

T2 Biosystems, Inc.  
Form 10-Q  
August 02, 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 June 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

Emerging growth company

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

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

As of July 31, 2018, the registrant had 43,767,645 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 June 30, 2018 and December 31, 2017</u>	1
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for three and six months ended June 30, 2018 and 2017</u>	2
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 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)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$70,710	\$ 41,799
Accounts receivable	1,593	467
Prepaid expenses and other current assets	864	708
Inventories	2,158	1,344
Total current assets	75,325	44,318
Property and equipment, net	8,503	10,015
Restricted cash	180	260
Other assets	206	268
Total assets	\$84,214	\$ 54,861
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$1,152	\$ 648
Accrued expenses and other current liabilities	4,210	6,218
Derivative liability	—	2,238
Notes payable	3,771	40,696
Deferred revenue	925	1,736
Current portion of lease incentives	257	246
Total current liabilities	10,315	51,782
Notes payable, net of current portion	38,344	1,008
Lease incentives, net of current portion	614	731
Deferred revenue, net of current portion	117	—
Derivative liability	1,879	—
Other liabilities	962	—
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2018 and December 31, 2017	—	—

Common stock, \$0.001 par value; 200,000,000 shares authorized; 43,472,411 and 35,948,900 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	43	36
Additional paid-in capital	323,195	267,421
Accumulated deficit	(291,255)	(266,117 )
Total stockholders' equity	31,983	1,340
Total liabilities and stockholders' equity	\$84,214	\$ 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		Six Months Ended	
	June 30, 2018	2017	June 30, 2018	2017
<b>Revenue:</b>				
Product revenue	\$ 1,220	\$ 735	\$ 2,268	\$ 1,366
Research revenue	2,711	221	3,974	531
Total revenue	3,931	956	6,242	1,897
<b>Costs and expenses:</b>				
Cost of product revenue	3,458	1,989	6,731	3,617
Research and development	3,749	7,112	8,467	13,697
Selling, general and administrative	7,611	5,759	13,366	11,633
Total costs and expenses	14,818	14,860	28,564	28,947
Loss from operations	(10,887 )	(13,904 )	(22,322 )	(27,050 )
Interest expense, net	(1,506 )	(1,654 )	(3,074 )	(3,291 )
Other income, net	69	102	159	181
Net loss and comprehensive loss	\$(12,324 )	\$(15,456 )	\$(25,237 )	\$(30,160 )
Net loss per share — basic and diluted	\$(0.32 )	\$(0.50 )	\$(0.68 )	\$(0.99 )
Weighted-average number of common shares used in computing				
net loss per share — basic and diluted	38,263,486	30,661,200	37,127,208	30,595,933

See accompanying notes to condensed consolidated financial statements.

## T2 BIOSYSTEMS, INC.

## CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended	
	June 30, 2018	2017
Cash flows from operating activities		
Net loss	\$(25,237)	\$(30,160)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,224	1,432
Stock-based compensation expense	5,279	2,550
Change in fair value of derivative instrument	(359 )	—
Loss on sale of T2 owned equipment	—	107
Impairment of property and equipment	173	—
Non-cash interest expense	1,127	1,291
Deferred rent	(106 )	(74 )
Changes in operating assets and liabilities:		
Accounts receivable	(1,126 )	(654 )
Prepaid expenses and other assets	(94 )	225
Inventories	(12 )	(212 )
Accounts payable	524	698
Accrued expenses and other liabilities	(1,154 )	(230 )
Deferred revenue	(595 )	48
Net cash used in operating activities	(20,356)	(24,979)
Cash flows from investing activities		
Purchases and manufacture of property and equipment	(599 )	(2,468 )
Net cash used in investing activities	(599 )	(2,468 )
Cash flows from financing activities		
Proceeds from issuance of common stock and stock options exercises, net	1,123	713
Proceeds from issuance of common stock in public offering, net of offering costs	49,379	—
Principal repayments of note payable	(716 )	(620 )
Net cash provided by financing activities	49,786	93
Net increase (decrease) in cash, cash equivalents and restricted cash	28,831	(27,354)
Cash, cash equivalents and restricted cash at beginning of period	42,059	73,748
Cash, cash equivalents and restricted cash at end of period	\$70,890	\$46,394
Supplemental disclosures of cash flow information		
Cash paid for interest	\$1,930	\$1,981
Supplemental disclosures of noncash activities		
Transfer of T2 owned instruments and components to inventory	802	—
Accrued property and equipment	\$101	\$51



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 June 30, 2018, the Company had cash and cash equivalents of \$70.7 million and an accumulated deficit of \$291.3 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 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.

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 June 30, 2018, together with funding available under the Term Loan Agreement (as defined below), will be sufficient to allow the Company to fund its current operating plan through August

31, 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 three months ended June 30, 2018. On June 4, 2018, the Company raised net proceeds of \$49.4 million through its June 2018 public offering. During the quarter ended June 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, which was one of the conditions for borrowing an additional \$10.0 million against the Term Loan Agreement (the "Term Loan Agreement") with CRG Servicing LLC ("CRG") (Note 6), which is available at any time through September 27, 2018.

