalone selling price based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, we estimate the standalone selling price taking into account available information such as market conditions and the expected costs and margin related to the performance obligations.

Contract Assets and Liabilities

At September 30, 2018, the Company has recorded \$0.9 million of contract assets, which represents unbilled amounts related to work performed under a co-development agreement for which the milestone has not yet been achieved but is probable of being achieved. The Company did not record any contract assets at December 31, 2017.

The Company's contract liabilities consist of upfront payments for research and development contracts and Maintenance Services on instrument sales. We classify these contract liabilities in deferred revenue as current or noncurrent based on the timing of when we expect to recognize revenue. At September 30, 2018 and December 31, 2017, the Company had contract liabilities of \$0.7 million and \$1.7 million, respectively. Revenue recognized in the nine months ended September 30, 2018 relating to contract liabilities at December 31, 2017 was \$1.7 million, and related to performance of research and development services and straight-line revenue recognition associated with maintenance agreements. No revenue was recognized during the three months ended September 30, 2018 relating to contract liabilities at December 31, 2017.

Cost to Obtain and Fulfill a Contract

The Company does not meet the recoverability criteria to capitalize costs to obtain or fulfill instrument purchases. Reagent rental agreements do not meet the recoverability criteria to capitalize costs to obtain the contracts and the costs to fulfill the contracts are under the scope of ASC 840. At the end of each reporting period, the Company assesses whether any circumstances have changed to meet the criteria for capitalization. The Company did not incur any expenses to obtain research and development agreements and costs to fulfill those contracts do not generate or enhance resources of the entity. As such, no costs to obtain or fulfill contracts have been capitalized at period end.

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, costs associated with the manufacture of developed products 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.

Accounting Standards 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 has adopted ASU 2016-15 retrospectively and has presented the statement of cash flows in accordance with this guidance. The adoption of ASU 2016-15 did not have a material impact on the consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (“ASU 2016-18”), which requires that a statement of cash flows explains the change in the total of cash, cash equivalents and restricted cash during the period. Amounts described as restricted cash should be included with cash and cash equivalents when reconciling the beginning of period and end of period amounts shown on the statement of cash flows. The Company has reflected restricted cash with cash and cash equivalents when reconciling the beginning and end of period amounts shown on the statement of cash flows in accordance with ASU 2016-18. The adoption of ASU 2016-18 did not have a material impact on the 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 adopted ASU 2014-09 on January 1, 2018 using the modified retrospective method for all contracts not completed as of the date of adoption. For contracts that were modified before the effective date, the Company reflected the aggregate effect of all modifications when identifying performance obligations and allocating transaction price, which did not have a material effect on the adjustment to accumulated deficit. The reported results for 2018 reflect the application of ASU 2014-09 guidance while the reported results for 2017 were prepared under the guidance of ASC 605, Revenue Recognition.

Accounting Standards Issued, Not Adopted

In February 2016, the FASB issued ASU No. 2016-02, Leases (“ASU 2016-02”), which requires lessees to reflect all leases with terms longer than 12 months on their balance sheets. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The FASB has subsequently issued amendments to the guidance, including the addition of an optional transition method. The adoption of ASU 2016-02 will result in an increase to the Company’s consolidated balance sheets for right-of-use assets and lease liabilities, and the Company is currently evaluating the other effects of adoption of ASU 2016-02 on the Company’s consolidated financial statements. This evaluation process includes reviewing all forms of leases and

performing a completeness assessment over the lease population. The Company will adopt ASU 2016-02, effective as of January 1, 2019 and expects to apply the alternative adoption approach at the adoption date and will recognize a cumulative-effect adjustment, if any, to the opening balance of retained earnings. The Company expects to make an accounting policy election that will keep leases with an initial term of 12 months or less off of the balance sheet and will result in recognizing those lease payments in the consolidated statements of operations on a straight-line basis over the lease term.

Emerging Growth Company Status

In April 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was enacted in the United States. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, as amended, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

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, 2018 and December 31, 2017 (in thousands):

	Balance at	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash	\$ 1,508	\$1,508	\$ —	\$ —
Money market funds	58,717	58,717	—	—
Restricted cash	180	180	—	—
	\$ 60,405	\$60,405	\$ —	\$ —
Liabilities:				
Derivative liability	\$ 2,063	\$—	\$ —	\$ 2,063
	\$ 2,063	\$—	\$ —	\$ 2,063

	Balance at	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	December 31, 2017			

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

Assets:				
Cash	\$ 3,463	\$3,463	\$ —	\$ —
Money market funds	38,336	38,336	—	—
Restricted cash	260	260	—	—
	\$ 42,059	\$42,059	\$ —	\$ —
Liabilities:				
Derivative liability	\$ 2,238	\$—	\$ —	\$ 2,238
	\$ 2,238	\$—	\$ —	\$ 2,238

The Company's Term Loan Agreement with CRG (Note 6) contains certain provisions that change the underlying cash flows of the instrument, including an interest-only period dependent on the achievement of receiving 510(k) clearance for the marketing of T2Bacteria by the FDA by a certain date (the "Approval Milestone"), which originally was April 30, 2018, and acceleration of the obligations under the Term Loan Agreement under an event of default. In addition, 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. The Company concluded that these features are not clearly and closely related to the host instrument, and represent a single compound derivative that is required to be re-measured at fair value on a quarterly basis.

During the fourth quarter of 2017, the Company received communication from the FDA that suggested the approval timeline of T2Bacteria could be longer than the Company initially anticipated. The delay resulted in an increase in the probability of not achieving the Approval Milestone by April 30, 2018, as well as an increase in the probability of the payment of contingent interest in future periods, based on the contractual payments that exist as of December 31, 2017. At December 31, 2017, the Company recorded a derivative liability related to the Company's Term Loan Agreement with CRG of \$2.2 million. The estimated fair value of the derivative liability was determined using a probability-weighted discounted cash flow model that includes principal and interest payments under the following scenarios: FDA approval by April 30, 2018 (40%), FDA approval after April 30, 2018 (20%) and no FDA approval (40%).

