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, 2019

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001	TTOO	The Nasdaq Global Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☒		

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

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

As of July 25, 2019, the registrant had 44,535,572 shares of common stock outstanding.

T2 BIOSYSTEMS, INC.

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PART I.
FINANCIAL INFORMATION

Item 1. Financial Statements

T2 BIOSYSTEMS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 28,422	$ 50,805
Accounts receivable	1,179	1,786
Inventories	3,100	2,677
Prepaid expenses and other current assets	713	1,340
Total current assets	33,414	56,608
Property and equipment, net	7,262	7,315
Operating lease right-of-use assets	4,108	—
Restricted cash	180	180
Other assets	206	206
Total assets	$ 45,170	$ 64,309
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Notes payable	$ 42,885	$ 42,373
Accounts payable	2,911	744
Accrued expenses and other current liabilities	8,823	6,073
Derivative liability	2,503	2,142
Deferred revenue	677	697
Current portion of lease incentives	—	268
Total current liabilities	57,799	52,297
Lease incentives, net of current portion	—	492
Operating lease liabilities, net of current portion	2,893	—
Deferred revenue, net of current portion	98	133
Commitments and contingencies (see Note 13)		
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized; 44,535,572 and 44,175,441 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	44	44
Additional paid-in capital	332,301	328,514
Accumulated deficit	(347,965)	(317,171)
Total stockholders' (deficit) equity	(15,620)	11,387
Total liabilities and stockholders' (deficit) equity	$ 45,170	$ 64,309

See accompanying notes to condensed consolidated financial statements.

T2 BIOSYSTEMS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue:				
Product revenue	$ 1,274	$ 1,220	$ 2,588	$ 2,268
Research revenue	71	2,711	213	3,974
Contribution revenue	459	—	788	—
Total revenue	1,804	3,931	3,589	6,242
Costs and expenses:				
Cost of product revenue	4,820	3,458	9,208	6,731
Research and development	4,048	3,749	7,949	8,467
Selling, general and administrative	6,722	7,611	13,776	13,366
Total costs and expenses	15,590	14,818	30,933	28,564
Loss from operations	(13,786)	(10,887)	(27,344)	(22,322)
Interest expense, net	(2,000)	(1,506)	(3,782)	(3,074)
Other income, net	139	69	332	159
Net loss and comprehensive loss	$ (15,647)	$ (12,324)	$ (30,794)	$ (25,237)
Net loss per share — basic and diluted	$ (0.35)	$ (0.32)	$ (0.69)	$ (0.68)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	44,426,402	38,263,486	44,354,771	37,127,208

See accompanying notes to condensed consolidated financial statements.

T2 BIOSYSTEMS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders' (Deficit)
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2017	35,948,900	$ 36	$ 267,421	$ (266,117)	$ 1,340
Stock-based compensation expense	—	—	1,381	—	1,381
Issuance of common stock from vesting of restricted stock, exercise of stock options and employee stock purchase plan	70,983	—	5	—	5
Prior year accumulated deficit adjustment from ASC 606 implementation	—	—	—	99	99
Net loss	—	—	—	(12,913)	(12,913)
Balance at March 31, 2018	36,019,883	$ 36	$ 268,807	$ (278,931)	$ (10,088)
Stock-based compensation expense	—	—	3,898	—	3,898
Issuance of common stock from vesting of restricted stock, exercise of stock options and employee stock purchase plan	382,114	—	1,119	—	1,119
Share issuance	55,414	—	—	—	-
Issuance of common stock from secondary offering, net	7,015,000	7	49,371	—	49,378
Net loss	—	—	—	(12,324)	(12,324)
Balance at June 30, 2018	43,472,411	$ 43	$ 323,195	$ (291,255)	$ 31,983

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders' (Deficit)
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2018	44,175,441	$ 44	$ 328,514	$ (317,171)	$ 11,387
Stock-based compensation expense	—	—	2,033	—	2,033
Issuance of common stock from vesting of restricted stock	163,802	—	—	—	-
Change in fair value of warrants upon modification	—	—	147	—	147
Net loss	—	—	—	(15,147)	(15,147)
Balance at March 31, 2019	44,339,243	$ 44	$ 330,694	$ (332,318)	$ (1,580)
Stock-based compensation expense	—	—	1,277	—	1,277
Issuance of common stock from vesting of restricted stock, exercise of stock options and employee stock purchase plan	196,329	—	330	—	330
Net loss	—	—	—	(15,647)	(15,647)
Balance at June 30, 2019	44,535,572	$ 44	$ 332,301	$ (347,965)	$ (15,620)