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. In addition, the Company is required to maintain a minimum cash balance under its Term Loan Agreement with CRG.

## 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 June 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 June 30, 2018, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2018 and 2017, the condensed consolidated statements of cash flows for the six months ended June 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 June 30, 2018, and the results of its operations and its cash flows for the three and six months ended June 30, 2018 and 2017. The results for the three and six months ended June 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.

## 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

5

---

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 June 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 six months ended was higher revenue of \$0.3 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 product sales, 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

6

---

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 consumable 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"). Warranty and 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 consolidated statements of operations and comprehensive loss, and is recognized over time using an input method as the work is completed, limited to payments earned. 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

We disaggregate our revenue from contracts with customers by type of products and services, as we believe 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,	Six months ended,
	June 30, 2018	June 30, 2018
<b>Product Revenue</b>		
Instruments	\$ 488	\$ 709
Consumables	575	1,321
Instrument Rentals	157	238
<b>Total Product Revenue</b>	<b>1,220</b>	<b>2,268</b>
Research Revenue	2,711	3,974
<b>Total Revenue</b>	<b>\$ 3,931</b>	<b>\$ 6,242</b>

## 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 June 30, 2018, the aggregate amount of transaction price allocated to remaining performance obligations for contracts with an original duration greater than one year was \$4.7 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 June 30, 2018, the Company has recorded \$0.2 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 June 30, 2018 and December 31, 2017, the Company had contract liabilities of \$0.8 million and \$1.7 million, respectively. Revenue recognized in the three and six months ended June 30, 2018 relating to contract liabilities at December 31, 2017 was \$0.4 million and \$1.7 million, respectively, and related to performance of research and development services and straight-line revenue recognition associated with maintenance agreements.

### 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 a contract 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 2016-15 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 applies to all leases. Under ASU 2016-02, a right-of-use asset and lease obligation will be recorded for all leases, whether operating or financing leases, while the statement of operations will present lease expense for operating leases and amortization and interest expense for financing leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 and interim periods within those years, which is the year ended December 31, 2019 for the Company. Entities are required to use a modified retrospective approach of adoption for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. Full retrospective application is prohibited. The Company is evaluating

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

#### 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 June 30, 2018 and December 31, 2017 (in thousands):

	Balance at June 30, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash	\$12,236	\$12,236	\$ —	\$ —
Money market funds	58,474	58,474	—	—
Restricted cash	180	180	—	—
	\$70,890	\$70,890	\$ —	\$ —
<b>Liabilities:</b>				
Derivative liability	\$1,879	\$—	\$ —	\$ 1,879
	\$1,879	\$—	\$ —	\$ 1,879

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

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 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, 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 June 30, 2018 is \$1.9 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	(359 )
Balance at June 30, 2018	\$1,879

#### 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 June 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 June 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):

	June 30,	December 31,
	2018	2017
Raw materials	\$ 779	\$ 539
Work-in-process	888	562
Finished goods	491	243
Total inventories, net	\$ 2,158	\$ 1,344

##### Property and Equipment

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



	June 30,	December 31,
	2018	2017
Office and computer equipment	\$409	\$ 409
Software	743	743
Laboratory equipment	4,429	4,224
Furniture	200	200
Manufacturing equipment	695	910
Manufacturing tooling and molds	576	255
T2-owned instruments and components	6,639	7,370
Leasehold improvements	3,437	3,437
Construction in progress	1,595	1,591
	18,723	19,139
Less accumulated depreciation and amortization	(10,220)	(9,124)
Property and equipment, net	\$8,503	\$ 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 June 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 June 30, 2018 and 2017 and \$0.5 million and \$0.4 million for the six months ended June 30, 2018 and 2017, respectively. Depreciation expense for T2-owned instruments used for internal research and development and clinical studies is recorded as a component of research and development expense. 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 three and six months ended June 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):

	June 30, December 31,	
	2018	2017
Accrued payroll and compensation	\$ 2,535	\$ 2,793
Accrued research and development expenses	348	818
Accrued professional services	638	1,018
Other accrued expenses	689	1,589
Total accrued expenses and other current liabilities	\$ 4,210	\$ 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 June 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):

June 30, December 31,	
2018	2017

Term loan agreement, net of deferred issuance costs of \$1.4 million and \$1.8 million, respectively	\$40,344	\$ 39,228
Equipment lease credit facility, net of deferred issuance cost of \$14 thousand and \$24 thousand, respectively	1,771	2,476
Total notes payable	42,115	41,704
Less: current portion of notes payable	(3,771 )	(40,696 )
Notes payable, net of current portion	\$38,344	\$ 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 June 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 may borrow up to an additional \$10.0 million at any time through and including July 27, 2018, provided that, among other conditions, the Company receives 510(k) clearance for the marketing of T2Bacteria by the FDA 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 non-current liability 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. The product revenue target for fiscal 2018 is \$7.0 million. At June 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.