In March 2018, the Term Loan Agreement was amended to extend the Approval Milestone to June 30, 2018, which was achieved in May 2018, to extend the additional \$10.0 million funding through September 27, 2018 and reduce the fiscal year 2018

product revenue target to \$7.0 million. The fair value of the derivative at September 30, 2018 is \$2.1 million. The estimated fair value of the derivative was determined using a probability-weighted discounted cash flow model that includes contingent interest payments under the following scenarios: 4% contingent interest beginning in 2020 (70%) and 4% contingent interest beginning in 2021 (30%). Should the Company's assessment of these probabilities change, including amendments of certain revenue targets, there could be a change to the fair value of the derivative liability.

The following table provides a roll-forward of the fair value of the derivative liability (in thousands):

Balance at December 31, 2017	\$2,238
Change in fair value of derivative liability, recorded as interest expense	(175)
Balance at September 30, 2018	\$2,063

4. Restricted Cash

The Company is required to maintain a security deposit for its operating lease agreement for the duration of the lease agreement and for its credit cards as long as they are in place. At September 30, 2018 and December 31, 2017, the Company had certificates of deposit for \$180,000 and \$260,000, respectively, which represented collateral as security deposits for its operating lease agreement for its facility and its credit cards. The \$80,000 change is classified as unrestricted cash at September 30, 2018.

5. 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,	
	2018	2017
Raw materials	\$ 715	\$ 539
Work-in-process	2,069	562
Finished goods	553	243
Total inventories, net	\$ 3,337	\$ 1,344

Property and Equipment

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

	September 30, December 31,	
	2018	2017
Office and computer equipment	\$ 409	\$ 409
Software	751	743
Laboratory equipment	4,390	4,224
Furniture	200	200
Manufacturing equipment	695	910
Manufacturing tooling and molds	576	255
T2-owned instruments and components	6,758	7,370
Leasehold improvements	3,437	3,437
Construction in progress	1,701	1,591
	18,917	19,139
Less accumulated depreciation and amortization	(10,727)	(9,124)
Property and equipment, net	\$ 8,190	\$ 10,015

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. At September 30, 2018, there were no raw materials and work-in-process inventory in T2-owned instruments and components compared to \$0.8 million at December 31, 2017. Completed T2-owned instruments are placed in service once installation procedures are completed and are depreciated over five years. 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 for the three months ended September 30, 2018 and 2017 and \$0.7 million for the nine months ended September 30, 2018 and 2017. 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. During the fourth quarter of 2017, the Company received communication from the FDA that suggested the approval timeline for T2Bacteria would be longer than the Company initially anticipated. The Company assessed the recoverability of T2-owned instruments based on delayed T2Bacteria cash flows and recorded an impairment charge of \$2.6 million, related to T2-owned instruments and components. The fair value used in the impairment calculation was based on the best estimated selling price of the underlying T2-owned instruments, less the estimated cost to sell the instruments. During the nine months ended September 30, 2018, the Company recorded a \$0.2 million impairment charge, in the cost of product revenue and selling, general and administrative, related to manufacturing equipment for the Candida 1.0 cartridge, which was replaced by the Candida 1.1 cartridge.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, December 31,	
	2018	2017
Accrued payroll and compensation	\$ 3,077	\$ 2,793
Accrued research and development expenses	189	818
Accrued professional services	566	1,018
Other accrued expenses	595	1,589
Total accrued expenses and other current liabilities	\$ 4,427	\$ 6,218

At December 31, 2017, a fee associated with the Company's Term Loan Agreement (Note 6) of \$0.6 million is included in accrued expenses and other current liabilities, to match the classification of the associated debt. At September 30, 2018, the Company's Term Loan Agreement with CRG and the associated fee are classified as non-current liabilities.

6. Notes Payable

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

	September 30, December 31,	
	2018	2017

Term loan agreement, net of deferred issuance costs of \$1.9 million and \$2.4 million, respectively	\$ 40,869	\$ 39,228
Equipment lease credit facility, net of deferred issuance cost of \$9 thousand and \$24 thousand, respectively	1,399	2,476
Total notes payable	42,268	41,704
Less: current portion of notes payable	(3,399)	(40,696)
Notes payable, net of current portion	\$ 38,869	\$ 1,008

The Term Loan Agreement with CRG is classified as a current liability on the balance sheet at December 31, 2017 based on the Company's consideration of the probability of violating the minimum liquidity covenant included in the Term Loan Agreement. The Term Loan Agreement with CRG is classified as a non-current liability at September 30, 2018, based on the remote probability of violating the minimum liquidity covenant, as a result of the Company's June 2018 public offering and FDA market clearance of T2Bacteria. The contractual terms of the agreement require principal payments of \$23.2 million and \$23.2 million during the years ended December 31, 2021 and 2022, respectively.

Term Loan Agreement

In December 2016, the Company entered into a Term Loan Agreement (the "Term Loan Agreement") with CRG. The Company initially borrowed \$40.0 million pursuant to the Term Loan Agreement and could 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 by a certain date (the "Approval Milestone"), which originally was April 30, 2018. 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. The Company is accruing the final payment fee as interest expense and it is included as a current liability at December 31, 2017 and a non-current liability at September 30, 2018 on the balance sheet.

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 certain 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, including a requirement to maintain a minimum cash balance. The Term Loan Agreement also requires the Company to achieve certain revenue targets, whereby the Company is required to pay double the amount of any shortfall as an acceleration of principal payments. In March 2018, the Term Loan Agreement was amended to extend the Approval Milestone to June 30, 2018, extend the additional \$10.0 million funding through September 27, 2018 and reduce the fiscal year 2018 product revenue target to \$7.0 million. At September 30, 2018, the Company classified \$2.0 million as current notes payable in anticipation of accelerated 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.

During the fourth quarter of 2017, the Company received communication from the FDA that suggested the approval timeline of T2Bacteria would be longer than the Company initially anticipated. The delay resulted in an increase in the probability of not achieving the Approval Milestone by April 30, 2018, as well an increase in the probability of the payment of contingent interest in future periods, based on the contractual payments requirements that exist as of December 31, 2017.