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,	
	2019	2018
Cash flows from operating activities		
Net loss	$ (30,794)	$ (25,237)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,172	1,224
Amortization of operating lease right-of-use assets	697	—
Stock-based compensation expense	3,310	5,279
Change in fair value of derivative instrument	361	(359)
Loss on disposal of property and equipment	(3)	—
Impairment of property and equipment	—	173
Non-cash interest expense	1,154	1,127
Deferred rent	—	(106)
Changes in operating assets and liabilities:		
Accounts receivable	607	(1,126)
Prepaid expenses and other assets	627	(94)
Inventories	(882)	(12)
Accounts payable	2,017	524
Accrued expenses and other liabilities	1,211	(1,154)
Deferred revenue	(55)	(595)
Operating lease liabilities	(1,129)	—
Net cash used in operating activities	(21,707)	(20,356)
Cash flows from investing activities		
Purchases and manufacture of property and equipment	(444)	(599)
Net cash used in investing activities	(444)	(599)
Cash flows from financing activities		
Proceeds from issuance of common stock and stock option exercises, net	330	1,123
Proceeds from issuance of common stock in public offering, net of offering costs	—	49,379
Principal repayments of finance leases	(562)	(716)
Net cash (used in) provided by financing activities	(232)	49,786
Net (decrease) increase in cash, cash equivalents and restricted cash	(22,383)	28,831
Cash, cash equivalents and restricted cash at beginning of period	50,985	42,059
Cash, cash equivalents and restricted cash at end of period	$ 28,602	$ 70,890
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 2,267	$ 1,930
Supplemental disclosures of noncash activities		
Transfer of T2 owned instruments and components to (from) inventory	$ (459)	$ 802
Incremental fair value of warrant modification	$ 147	—
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 4,805	—
Purchases of property and equipment included in accounts payable and accrued expenses	$ 193	$ 101

See accompanying notes to condensed consolidated financial statements.

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, cerebral spinal fluid 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, 2019, the Company had cash and cash equivalents of $28.4 million and an accumulated deficit of $348.0 million. The future success of the Company is dependent on its ability to successfully commercialize its products, obtain regulatory clearance for and successfully launch its future product candidates, obtain additional capital and ultimately attain profitable operations. Historically, the Company has funded its operations primarily through its August 2014 initial public offering, its December 2015 public offering, its September 2016 private investment in public equity ("PIPE") financing, its September 2017 public offering, its June 2018 public offering, private placements of redeemable convertible preferred stock and debt financing arrangements.

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

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

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

Management believes that its existing cash and cash equivalents at June 30, 2019, along with funding available through our Equity Distribution Agreement (the "Sales Agreement") with Canaccord Genuity LLC, as agent ("Canaccord") and our Purchase

Agreement (the “Purchase Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”) (Note 7), will be sufficient to allow us to fund our current operating plan at least a year from issuance of these financial statements. However, because certain elements of our operating plan are outside of our control, including our ability to sell shares under the Sales Agreement and the Purchase Agreement, they cannot be considered probable. Under ASC 205-40, the future receipt of potential funding from the Company’s Co-Development partners and other resources cannot be considered probable at this time because none of the plans are 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 Servicing LLC (“CRG”) (Note 6).

These conditions raise substantial doubt regarding the Company’s ability to continue as a going concern for a period of one year after the date that the financial statements are issued. Management's plans to alleviate the conditions that raise substantial doubt include raising additional funding, earning milestone payments pursuant to the Company’s Co- Development agreements, delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels for the Company to continue as a going concern for a period of twelve months from the date the financial statements are issued. Management has concluded the likelihood that its plan to obtain sufficient funding from one or more of these sources or adequately reduce expenditures will be successful, while reasonably possible, is less than probable. Accordingly, the Company has concluded that substantial doubt exists 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 these condensed consolidated financial statements.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company’s financial statements have been prepared in conformity with accounting principles generally accepted 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.

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, 2018.

The accompanying interim condensed consolidated balance sheet as of June 30, 2019, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2019 and 2018, the condensed consolidated statements of stockholders’ equity (deficit) for the six months ended June 30, 2019 and 2018, the condensed consolidated statements of cash flows for the six months ended June 30, 2019 and 2018 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, 2019, and the results of its operations for the three and six months ended June 30, 2019 and 2018 and its cash flows for the six months ended June 30, 2019 and 2018. The results for the three and six months ended June 30, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019, 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.

Geographic Information

The Company sells its products domestically and internationally. For the three months ended June 30, 2019, there were no international customers that represented greater than 10% of total revenue. For the six months ended June 30, 2019, the Company derived approximately 10% of its total revenue from one international customer. For the three and six months ended June 30, 2018, there were no international customers that represented greater than 10% of total revenue. Total international sales were approximately $0.6 million or 31% of total revenue and $0.5 million or 12% of total revenue for the three months ended June 30, 2019 and 2018, respectively. Total international sales were approximately $1.2 million or 34% of total revenue and $0.8 million or 13% of total revenue for the six months ended June 30, 2019 and 2018, respectively.