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. 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 June 30, 2018 is \$1.9 million. The Company reclassified the derivative liability to non-current liabilities, at June 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 \$49.4 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 43,472,411 and 35,948,900 were outstanding as of June 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 June 30, 2018, there were 765,543 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 June 30, 2018, there were 319,000 shares available for future grant under the Inducement Plan.

#### Stock Options

During the six months ended June 30, 2018 and 2017, the Company granted stock options with an aggregate fair value of \$5.0 million and \$2.3 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	Weighted-Average	Remaining	Aggregate
	Shares	Exercise Price Per	Contractual Term	Intrinsic
		Share	(In years)	Value
Outstanding at December 31, 2017	3,785,083	\$ 7.31	6.88	\$ 1,989
Granted	1,422,750	5.61		
Exercised	(202,677 )	5.24		578
Forfeited	(568,056 )	6.46		
Cancelled	(83,121 )	13.73		
Outstanding at June 30, 2018	4,353,979	6.84	7.20	10,300
Exercisable at June 30, 2018	2,344,189	7.34	5.48	6,348
Vested or expected to vest at June 30, 2018	3,850,868	6.97	6.91	9,241



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

The weighted-average grant date fair values of stock options granted in the six month periods ended June 30, 2018 and 2017 were \$3.51 per share and \$3.11 per share, respectively, and were calculated using the following estimated assumptions:

	Six Months Ended June 30, 2018		2017	
Weighted-average risk-free interest rate	2.64%		1.99%	
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 six months ended June 30, 2018 and 2017 were \$1.5 million and \$2.0 million, respectively.

As of June 30, 2018, there was \$7.3 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 2.98 years as of June 30, 2018.

#### Restricted Stock Units

During the six months ended June 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 six months ended June 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 \$2.5 million and \$2.7 million for the three and six months ended June 30, 2018, respectively. During the three months ended June 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. The restricted stock units with market conditions that vested during the three months ended June 30, 2018 are not reflected as outstanding shares 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	(467,547 )	5.35
Forfeited	(66,284 )	5.66
Cancelled	—	—
Nonvested at June 30, 2018	1,289,856	5.01

During the six months ended June 30, 2018, 467,547 restricted stock units vested and 14,803 shares were withheld to cover employee tax. As of June 30, 2018, there was \$4.6 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 0.95 years, as of June 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		Six Months Ended	
	June 30, 2018	2017	June 30, 2018	2017
Cost of product revenue	\$198	\$36	\$219	\$65
Research and development	682	393	1,052	691
Selling, general and administrative	2,994	902	3,960	1,699
Total stock-based compensation expense	\$3,874	\$1,331	\$5,231	\$2,455

For the three months ended June 30, 2018 and 2017, \$0.0 million and \$0.1 million of stock-based compensation expenses were capitalized as part of inventory or T2Dx instruments and components, respectively. For the six months ended June 2018 and 2017, \$0.0 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 Six Months Ended	
	June 30, 2018	2017
Options to purchase common shares	4,353,979	4,006,148
Restricted stock units	1,289,856	597,220
Warrants to purchase common stock	528,958	528,958
Total	6,172,793	5,132,326

## 11. Co-Development Agreements

### Canon US Life Sciences

On September 21, 2016, Canon became a related party when the Company sold the Canon Shares for an aggregate cash purchase price of \$39.7 million, which represented 19.9% of the outstanding shares of common stock of the Company. On February 3, 2015, the Company entered into a Co-Development Partnership Agreement (the "Co-Development Agreement") with Canon U.S. Life Sciences, Inc. ("Canon US Life Sciences") to develop a diagnostic test panel to rapidly detect Lyme disease. Under the terms of the Co-Development Agreement, the Company received an upfront payment of \$2.0 million from Canon US Life Sciences, and the agreement includes an additional \$6.5 million of consideration upon achieving certain development and regulatory milestones for total aggregate payments of up to \$8.5 million. In October 2015 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).

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 \$1.3 million for the three months ended June 30, 2018 and did not record any revenue for the three months ended June 30, 2017. The Company recorded revenue of \$1.3 million and \$0.3 million during the six months ended June 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.

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 \$0.9 million and \$0.2 million for the three months ended June 30, 2018 and 2017, respectively, and \$2.2 million and \$0.2 million for the six months ended June 30, 2018 and 2017, respectively, under the Allergan Agreement. The Company expects to record revenue over the next six 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 \$0.5 million for the three and six months ended June 30, 2018 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 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.





## 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. Two additional diagnostic applications in development are called T2Resistance and T2Lyme, which are focused on bacterial sepsis infections and Lyme disease, respectively. 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 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 June 30, 2018 was \$291.3 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, T2 Bacteria, 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 June 30, 2018, together with funding available under the Term Loan Agreement with CRG, will be sufficient to allow us to fund our current operating plan through August 31, 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 three months ended June 30, 2018. On June 4, 2018, we raised net proceeds of \$49.4 million through our June 2018 public offering. During the quarter ended June 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, which was one of the conditions for borrowing an additional \$10.0 million against the Term Loan Agreement with CRG (Note 6), which is available at any time through September 27, 2018.

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, we are required to maintain a minimum cash balance under our Term Loan Agreement with CRG.

#### 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, or 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 incurrance 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