The Company assessed the terms and features of the Term Loan Agreement, including the interest-only period dependent on the achievement of the Approval Milestone by June 30, 2018, which was achieved in May 2018, and the acceleration of the obligations under the Term Loan Agreement under an event of default, of the Term Loan Agreement in order to identify any potential embedded features that would require bifurcation. In addition, 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. The Company concluded that the features of the Term Loan Agreement are not clearly and closely related to the host instrument, and represent a single compound derivative that is required to be re-measured at fair value on a quarterly basis. At December 31, 2017, the Company recorded a derivative liability related to the Company's Term Loan Agreement with CRG of \$2.2 million. The fair value of the derivative at September 30, 2018 is \$2.1 million. The Company reclassified the derivative liability to non-current liabilities, at September 30, 2018, to match the classification of the related Term Loan Agreement.

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 \$28.0 million of outstanding debt. Upon the repayment of all amounts owed by the Company related to debt outstanding prior to the Term Loan Agreement, all commitments related to prior debt 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 (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 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.

7. 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.

Public Offering

On September 15, 2017, the Company sold 5,031,250 shares of its common stock in a public offering 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.

On June 4, 2018, the Company sold 7,015,000 shares of its common stock in a public offering at \$7.50 per share, for an aggregate gross cash purchase price of \$52.6 million, or proceeds of \$49.2 million after underwriters discount and expenses.

Common Stock

The Company authorized 200,000,000 shares of common stock, \$0.001 par value per share, of which 44,038,754 and 35,948,900 were outstanding as of September 30, 2018 and December 31, 2017, respectively.

8. 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 primarily 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, 2018, there were 755,341 shares available for future grant under the 2014 Plan.

Inducement Award Plan

The Company's Inducement Award Plan ("Inducement Plan"), which was adopted in March 2018, provides for the granting of equity awards to new employees, which includes options, restricted stock awards, restricted stock units, performance awards, dividend equivalent awards, stock payment awards and stock appreciation rights. The aggregate number of shares of common stock which may be issued or transferred pursuant to awards under the Inducement Plan is 625,000 shares. Any awards that forfeit, expire, lapse, or are settled for cash without the delivery of shares to the holder are available for the grant of an award under the Inducement Plan. Any shares repurchased by or surrendered to the Company that are returned shall be available for grant of an award under the Inducement Plan. The payment of dividend equivalents in cash in conjunction with any outstanding Award shall not be counted against the shares available for issuance under the Inducement Plan. As of September 30, 2018, there were 262,750 shares available for future grant under the Inducement Plan.

Stock Options

During the nine months ended September 30, 2018 and 2017, the Company granted stock options with an aggregate fair value of \$5.5 million and \$2.5 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, 2017	3,785,083	\$ 7.31	6.88	\$ 1,989
Granted	1,542,250	5.66		
Exercised	(395,245)	3.90		1,294
Forfeited	(595,291)	6.46		
Cancelled	(100,202)	13.73		
Outstanding at September 30, 2018	4,236,595	6.99	7.17	8,570
Exercisable at September 30, 2018	2,308,545	7.74	5.59	5,222
Vested or expected to vest at September 30, 2018	3,775,876	7.14	6.92	7,731

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

Included in the stock options outstanding as of December 31, 2017 are 106,066 performance based options, which were forfeited during the nine month period ended September 30, 2018 as the performance conditions were not achieved.

The weighted-average grant date fair values of stock options granted in the nine month periods ended September 30, 2018 and 2017 were \$3.55 per share and \$3.04 per share, respectively, and were calculated using the following estimated assumptions:

	Nine Months Ended September 30, 2018		2017	
Weighted-average risk-free interest rate	2.66	%	1.98	%
Expected dividend yield	—	%	—	%
Expected volatility	68	%	63	%
Expected terms	6.0		6.0	
	years		years	

The total fair values of stock options that vested during the nine months ended September 30, 2018 and 2017 were \$2.3 million and \$3.5 million, respectively.

As of September 30, 2018, there was \$6.8 million of total unrecognized compensation cost related to unvested stock options granted under the Stock Incentive Plans. Total unrecognized compensation cost will be adjusted for future changes in the estimated forfeiture rate. The Company expects to recognize that cost over a remaining weighted-average period of 2.90 years as of September 30, 2018.

Restricted Stock Units

During the nine months ended September 30, 2018, 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, excluding any restricted stock units with market conditions, 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 \$6.2 million, which are being amortized into compensation expense over the vesting period of the options as the services are being provided.

Included in the restricted stock units granted during the nine months ended September 30, 2018 are 1,179,090 restricted stock units with market conditions, which vest upon the achievement of stock price targets. The compensation cost for restricted stock units with market conditions is being recorded over the derived service period and was \$0.9 million and \$3.6 million for the three and nine months ended September 30, 2018, respectively. During the nine months ended September 30, 2018, 294,775 restricted stock units with market conditions vested upon achievement of a stock price target causing acceleration of the remaining expense for these units. These restricted stock units vested during the three months ended June 30, 2018 but were not reflected as outstanding shares until the three months ended September 30, 2018 due to a deferred release date.

The following is a summary of restricted stock unit activity under the 2014 Plan (in thousands, except share and per share amounts):

	Weighted-Average	
	Number of	Grant Date Fair
	Shares	Value
Nonvested at December 31, 2017	606,497	5.23
Granted	1,217,190	5.06
Vested	(546,547)	5.33
Forfeited	(75,017)	5.63
Cancelled	—	—
Nonvested at September 30, 2018	1,202,123	4.99

During the nine months ended September 30, 2018, 546,547 restricted stock units vested and 14,803 shares were withheld to cover employee tax. As of September 30, 2018, there was \$3.2 million of total unrecognized compensation cost related to unvested restricted stock units granted under the Stock Incentive Plans, including the unrecognized compensation expense of stock options with market conditions deemed probable of vesting. The Company expects to recognize that cost over a remaining weighted-average period of 0.66 years, as of September 30, 2018.

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, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Cost of product revenue	\$23	\$18	\$408	\$87
Research and development	409	340	1,271	1,047
Selling, general and administrative	1,601	862	5,561	2,555
Total stock-based compensation expense	\$2,033	\$1,220	\$7,240	\$3,689

For the three months ended September 30, 2018 and 2017, \$0.2 million and \$0.0 million of stock-based compensation expenses were capitalized as part of inventory or T2Dx instruments and components, respectively. For the nine months ended September 30, 2018 and 2017, \$0.3 million and \$0.1 million of stock-based compensation expenses were capitalized as part of inventory or T2 instruments and components, respectively.