As of June 30, 2019 and December 31, 2018, the Company had outstanding receivables of $0.5 million and $0.9 million, respectively, from customers located outside of the U.S.

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting the weighted-average number of shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, stock options and unvested restricted stock and restricted stock contingently issuable upon achievement of certain market conditions 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, 2019 and December 31, 2018, 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.

Leases

The Company adopted Topic 842, *Leases* ("ASC 842"), using the modified retrospective approach through a cumulative-effect adjustment and utilizing the effective date of January 1, 2019 as its date of initial application, with prior periods unchanged and presented in accordance with the previous guidance in Topic 840, *Leases* ("ASC 840").

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Most leases with a term greater than one year are recognized on the balance sheet as right-of-use

assets, lease liabilities and long-term lease liabilities. The Company has elected not to recognize on the balance sheet leases with terms of one year or less. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. However, certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued lease payments. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rates, which are the rates incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

In accordance with the guidance in ASC 842, components of a lease should be split into three categories: lease components (e.g. land, building, etc.), non-lease components (e.g. common area maintenance, consumables, etc.), and non-components (e.g. property taxes, insurance, etc.) Then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components.

The Company made the policy election to not separate lease and non-lease components. Each lease component and the related non-lease components are accounted for together as a single component.

Revenue Recognition

The Company generates revenue from the sale of instruments, consumable diagnostic tests, related services, reagent rental agreements and research and development agreements with third parties. Pursuant to ASC 606, *Revenue from Contracts with Customers* (“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. Excluded from the transaction price are sales tax and other similar taxes which are presented on a net basis.

Product revenue is generated by the sale of instruments and consumable diagnostic tests predominantly through the Company’s direct sales force in the United States and distributors in geographic regions outside the United States. The Company does not offer product return or exchange rights (other than those relating to defective goods under warranty) or price protection allowances to its customers, including its distributors. Payment terms granted to distributors are the same as those granted to end-user customers and payments are not dependent upon the distributors’ receipt of payment from their end-user customers. The Company either sells instruments to customers and international distributors, or retains title and places the instrument at the customer site pursuant to a reagent rental agreement. When an instrument is purchased by a customer, the Company recognizes revenue when the related performance obligation is satisfied (i.e. when the control of an instrument has passed to the customer; typically, at shipping point). When the instrument is placed under a reagent rental agreement, the Company’s customers generally agree to fixed term agreements, which can be extended, and incremental charges on each consumable diagnostic test purchased. Revenue from the sale of consumable diagnostic tests (under a reagent rental agreement) is recognized upon shipment. The transaction price from consumables purchases is allocated between the lease of the instrument (under a contingent rent methodology as provided for in ASC 842, *Leases*), and the consumables when related performance obligations are satisfied, as a component of lease and product revenue, and is included as Instrument Rentals in the below table. Revenue associated with reagent rental consumables purchases is currently classified as variable consideration and constrained until a purchase order is received and related performance obligations have been satisfied. Shipping and handling costs billed to customers in connection with a product sale are recorded as a component of the transaction price and allocated to product revenue in the consolidated statements of operations and comprehensive loss as they are incurred by the Company in fulfilling its performance obligations.

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

represent separate purchasing decisions. The Company recognizes revenue allocated to the extended Maintenance Services performance obligation on a straight-line basis over the service delivery period.

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

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

Grants received, including cost reimbursement agreements, are assessed to determine if the agreement should be accounted for as an exchange transaction or a contribution. An agreement is accounted for as a contribution if the resource provider does not receive commensurate value in return for the assets transferred. Contribution revenue is recognized when all donor-imposed conditions have been met.

Disaggregation of Revenue

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

	Three months ended, June 30,		Six months ended, June 30,	
	2019	2018	2019	2018
Product Revenue				
Instruments	$ 462	$ 488	$ 997	$ 709
Consumables	717	575	1,450	1,321
Instrument rentals	95	157	141	238
Total Product Revenue	1,274	1,220	2,588	2,268
Research Revenue	71	2,711	213	3,974
Contribution Revenue	459	—	788	—
Total Revenue	$ 1,804	$ 3,931	$ 3,589	$ 6,242

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, 2019, the aggregate amount of transaction price allocated to remaining performance obligations for contracts with an original duration greater than one year was $3.5 million, of which $3.0 million is constrained revenue. 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

The Company did not record any contract assets at June 30, 2019 and December 31, 2018.

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. Contract liabilities were $0.7 million at June 30, 2019 and $0.6 million at December 31, 2018. Revenue recognized in the three and six months ended June 30, 2019 relating to contract liabilities at December 31, 2018 was $0.1 million and $0.2 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 842. At the end of each reporting period, the Company assesses whether any circumstances have changed to meet the criteria for capitalization. The Company did not incur any expenses to obtain research and development agreements and costs to fulfill those contracts do not generate or enhance resources of the entity. As such, no costs to obtain or fulfill contracts have been capitalized at period end.