9. 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 was \$1.8 million.

10. 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 and Nine Months Ended	
	September 30,	
	2018	2017
Options to purchase common shares	4,236,595	3,833,300
Restricted stock units	1,202,123	750,320
Warrants to purchase common stock	528,958	528,958
Total	5,967,676	5,112,578

11. Co-Development Agreements

Canon US Life Sciences

On February 3, 2015, the Company entered into a Co-Development Partnership Agreement (the "Co-Development Agreement") with Canon U.S. Life Sciences, Inc. ("Canon US Life Sciences") to develop a diagnostic test panel to rapidly detect Lyme disease. Under the terms of the Co-Development Agreement, the Company received an upfront payment of \$2.0 million from Canon US Life Sciences, and the agreement includes an additional \$6.5 million of consideration upon achieving certain development and regulatory milestones for total aggregate payments of up to \$8.5 million. In October 2015 and June 2018, the Company achieved specified technical requirements and received \$1.5 million and \$2.0 million, respectively, related to the achievement of the milestones. The Company is eligible to receive an additional \$3.0 million under the arrangement related to the achievement of a regulatory milestone. 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). 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.

The Company evaluated the promised goods and services under the Co-Development Agreement and determined that the Co-Development Agreement included one performance obligation, the research and development services. The Company is recognizing revenue for research and development services as a component of research revenue in the condensed consolidated financial statements over time, as the services are delivered. The Company uses the input method by allocating and recognizing revenue over time based on the total full-time equivalent effort incurred to date as a percentage of total full-time equivalent time expected, 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.

Under the Co-Development Agreement, the Company recorded revenue of \$0.2 million for the three months ended September 30, 2018 and did not record any revenue for the three months ended September 30, 2017. The Company recorded revenue of \$1.5 million and \$0.3 million during the nine months ended September 30, 2018 and 2017. Under the Co-Development Agreement, the Company expects to record revenue over the next two years, provided 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 a royalty based on its sales for a period of time.

The Company evaluated the promised goods and services under the Allergan Agreement and determined that the Allergan Agreement included two performance obligations, the research and development services for the T2Bacteria II Panel and the research and development services for the T2GNR Panel. The Company uses the input method by allocating and recognizing revenue over time based on the total full-time equivalent effort incurred to date as a percentage of total full-time equivalent time expected, 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 \$0.7 million and \$0.4 million for the three months ended September 30, 2018 and 2017, respectively, and \$2.9 million and \$0.6 million for the nine months ended September 30, 2018 and 2017, respectively, under the Allergan Agreement. The Company expects to record revenue over the next three months, provided development and regulatory milestones are achieved.

CARB-X

In March 2018, the Company was awarded a grant of up to \$2.0 million from CARB-X. The collaboration with CARB-X will be used to accelerate the development of new tests to identify bacterial pathogens and resistance markers directly in whole blood more rapidly than is possible using today’s diagnostic tools. The new tests aim to expand the T2Dx instrument product line by detecting 20 additional bacterial species and resistance targets, with a focus on blood borne pathogens on the United States Centers for Disease Control and Prevention (“CDC”) antibiotic resistance threat list.

Under this cost-sharing agreement, the Company may be reimbursed up to \$1.1 million, with the possibility of up to an additional \$0.9 million based on the achievement of certain project milestones.

The Company recorded revenue of \$0.4 million and \$0.9 million for the three and nine months ended September 30, 2018, respectively, under the CARB-X Agreement. The Company expects to record revenue over the next two years, based upon cost-sharing and the achievement of certain project milestones.

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 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 the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described under the sections in this Quarterly Report on Form 10-Q entitled “Item 1A.—Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Quarterly Report on Form 10-Q. These forward looking statements are subject to numerous risks, including, without limitation, the following:

- our status as an early stage company;
- 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 limited sales history;
- our ability to gain the support of leading hospitals and key thought leaders and publish the results of our clinical trials in peer-reviewed journals;
- our ability to successfully manage our growth;
- our future capital needs and our need to raise additional funds;
- the performance of our diagnostics;
- our ability to compete in the highly competitive diagnostics market;
- our ability to obtain marketing 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;
- our ability to recruit, train and retain key personnel;
- our ability to protect and enforce our intellectual property rights, including our trade secret protected proprietary rights in T2MR;
- our dependence on third parties;
- our ability to continue as a going concern;
- manufacturing and other product risks;
- the impact of the adoption of new accounting standards; and
- the Tax Cuts and Jobs Act of 2017 (Tax Reform).

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, 2017, 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.

19

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, or T2MR, to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. 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, or 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, or the T2Dx and the T2Candida Panel, which have the ability to rapidly identify the five clinically relevant species of Candida, a fungal pathogen known to cause sepsis. On May 24, 2018, we received market clearance from the FDA for our T2Bacteria Panel, which has the ability to rapidly identify five of the most common and deadly sepsis-causing bacteria directly from whole blood. In the United States, we have built a direct sales force that is primarily targeting the top 1,200 hospitals with the highest concentration of patients at risk for sepsis-related infections. Internationally, we have primarily partnered with distributors that target large hospitals in their respective international markets. A Candida auris assay is also available as a research use only product for blood-based and environmental testing. Two additional diagnostic applications in development are called T2Carba Resistance+ and T2Lyme, which are focused on gram-negative bacterial sepsis infections and Lyme disease, respectively. Diagnostic applications for additional bacteria species and resistance markers are in development as part of a collaboration with CARB-X. We expect that existing reimbursement codes will support our sepsis and Lyme disease product candidates, and that the anticipated economic savings associated with our sepsis products will be realized directly by hospitals.

We believe our sepsis products, which include T2Candida and 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. Our T2Candida Panel's and T2Bacteria Panel'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, or the CDC, recently called "one of our most serious health threats." The addition of the use of our products, T2Bacteria and T2Candida, which both run on the T2Dx instrument, with the standard of care for the management of patients suspected of sepsis, enables clinicians to potentially treat 90% of patients with sepsis pathogen infections with the right targeted therapy within the first twelve hours of development of 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 typically have a bacterial infection and 10% typically have Candida infections. T2Candida and T2Bacteria are designed to identify pathogens commonly not 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, 2018 was \$302.0 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 initial FDA-cleared products, T2Dx and T2Candida. In addition, we will continue to incur significant costs and expenses as we increase commercialization efforts for our most recent FDA-cleared product, T2Bacteria, and 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, T2Bacteria, and future T2MR-based diagnostics.

Pursuant to the requirements of Accounting Standards Codification (“ASC”) 205-40, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management’s plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company’s ability to continue as a going concern. The mitigating effect of management’s plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued.

We believe that our existing cash and cash equivalents at September 30, 2018 will be sufficient to allow us to fund our current operating plan through November 30, 2019. At December 31, 2017, we had concluded that substantial doubt existed about our ability to continue as a going concern for a period of at least twelve months from the date of issuance of those consolidated financial statements. However, we alleviated the substantial doubt during the nine months ended September 30, 2018. On June 4, 2018, we raised net proceeds of \$49.2 million through our June 2018 public offering. During the nine months ended September 30, 2018, we also received a \$2.0 million milestone payment from a co-development partner and received 510(k) clearance for the marketing of T2Bacteria.

At December 31, 2017, the conditions that raised substantial doubt regarding our ability to continue as a going concern resulted from certain elements of our operating plan being outside of our control, including the approval of T2Bacteria and receipt of certain development and regulatory milestone payments under our co-development agreements. Under ASC 205-40, the future receipt of potential funding from our co-development partners and other resources cannot be considered probable if the plans are not entirely within our control. The Term Loan Agreement with CRG 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, and maintain a minimum liquidity amount. Should we have fallen short of the revenue target we would have sought a waiver of this provision. There can be no assurances that we would have been successful in obtaining a waiver.

Our Commercial Products and the Unmet Clinical Need

Our FDA-cleared products, the T2Dx instrument, T2Candida, and T2Bacteria utilize T2MR to detect species-specific Candida and sepsis-causing bacteria, respectively, 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 and T2Bacteria run on the T2Dx and provide high sensitivity with a limit of detection as low as 1 CFU/mL, even in the presence of antimicrobial therapy.

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 \$27 billion in the United States, building on previous data demonstrating that sepsis was responsible for 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 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.

Data from our pivotal clinical trial for T2Bacteria demonstrated that the T2Bacteria Panel can deliver actionable results in an average of 5.4 hours, compared to an average of 60 hours for detecting the same species by blood culture. In addition, T2Bacteria identified 69 patients with bloodstream infections that were missed by the paired blood culture that was simultaneously run. The pivotal study was a large study of over 1,400 patient samples collected across 11 hospital and hospital systems across the United States. The investigators concluded the following: (a) T2Bacteria demonstrated accuracy, including overall sensitivity of 90% and overall average specificity of 98%; (b) blood culture species identification results took an average of 3 days while T2Bacteria took an average of only 5.4 hours in the clinical trial, providing results more than 2.5 days faster; (c) 66% of patients in the clinical trial with a bloodstream infection confirmed by T2 and blood culture could have benefited from earlier appropriate antibiotics based on the rapid T2Bacteria result. A separate presentation on the T2Bacteria Panel at ASM Microbe 2018 by clinicians at Ochsner Medical Center found the following: (a) T2Bacteria detected 14 infections missed by a paired blood culture – but proven to be a true infection by other cultures; (b) the T2Bacteria Panel identified every infection detected by blood culture of the target species (100% sensitivity); and (c) T2Bacteria was accurate in identifying samples without an infection, with 99% average specificity. The authors concluded that the advantages of T2Bacteria over blood culture could make it a valuable tool to enable faster time to targeted antibiotic therapy and reduced use of unnecessary antibiotics. Also at ASM Microbe 2018, in a late-breaker poster from Northwestern University, clinicians found the T2Bacteria Panel was accurate compared to blood culture and detected 18 clinically important urinary and respiratory infections that were missed by blood culture. The authors concluded that T2Bacteria may improve patient care by providing clinicians rapid and actionable information for treating patients. In November 2015, the Company presented preliminary data demonstrating the ability of our T2Bacteria Panel product candidate to provide the rapid and sensitive identification of certain sepsis-causing bacteria included in the panel, directly from whole blood. The bacteria species included in T2Bacteria are *Staphylococcus aureus*, *Enterococcus faecium*, *Escherichia coli*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*. The five bacteria species in our T2Bacteria Panel are responsible for about half of all septic infections. Additionally, when combined with the use of T2Candida and the practice of empirically administering broad spectrum antibiotics, the rapid detection of these bacteria may enable 90% of patients with sepsis to receive rapid and appropriate therapy. The T2Bacteria Panel that is CE Marked includes *A. baumannii*, which has an estimated incidence rate of 3.6% in Europe, higher than the 1% incidence rate in the United States.

Our T2Candida Panel

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.

Our directT2 pivotal clinical trial was designed to evaluate the sensitivity and specificity of T2Candida on the T2Dx instrument. 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 instrument 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*.

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.

At ASM Microbe 2018, in a late-breaker poster from the Centers for Disease Control and Prevention (CDC) on their validation of the Research Use Only diagnostic for the detection of the emerging superbug *Candida auris*, found that the T2MR technology provided accurate diagnostic results from patient skin samples. The poster concludes that T2MR could be used to provide a more rapid response to future outbreaks.

Our T2Bacteria Panel

On May 24, 2018, we received market clearance from the FDA for our T2Bacteria Panel, a multiplex diagnostic panel that detects five major bacterial pathogens associated with sepsis and, in conjunction with T2Candida and standard empiric therapy regimens, may enable the early, appropriate treatment of 90% of sepsis patients. T2Bacteria, which also runs on the T2Dx, addresses 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.

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 human whole blood specimens from patients with suspected bacteremia. The T2Bacteria Panel is designed to identify five species of bacteria directly from human whole blood specimens: *Enterococcus faecium*, *Escherichia*

coli, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Staphylococcus aureus*. Outside of the United States, the CE marked T2Bacteria panel identifies all 5 of these species along with a 6th species, *Acinetobacter Baumannii*.