Cost of Product Revenue

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

Research and Development Costs

Costs incurred in the research and development of the Company's product candidates are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including activities associated with performing services under research revenue arrangements and contribution agreements, 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 February 2016, the FASB issued ASU 2016-02, Leases ("ASU 2016-02") in order to increase transparency and comparability among organizations by recognizing right-of-use assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous generally accepted accounting principles. ASU 2016-02 requires a lessee to recognize a lease liability for its future lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term on the balance sheet for most lease arrangements. The new standard also changes many key definitions, including the definition of a lease. The new standard includes a short-term lease exception for leases with a term of 12 months or less, as part of which a lessee can make an accounting policy election not to recognize right-of-use assets and lease liabilities. Lessees will continue to differentiate between finance leases (previously referred to as capital leases) and operating leases using classification criteria that are substantially similar to the previous guidance in ASC 840.

ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 (including interim periods within those periods) and early adoption is permitted. In August 2018, the FASB issued ASU 2018-11, *Leases, Targeted Improvements*, which provides a new transition option in which an entity initially applies ASU 2016-02 at the adoption date and recognizes a cumulative-effect adjustment in the period of adoption. Prior period comparative balances will not be adjusted. The Company used the new transition option and was also utilizing the package of practical expedients that allows it to not reassess: (1) whether any expired or existing contracts are or contain leases, (2) lease classification for any expired or existing leases, and (3) initial direct costs for any existing leases. We also used the short-term lease exception for leases with a term of twelve months or less. Additionally, the Company used the practical expedient that allowed each separate lease component of a contract and its associated non-lease components to be treated as a single lease component. As of the January 1, 2019 effective date the Company identified eight operating lease arrangements and two finance lease arrangements in which it is a lessee. The adoption of this standard resulted in the recognition of operating lease liabilities and right-of-use assets of $5.6 million and $4.8 million, respectively, on the Company's balance sheet, with the difference relating to a reclassification of the current accrued rent liability of $0.8 million as a reduction to the right-of-use-assets for its operating leases.

In calculating the present value of the lease payments, the Company applied an individual discount rate for each of its leases, and determined the appropriate discount rate based on the remaining lease terms at the date of adoption. As the lessee to several lease agreements, the Company did not have insight into the relevant information that would be required to arrive at the rate implicit in the lease. Therefore, the Company utilized its outstanding borrowings as a benchmark to determine its incremental borrowing rate for its leases. The benchmark rate was adjusted to arrive at an appropriate discount rate for each lease.

Under the new guidance, lessor accounting is largely unchanged. As of June 30, 2019, the Company was the lessor of T2Dx instruments. The lease agreements typically do not include fixed rental payments, but rather rental revenue is earned through usage-based variable lease payments. In accordance with ASC 842 the Company recognized lease revenue related to variable lease payments in the period in which it was earned. For the three and six months ended June 30, 2019, the Company recognized $0.1 million and $0.1 million, respectively, of lease revenue for instrument rentals.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation: Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"), which expands the scope of *Compensation – Stock Compensation* ("Topic 718") to include share-based payment transactions for acquiring goods and services from nonemployees. This amendment applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The Company adopted ASU 2018-07 on January 1, 2019. The impact was immaterial to the financial statements.

In June 2018, the FASB issued ASU No. 2018-08, *Not-For-Profit Entities – Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made* ("ASU 2018-08"). ASU 2018-18 clarifies how an entity determines whether a resource provider is participating in an exchange transaction by evaluating whether the resource provider is receiving commensurate value in return for the resources transferred. The guidance is effective for annual periods beginning after June 15, 2018, including interim periods within those annual periods, and has been adopted on a modified prospective basis. The modified prospective adoption is applied to agreements that are not completed as of the effective date, or entered into after the effective date. Under the modified prospective adoption approach, prior period results have not been restated and no cumulative-effect adjustment has been recorded. As a result of applying ASU 2018-18, the Company recorded revenue earned under its agreement with CARB-X (Note 11) as contribution revenue during the three and six months ended June 30, 2019.

Accounting Standards Issued, Not Adopted

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement* ("ASU 2018-13"), which eliminates, adds and modifies certain disclosure requirements for fair value measurements. The amendment is effective for interim and annual reporting periods beginning after December 15, 2019.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements* ("ASU 2018-18"), which clarifies the interaction between ASC 808, Collaborative Arrangements and ASC 606, Revenue from Contracts with Customers. Certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, ASU 2018-18 precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue if the counterparty is not a customer for that transaction. ASU 2018-18 should be applied retrospectively to the date of initial application of ASC 606. This guidance is effective for interim and fiscal periods beginning after December 15, 2019.