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.

Our T2Direct Diagnostics

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 addition of the use of our products, T2Bacteria and T2Candida, which both run on the T2Dx instrument, with the standard of care for the management of patients suspected of sepsis enables clinicians to potentially treat 90% of patients with sepsis pathogen infections with the right targeted therapy 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 T2Bacteria are designed to identify pathogens commonly not covered by broad spectrum antibiotic drugs.

We believe our products provide 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 our products address 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 instrument 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 instrument 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 development and we initiated a T2Lyme clinical trial in May 2018.

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, related services, reagent rental agreements 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 and is recognized over time, using an input method as the work is completed, limited to payments earned. Costs incurred to deliver the services are recorded as research and development expense in the condensed consolidated financial statements. The timing of receipt of cash from the Company's research and development agreements generally differs from when revenue is recognized. Milestones are contingent on the occurrence of future events and are considered variable consideration being constrained until the Company believes a significant revenue reversal will not occur.

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. 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 the related performance obligation is satisfied (i.e. when the control of an instrument has passed to the customer; typically, at shipping point). 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 (under a reagent rental agreement), which includes the incremental charge, is recognized upon shipment. Revenue associated with reagent rental consumable purchases is currently classified as variable consideration and constrained until a purchase order is received and related performance obligations have been satisfied (or partially satisfied). The transaction price from consumables purchases is allocated between the lease of the instrument (under a contingent rent methodology as provided for in ASC 840), and the consumables when related performance obligations are satisfied as a component of lease and product revenue.

Direct sales of instruments include warranty, maintenance and technical support services typically for one year following the installation of the purchased instrument (“Maintenance Services”). Maintenance Services are separate performance obligations as they are service based warranties and are recognized straight-line over the service delivery period. After the completion of the initial Maintenance Services period, customers have the option to renew or extend the Maintenance Services typically for additional one-year periods in exchange for additional consideration. The extended Maintenance Services are also service based warranties and classified as separate performance obligations. The Company will recognize the revenue allocated to the extended Maintenance Services performance obligation straight-line over the service delivery period. The Company warrants that consumable diagnostic tests will be free from defects, when handled according to product specifications, for the stated life of the product. To fulfill valid warranty claims, the Company provides replacement product free of charge. Accordingly, the Company accrues warranty expense associated with the estimated defect rates of the consumable diagnostic tests.

Our consumable diagnostic tests can only be used with our instruments, and accordingly, as we expect the installed base of our instruments to continue to grow, we expect the following to occur:

25

- 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.

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, changes in fair value of our derivative liability and the amortization of deferred financing costs and debt discount, 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, 2017 remained materially consistent, other than the January 1, 2018 adoption of ASC 606, Revenue from Contracts with Customers ("ASC 606"), which did not have a material impact on the condensed consolidated financial statements (Note 2). 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, 2017.

Results of Operations for the Three Months Ended September 30, 2018 and 2017

	Three Months Ended		
	September 30, 2018	2017	Change
	(in thousands)		
Revenue:			
Product revenue	\$1,218	\$739	\$479
Research revenue	1,248	369	879
Total revenue	2,466	1,108	1,358
Costs and expenses:			
Cost of product revenue	3,042	2,106	936
Research and development	2,725	5,880	(3,155)
Selling, general and administrative	5,873	5,559	314
Total costs and expenses	11,640	13,545	(1,905)
Loss from operations	(9,174)	(12,437)	3,263
Interest expense, net	(1,836)	(1,718)	(118)
Other income, net	243	79	164
Net loss	\$(10,767)	\$(14,076)	\$3,309

Product revenue

Product revenue was \$1.2 million for the three months ended September 30, 2018 compared to \$0.7 million for the three months ended September 30, 2017, an increase of \$0.5 million. The increase was driven primarily by higher T2Dx instrument sales of \$0.4 million and higher comparable sales of consumables of \$0.1 million.

Research revenue

Research revenue was \$1.3 million for the three months ended September 30, 2018, compared to \$0.4 million for the three months ended September 30, 2017, an increase of \$0.9 million. The increase was the result of \$0.4 million of revenue recognized related to our cost-sharing agreement with CARB-X, which was executed in March 2018, an increase of \$0.3 million from services delivered under our Co-Development Agreement with Allergan Sales, LLC, and an increase of \$0.2 million from our Co-Development Agreement with Canon US Life Sciences.

Cost of product revenue

Cost of product revenue was \$3.0 million for the three months ended September 30, 2018, compared to \$2.1 million for the three months ended September 30, 2017, an increase of \$0.9 million. The increase in cost was driven by an increase of \$0.8 million due to higher T2Dx instrument sales and \$0.1 million due to higher consumable sales.

Research and development expenses

Research and development expenses were \$2.7 million for the three months ended September 30, 2018, compared to \$5.9 million for the three months ended September 30, 2017, a decrease of \$3.2 million. Clinical and preclinical expenses decreased by \$1.1 million due to completion of the T2Bacteria clinical trial and T2Lyme pre-clinical trial. Payroll expenses decreased \$1.0 million due to fewer full time employees, as a result of our cost savings initiative. Facilities and lab related expenses decreased by \$0.8 million. The decrease in facilities is driven by less depreciation from T2-owned instruments, which were classified as R&D while being used in the T2Bacteria clinical trial. Lab supplies consumption has decreased since completion of the T2Bacteria clinical trial. Outside services decreased by \$0.3 million, as a result of less consulting services due to completion of the T2Bacteria clinical trial and T2Lyme pre-clinical trial.

Selling, general and administrative expenses

Selling, general and administrative expenses were \$5.9 million for the three months ended September 30, 2018, compared to \$5.6 million for the three months ended September 30, 2017, an increase of \$0.3 million. The increase was attributed to increased stock compensation expense of \$0.7 million primarily associated with restricted stock units with market conditions and increased marketing spend, associated with the launch of T2Bacteria of \$0.1 million. These increases were offset by a \$0.4 million decrease in professional fees, and \$0.1 million from decreased payroll expenses due to fewer full time employees, as a result of our cost savings initiative.