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, 2019 and December 31, 2018 (in thousands):

	Balance at June 30, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash	$ 14,181	$ 14,181	$ —	$ —
Money market funds	14,241	14,241	—	—
Restricted cash	180	180	—	—
	$ 28,602	$ 28,602	$ —	$ —
Liabilities:				
Derivative liability	$ 2,503	$ —	$ —	$ 2,503
	$ 2,503	$ —	$ —	$ 2,503

	Balance at December 31, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash	$ 6,868	$ 6,868	$ —	$ —
Money market funds	43,937	43,937	—	—
Restricted cash	180	180	—	—
	$ 50,985	$ 50,985	$ —	$ —
Liabilities:				
Derivative liability	$ 2,142	$ —	$ —	$ 2,142
	$ 2,142	$ —	$ —	$ 2,142

The Company's Term Loan Agreement with CRG (Note 6) contains certain provisions that change the underlying cash flows of the instrument, including 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.

In March 2019, the Term Loan Agreement was amended to reduce the 2019 minimum revenue target to $9.0 million and delete the 2018 revenue target. The fair value of the derivative at June 30, 2019 and December 31, 2018 is $2.5 million and $2.1 million, respectively. The estimated fair value of the derivative, at both dates, 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, 2018	$	2,142
Change in fair value of derivative liability, recorded as interest expense		361
Balance at June 30, 2019	$	2,503

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, 2019 and December 31, 2018, the Company had certificates of deposit for $180,000, which represented collateral as security deposits for its operating lease agreement for its facility and its credit cards.

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, 2019	December 31, 2018
Raw materials	$ 1,241	$ 639
Work-in-process	1,300	1,713
Finished goods	559	325
Total inventories, net	$ 3,100	$ 2,677

Property and Equipment

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

	June 30, 2019	December 31, 2018
Office and computer equipment	$ 409	$ 409
Software	762	751
Laboratory equipment	4,747	4,636
Furniture	194	200
Manufacturing equipment	695	695
Manufacturing tooling and molds	255	255
T2-owned instruments and components	7,483	6,796
Leasehold improvements	3,461	3,437
Construction in progress	1,589	1,443
	19,595	18,622
Less accumulated depreciation and amortization	(12,333)	(11,307)
Property and equipment, net	$ 7,262	$ 7,315

Construction in progress is primarily comprised of equipment 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, 2019, there were $1.0 million of raw materials and work-in-process inventory in T2-owned instruments and components compared to $0.3 million at December 31, 2018. 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, 2019 and 2018 and $0.4 million and $0.5 million for the six months ended June 30, 2019 and 2018, 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. Depreciation and amortization expense of $0.6 million was charged to operations for the three months ended June 30, 2019 and 2018 and $1.2 million for the six months ended June 30, 2019 and 2018. Included within property and equipment, net, are assets under finance leases. Total property and equipment, gross, included $3.6 million for property and equipment recorded under finance leases as of June 30, 2019 and December 31, 2018. Accumulated depreciation and amortization included $2.8 million and $2.6 million for property and equipment recorded under finance leases as of June 30, 2019 and December 31, 2018, respectively.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	June 30, 2019	December 31, 2018
Accrued payroll and compensation	$ 2,773	$ 2,940
Accrued research and development expenses	281	359
Accrued professional services	517	576
Operating lease liabilities	1,844	—
Other accrued expenses	3,408	2,198
Total accrued expenses and other current liabilities	$ 8,823	$ 6,073

At June 30, 2019 and December 31, 2018, the Company classified $1.9 million and $1.4 million, respectively, related to a fee associated with the Company's Term Loan Agreement (Note 6), as other accrued expenses in the table above to match the current classification of the associated debt.

6. Notes Payable

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

	June 30, 2019	December 31, 2018
Term loan agreement, net of deferred issuance costs of $1.4 million and $1.8 million, respectively	$ 42,426	$ 41,419
Equipment lease credit facility, net of immaterial deferred issuance costs	459	954
Total notes payable	42,885	42,373
Less: current portion of notes payable	(42,885)	(42,373)
Notes payable, net of current portion	$ —	$ —

The Term Loan Agreement with CRG is classified as a current liability on the balance sheet at June 30, 2019 and December 31, 2018 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 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. 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, which has a six-year term with four years of interest-only payments (through December 30, 2020), 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 11.5%, 3.5% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount. In addition, if the Company achieves certain financial performance metrics, the loan will convert to interest-only until the December 30, 2022 maturity, at which time all unpaid principal and accrued unpaid interest will be due and payable. The Company is required to pay CRG a financing fee based on the loan principal amount drawn. The Company is also required to pay a final payment fee of 8.0% of the principal outstanding upon repayment. The Company is accruing the final payment fee as interest expense and it is included as a current liability at June 30, 2019 and December 31, 2018 on the balance sheet.

The Company may prepay all or a portion of the outstanding principal and accrued unpaid interest under the Term Loan Agreement at any time upon prior notice subject to a certain prepayment fee during the first five years of the term and no prepayment fee thereafter. As security for its obligations under the Term Loan Agreement the Company entered into a security agreement with CRG whereby the Company granted a lien on substantially all of its assets, including intellectual property. The Term Loan Agreement also contains customary affirmative and negative covenants for a credit facility of this size and type, including a requirement to maintain a minimum cash balance. The Term Loan Agreement also requires the Company to achieve certain revenue targets, whereby the Company is required to pay double the amount of any shortfall as an acceleration of principal payments. In March 2019, the Term Loan Agreement was amended to reduce the 2019 minimum revenue target to $9.0 million and delete the 2018 revenue covenant. In exchange for the amendment, the Company agreed to reset the strike price of the warrants, issued in connection with the Term Loan Agreement, from $8.06 per share to $4.35 per share. The Term Loan Agreement includes a subjective acceleration clause whereby an event of default, including a material adverse change in the business, operations, or conditions (financial or otherwise), could result in the acceleration of the obligations under the Term Loan Agreement. Under certain circumstances, a default interest rate of an additional 4.0% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default. CRG has not exercised its right under this clause, as there have been no such events. The Company believes the likelihood of CRG exercising this right is remote.

The Company assessed the terms and features of the Term Loan Agreement, including the interest-only period and the acceleration of the obligations under the Term Loan Agreement under an event of default, in order to identify any potential embedded features that would require bifurcation. In addition, under certain circumstances, a default interest rate of an additional 4.0% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default, 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.

The fair value of the derivative at June 30, 2019 and December 31, 2018 is $2.5 million and $2.1 million, respectively. The Company classified the derivative liability as accrued expenses and other current liabilities on the balance sheet at June 30, 2019 and December 31, 2018 to match the classification of the related Term Loan Agreement.

In connection with the Term Loan Agreement entered into in December 2016, the Company issued to CRG warrants to purchase a total of 528,958 shares of the Company’s common stock (Note 9).

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 made 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 finance leases and are included in property and equipment on the balance sheet. The amortization of the assets conveyed under the Credit Facility is included as a component of depreciation expense.

7. Stockholders’ Equity

Equity Distribution Agreement

On July 30, 2019, the Company entered into the Sales Agreement with Canaccord, as agent, pursuant to which the Company may offer and sell shares of common stock, for aggregate gross sale proceeds of up to $30,000,000 from time to time through Canaccord.

Upon delivery of a placement notice based on the Company’s instructions and subject to the terms and conditions of the Sales Agreement, Canaccord may sell the shares by methods deemed to be an “at the market” offering, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, or by any other method permitted by law, including negotiated transactions, subject to the prior written consent of the Company. The Company is not obligated to make any sales of shares under the Sales Agreement. The Company or Canaccord may suspend or terminate the offering of shares upon notice to

the other party, subject to certain conditions. Canaccord will act as sales agent on a commercially reasonable efforts basis consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of Nasdaq.

The Company has agreed to pay Canaccord for its services of acting as agent 3% of the gross proceeds from the sale of the shares pursuant to the Sales Agreement. The Company has also agreed to provide Canaccord with customary indemnification for certain liabilities. At June 30, 2019, legal and accounting fees associated with the Sales Agreement were immaterial. Legal and accounting fees are expected to be reclassified to share capital upon issuance of shares under the Sales Agreement.

Purchase Agreement

On July 29, 2019, the Company entered into a $30,000,000 Purchase Agreement with Lincoln Park, pursuant to which the Company may sell and issue to Lincoln Park, and Lincoln Park is obligated to purchase, up to $30,000,000 in value of its shares of common stock from time to time over a 36-month period starting from the effective date of the respective registration statement.

The Company may direct Lincoln Park, at its sole discretion, and subject to certain conditions, to purchase up to 200,000 shares of common stock on any business day, provided that at least one business day has passed since the most recent purchase. The amount of a purchase may be increased under certain circumstances provided, however, that Lincoln Park's committed obligation under any single purchase shall not exceed $2,000,000. The purchase price of shares of common stock related to the future funding will be based on the then prevailing market prices of such shares at the time of sales as described in the Purchase Agreement.

Public Offering

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, resulting in net proceeds of $49.2 million after underwriters discount and expenses.

8. Stock-Based Compensation

Stock Incentive Plans

2006 Stock Incentive Plan

The Company's 2006 Stock Option Plan ("2006 Plan") was established for granting stock incentive awards to directors, officers, employees and consultants of the Company. Upon closing of the Company's IPO in August 2014, the Company ceased granting stock incentive awards under the 2006 Plan. The 2006 Plan provided for the grant of incentive and non-qualified stock options and restricted stock grants as determined by the Company's board of directors. Under the 2006 Plan, stock options were generally granted with exercise prices equal to or greater than the fair value of the common stock as determined by the board of directors, expired no later than 10 years from the date of grant, and vest over various periods not exceeding 4 years.