Interest expense, net

Interest expense, net, was \$1.8 million for the three months ended September 30, 2018, compared to \$1.7 million for the three months ended September 30, 2017, an increase of \$0.1 million.

Other income, net

Other income, net, was \$0.2 million of net income for the three months ended September 30, 2018 and \$0.1 million of net income for the three months ended September 30, 2017, an increase of \$0.1 million.

Results of Operations for the Nine Months Ended September 30, 2018 and 2017

	Nine Months Ended		
	September 30, 2018	2017	Change
	(in thousands)		
Revenue:			
Product revenue	\$3,486	\$2,105	\$1,381
Research revenue	5,222	900	4,322

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

Total revenue	8,708	3,005	5,703
Costs and expenses:			
Cost of product revenue	9,773	5,722	4,051
Research and development	11,193	19,577	(8,384)
Selling, general and administrative	19,238	17,192	2,046
Total costs and expenses	40,204	42,491	(2,287)
Loss from operations	(31,496)	(39,486)	7,990
Interest expense, net	(4,910)	(5,008)	98
Other income, net	402	260	142
Net loss	\$(36,004)	\$(44,234)	\$8,230

28

Product revenue

Product revenue was \$3.5 million for the nine months ended September 30, 2018 compared to \$2.1 million for the nine months ended September 30, 2017, an increase of \$1.4 million. The increase was driven primarily by higher T2Dx instrument sales of \$0.9 million and higher comparable sales of consumables of \$0.5 million, which may be attributed to a larger install base and improved customer adoption.

Research revenue

Research revenue was \$5.2 million for the nine months ended September 30, 2018, compared to \$0.9 million for the nine months ended September 30, 2017, an increase of \$4.3 million. The increase was the result of higher revenue recognized from services delivered under our Co-Development Agreement with Allergan Sales, LLC of \$2.3 million, higher revenue recognized from services delivered under our Co-Development Agreement with Canon US Life Sciences of \$1.2 million, a result of achieving a \$2.0 million milestone during the nine months ended September 30, 2018 and revenue of \$0.8 million from our cost-sharing agreement with CARB-X, which was executed during the nine months ended September 30, 2018.

Cost of product revenue

Cost of product revenue was \$9.8 million for the nine months ended September 30, 2018, compared to \$5.7 million for the nine months ended September 30, 2017, an increase of \$4.1 million. The increase in cost was driven by an increase of \$2.3 million due to higher T2Dx instrument sales, an increase of \$1.0 million related to idle capacity in the first half of the year resulting from the anticipation of T2Bacteria approval by the FDA and an increase of \$0.8 million due to higher consumable sales.

Research and development expenses

Research and development expenses were \$11.2 million for the nine months ended September 30, 2018, compared to \$19.6 million for the nine months ended September 30, 2017, a decrease of \$8.4 million. Clinical and preclinical expenses decreased by \$2.6 million due to completion of the T2Bacteria clinical trial and T2Lyme pre-clinical trial. Facilities and lab related expenses decreased by \$2.6 million. The decrease in facilities is driven by less depreciation from T2-owned instruments which were classified as R&D while being used in the T2Bacterial clinical trial. Lab supplies consumption has decreased since completion of the T2Bacteria trial. Payroll expenses decreased by \$2.6 million due to fewer full time employees, as a result of our cost savings initiative. Outside services decreased by \$0.6 million as a result of less consulting services due to completion of the T2Bacteria clinical trial and T2Lyme pre-clinical trial.

Selling, general and administrative expenses

Selling, general and administrative expenses were \$19.2 million for the nine months ended September 30, 2018, compared to \$17.2 million for the nine months ended September 30, 2017, an increase of \$2.0 million. The increase was attributed to increased stock compensation expense of \$3.0 million primarily associated with restricted stock units with market conditions. The increase was offset by a \$0.9 million decrease in professional fees, and \$0.2 million of decreased payroll expenses due to fewer full time employees, as a result of our cost savings initiative.

Interest expense, net

Interest expense, net, was \$4.9 million for the nine months ended September 30, 2018, compared to \$5.0 million for the nine months ended September 30, 2017, a decrease of \$0.1 million.

Other income, net

Other income, net, was \$0.4 million of net income for the nine months ended September 30, 2018 and \$0.3 million of net income for the nine months ended September 30, 2017, an increase of \$0.1 million.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception, and as of September 30, 2018, and December 31, 2017 we had an accumulated deficit of \$302.0 million and \$266.1 million respectively. Having obtained clearance from the FDA and a CE mark in Europe to market the T2Dx, T2Candida, and T2Bacteria, the Company has incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution. 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.

Historically, we have funded our operations primarily through our August 2014 initial public offering, December 2015 public offering, September 2016 private investment in public equity financing, its September 2017 public offering, its June 2018 public offering, private placements of redeemable convertible preferred stock and debt financing arrangements.

Plan of operations and future funding requirements

As of September 30, 2018 and December 31, 2017 we had unrestricted cash and cash equivalents of approximately \$60.2 million and \$41.8 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.

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.

Going Concern

We believe that our existing cash and cash equivalents at September 30, 2018, will be sufficient to allow us to fund our current operating plan through November 30, 2019. At December 31, 2017, we had concluded that substantial doubt existed about our ability to continue as a going concern for a period of at least twelve months from the date of issuance of those consolidated financial statements. However, we alleviated the substantial doubt during the nine months ended September 30, 2018. On June 4, 2018, we raised net proceeds of \$49.2 million through its June 2018 public offering. During the nine months ended September 30, 2018, we also received a \$2.0 million milestone payment from a co-development partner and received 510(k) clearance for the marketing of T2Bacteria.

At December 31, 2017, the conditions that raised substantial doubt regarding our ability to continue as a going concern resulted from certain elements of our operating plan being outside of our control, including the approval of T2Bacteria and receipt of certain development and regulatory milestone payments under our co-development agreements. Under ASC 205-40, the future receipt of potential funding from our co-development partners and other resources cannot be considered probable if the plans are not entirely within our control. In addition, the Term Loan Agreement with CRG 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, and maintain a minimum liquidity amount. Should we have fallen short of the revenue target we would have sought a waiver of this provision. There can be no assurances that we would have been successful in obtaining a waiver. We are also required to maintain a minimum cash balance under our Term Loan Agreement with CRG.