2014 Stock Incentive Plan

The Company's 2014 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, 2019, there were 1,394,529 shares available for future grant under the Stock Incentive Plans.

Inducement Award Plan

The Company's Amended and Restated Inducement Award Plan ("Inducement Plan"), which was adopted in March 2018 and amended and restated in February 2019, 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 1,625,000 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, 2019, there were 856,999 shares available for future grant under the Inducement Plan.

Stock Options

During the six months ended June 30, 2019 and 2018, the Company granted stock options with an aggregate fair value of $2.6 million and $5.0 million, respectively, which are being amortized into compensation expense over the vesting period of the options as the services are being provided.

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

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	4,241,833	$ 6.98	7.02	$ 471
Granted	1,335,250	2.99		
Exercised	—	—		—
Forfeited	(270,568)	5.42		
Cancelled	(38,419)	9.55		
Outstanding at June 30, 2019	5,268,096	6.03	7.11	19
Exercisable at June 30, 2019	2,832,083	7.52	5.37	—
Vested or expected to vest at June 30, 2019	4,711,775	6.26	6.85	17

The weighted-average grant date fair values of stock options granted in the six month periods ended June 30, 2019 and 2018 were $1.93 per share and $3.51 per share, respectively, and were calculated using the following estimated assumptions:

	Six Months Ended June 30,	
	2019	2018
Weighted-average risk-free interest rate	2.37%	2.64%
Expected dividend yield	—%	—%
Expected volatility	72%	68%
Expected terms	6.0 years	6.0 years

The total fair values of options that vested during the six months ended June 30, 2019 and 2018 were $1.7 million and $1.5 million, respectively.

As of June 30, 2019, there was $6.3 million of total unrecognized compensation cost related to non-vested stock options granted under the Stock Incentive Plans and Inducement Plan. 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 2.8 years as of June 30, 2019.

Restricted Stock Units

During the six months ended June 30, 2019, 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. As of December 31, 2018, 78,172 restricted stock units had vested but were not reflected as outstanding shares due to a deferred release date. These restricted stock units are reflected as outstanding shares at June 30, 2019. During the year ended December 31, 2018, an additional 73,172 restricted stock units vested but are not reflected as outstanding shares at June 30, 2019 and December 31, 2018 due to a deferred release date. The fair value of the restricted stock units, at the time of the grant, is expensed on a straight line basis. The granted restricted stock units had an aggregate fair value of $1.9 million, which are being amortized into compensation expense over the vesting period of the restricted stock units as the services are being provided.

Included in the nonvested restricted stock units at June 30, 2019 are 791,247 restricted stock units with market conditions, which vest upon the achievement of stock price targets. The compensation cost for restricted stock units with market conditions is being recorded over the derived service period and was $0.2 million and $2.5 million for the three months ended June 30, 2019 and 2018, respectively, and $0.9 million and $2.7 million for the six months ended June 30, 2019 and 2018, respectively.

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

	Number of Shares	Weighted-Average Grant Date Fair Value
Nonvested at December 31, 2018	1,198,634	5.04
Granted	589,142	3.23
Vested	(139,629)	6.84
Forfeited	(212,560)	4.47
Cancelled	—	—
Nonvested at June 30, 2019	1,435,587	4.21

As of June 30, 2019, there was $2.1 million of total unrecognized compensation cost related to nonvested restricted stock units granted under the 2014 Plan. 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 2.0 years, as of June 30, 2019.

Stock-Based Compensation Expense

The following table summarizes the stock-based compensation expense resulting from awards granted under Stock Incentive Plans, including the Inducement Plan and 2014 ESPP, that was recorded in the Company's results of operations for the periods presented (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Cost of product revenue	$ —	$ 198	$ 49	$ 219
Research and development	436	682	831	1,052
Selling, general and administrative	848	2,994	2,353	3,960
Total stock-based compensation expense	$ 1,284	$ 3,874	$ 3,233	$ 5,231

For the three months ended June 30, 2019 and 2018, stock-based compensation expenses capitalized as part of inventory or T2Dx instruments and components, respectively, were immaterial. For the six months ended June 30, 2019 and 2018, $0.1 million and $0.0 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 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 $4.35 per share, which was amended in March 2019 from an original 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 amended warrants was

$0.9 million. The incremental fair value of the modified instrument of $0.1 million was recorded as debt discount and additional paid-in-capital.

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,	
	2019	2018
Options to purchase common shares	5,268,096	4,353,979
Restricted stock units	1,435,587	1,289,856
Warrants to purchase common stock	528,958	528,958
Total	7,232,641	6,172,793

11. Co-Development Agreements

Canon US Life Sciences

On February 3, 2015, the Company entered into a Co-Development Partnership Agreement (the "Co-Development Agreement") with Canon U.S. Life Sciences, Inc. ("Canon US Life Sciences") to develop a diagnostic test panel to rapidly detect Lyme disease. 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.