Cash flows

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

	Nine Months Ended	
	September 30, 2018	2017
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$(30,450)	\$(36,641)
Investing activities	(950)	(2,601)
Financing activities	49,746	18,651
Net increase (decrease) in cash, cash equivalents and restricted cash	\$18,346	\$(20,591)

Net cash used in operating activities

Net cash used in operating activities was approximately \$30.5 million for the nine months ended September 30, 2018, and consisted of a net loss of \$36.0 million adjusted for non-cash items including stock-based compensation expense of \$7.5 million, depreciation and amortization expense of \$1.9 million, non-cash interest expense of \$1.7 million, an impairment charge of \$0.2 million, offset by a change in the fair value of the derivative instrument of \$0.2 million, deferred rent of \$0.2 million, and a net change in operating assets and liabilities of \$5.3 million, primarily related to an increase in accounts receivable of \$1.3 million from increased instrument sales and our cost-sharing agreement with CARB-X, an increase in prepaid expenses and other assets of \$1.3 million primarily due to unbilled receivables from our Co-Development Agreement with Allergan Sales, LLC, an increase in inventories, net, of \$1.2 million, a decrease in accrued expenses and accounts payable of \$0.8 million due to clinical and professional fees and a decrease in deferred revenue of \$0.8 million primarily from our Co-Development Agreement with Allergan Sales, LLC.

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 investing activities

Net cash used in investing activities was approximately \$1.0 million for the nine months ended September 30, 2018, and consisted of costs to acquire property and equipment.

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.

Net cash provided by financing activities

Net cash provided by financing activities was approximately \$49.7 million for the nine months ended September 30, 2018, and consisted primarily of the net proceeds from the June 2018 public offering of \$49.2 million and proceeds from the exercise of stock options of \$1.6 million which were partially offset by \$1.1 million of repayments of notes payable.

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 \$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 \$0.8 million of repayments of notes payable.

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 could 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 by a certain date (the “Approval Milestone”), which originally was April 30, 2018 (the “Original Approval Milestone Date”). 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. In March 2018, the Term Loan Agreement was amended to extend the Original Approval Milestone Date to June 30, 2018, extend the additional \$10.0 million funding through September 27, 2018 and reduce the fiscal year 2018 product revenue target to \$7.0 million. In May 2018, we achieved the Approval Milestone by obtaining market clearance from the U.S. Food and Drug Administration (“FDA”) for our T2Bacteria Panel.

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. At September 30, 2018, the Company classified \$2.0 million as current notes payable in anticipation of accelerated 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, including the interest-only period and the acceleration of the obligations under the Term Loan Agreement under an event of default, in order to identify any potential embedded features that would require bifurcation. In addition, 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. We concluded that these features are not clearly and closely related to the host instrument, and represent a single compound derivative that is required to be re-measured at fair value on a quarterly basis. As such, we recorded a derivative liability of \$2.1 million as of September 30, 2018.

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 \$28.0 million of outstanding debt. Upon the repayment of all amounts owed by us related to debt outstanding prior to the Term Loan Agreement, all commitments related to prior debt terminated and all security interests granted by us were released.

In connection with the Term Loan Agreement entered into in December 2016, we issued to CRG four separate warrants to purchase a total of 528,958 shares of 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 sale of all or substantially all of our assets. 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, 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

The Term Loan Agreement with CRG was classified as a current liability in 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, 2017. As of September 30, 2018, the Term Loan Agreement with CRG is classified as a non-current liability, in accordance with the contractual terms of the agreement, which require principal and interest payments of \$0.9 million, \$7.7 million, and \$56.2 million during the years ended December 31, 2018, 2019-2020 and 2021-2022, respectively. There were no other material changes to our contractual obligations and commitments from those described under Management's Discussion and Analysis of Financial Condition and Results of Operations in the Annual Report on Form 10-K for the year ended December 31, 2017.

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, 2018 and December 31, 2017, we had cash and cash equivalents of \$60.2 million and \$41.8 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, 2018 and December 31, 2017, 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, 2018. 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 due to a material weakness that existed at December 31, 2017 relating to the accounting for instruments which are classified as either inventory or property and equipment depending on their future use which had not yet been remediated, the Company's disclosure controls and procedures were not effective as of September 30, 2018.

At December 31, 2017, the Company concluded that a deficiency exists in the design and execution of the review control over the accounting of instrument valuation, including the recoverability analyses for the Company's instruments. Management determined that its accounting process for the review of these accounts lacked adequate levels of monitoring and review to appropriately identify and correct errors in the calculation in a timely manner. This control deficiency resulted in certain material and immaterial misstatements in the preliminary financial statement accounts that were corrected prior to the issuance of the annual consolidated financial statements. The errors noted were all related to and corrected in the fourth quarter. The control deficiency creates a possibility that a material misstatement to our consolidated financial statements will not be prevented or detected on a timely basis.

We are developing and implementing new control processes and procedures to address this weakness. We are undertaking steps to design and implement sufficient controls over accounting for inventory. These steps include increasing oversight by our management in the calculation and reporting of instrument valuation, including the recoverability analyses related to instruments reported in the Company's balance sheet in both inventory and property and equipment.

(b) Changes in Internal Control over Financial Reporting

Except as noted above, during the quarter ended September 30, 2018, there have been no changes to the Company's internal control over financial reporting 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, 2017, 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, 2017, except that the conditions and events that previously raised substantial doubt about our ability to continue as a going concern no longer exist. On June 4, 2018, we raised net proceeds of \$49.2 million through a public offering. During the nine months ended September 30, 2018, we also received a \$2.0 million milestone payment from a co-development partner and received 510(k) clearance for the marketing of T2Bacteria.

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 Fourth Amendment to Lease, dated August 31, 2018 (incorporated by referenced to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on September 7, 2018)
- 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, 2018, 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 1, 2018 By: /s/ JOHN MCDONOUGH
John McDonough
President, Chief Executive Officer and Director
(principal executive officer)

Date: November 1, 2018 By: /s/ JOHN SPRAGUE
John Sprague
Chief Financial Officer
(principal financial and accounting officer)