Under the Co-Development Agreement, the Company recorded revenue of $0.1 million and $1.3 million for the three months ended June 30, 2019 and 2018, respectively. The Company recorded revenue of $0.1 million and $1.3 million during the six months ended June 30, 2019 and 2018, respectively. The Company expects to record revenue over the next seven months.

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 T2Candida, T2Bacteria, and the Developed Products under the Allergan Agreement to certain agreed-upon customers. The Company achieved the final developmental milestone under the Allergan Agreement in October 2018.

The Company did not record any revenue for the three and six months ended June 30, 2019 and recorded revenue of $0.9 million and $2.2 million for the three and six months ended June 30, 2018, respectively, under the Allergan Agreement.

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. In January 2019, the Company was awarded the $0.9 million reimbursement option.

The Company recorded revenue of $0.5 million for the three months ended June 30, 2019 and 2018, respectively, under the CARB-X Agreement. The Company recorded revenue of $0.8 million and $0.5 million for the six months ended June 30, 2019 and 2018, respectively, under the CARB-X Agreement. The Company recorded CARB-X revenue as contribution revenue in 2019 upon

adoption of a new accounting standard and research revenue in 2018. The Company expects to record revenue over the next three months, based upon cost-sharing and the achievement of certain project milestones.

12. Leases

Operating Leases

The Company leases certain office space, laboratory space, and equipment. At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. The Company does not recognize right-of-use assets or lease liabilities for leases determined to have a term of 12 months or less. For new and amended leases beginning in 2019 and after, the Company has elected to account for the lease and non-lease components as a combined lease component.

In August 2010, the Company entered into an operating lease for office and laboratory space at its headquarters in Lexington, Massachusetts. The lease commenced in January 2011, with the Company providing a security deposit of $400,000. In accordance with the operating lease agreement, the Company reduced its security deposit to $180,000 in January 2018, which is recorded as restricted cash in the consolidated balance sheets. In March 2017, the Company entered into an amendment to extend the term to December 2021.

In May 2013, the Company entered into an operating lease for additional office, laboratory and manufacturing space in Wilmington, Massachusetts. In August 2018, the Company entered into an amendment to extend the term to December 2020.
In November 2014, the Company entered into an agreement to rent additional office space in Lexington, Massachusetts. In April 2015, the Company entered into an amendment to extend the term to December 31, 2017. In connection with this agreement, the Company paid a security deposit of $50,000, which is recorded as a component of other assets in the consolidated balance sheets. In May 2015, the Company entered into an amendment to expand existing manufacturing facilities in Lexington, Massachusetts. In September 2017, the Company entered into an amendment to extend the term to December 31, 2021.

In November 2014, the Company entered into a lease for additional laboratory space in Lexington, Massachusetts. The lease term commenced in April 2015 and extended for six years. The rent expense, inclusive of the escalating rent payments, is recognized on a straight-line basis over the lease term. As an incentive to enter into the lease, the landlord paid approximately $1.4 million of the $2.2 million space build-out costs. Prior to the adoption of ASC 842, the incentive was recorded as a component of lease incentives on the consolidated balance sheets and was amortized as a reduction in rent expense on a straight-line basis over the term of the lease. Upon adoption of the new standard the unamortized balance of the lease incentive as of January 1, 2019 was reclassed as a reduction to the initial recognition of the right-of-use asset related to this lease. In connection with this lease agreement, the Company paid a security deposit of $281,000, which is recorded as a component of both prepaid expenses and other current assets and other assets in the consolidated balance sheets.

Operating leases are amortized over the lease term and included in costs and expenses in the condensed consolidated statement of operations and comprehensive loss. Variable lease costs are recognized in costs and expenses in the condensed consolidated statement of operations and comprehensive loss as incurred.

Finance Leases

In October 2015, the Company signed a $10.0 million Credit Facility (the “Credit Facility”) to fund capital equipment needs. As one of the conditions of the agreement, the Credit Facility is capped at a maximum of $5.0 million. Under the Credit Facility, the lender 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 made 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 finance leases and are included in property and equipment on the balance sheet. The amortization of the assets conveyed under the Credit Facility is included as a component of depreciation expense.

The following table summarizes the effect of operating and finance lease costs in the Company's condensed consolidated statement of operations and comprehensive loss (in thousands):

Lease cost	Three months ended June 30, 2019	Six months ended June 30, 2019
Finance lease cost:		
Amortization of right-of-use assets	$ 118	$ 234
Interest on lease liabilities	9	36
Operating lease cost	499	998
Variable lease cost	148	320
Total lease cost	$ 774	$ 1,588

The following table summarizes supplemental information for the Company's finance and operating leases:

Other information	Six months ended June 30, 2019
Weighted-average remaining lease term - finance leases (in years)	—
Weighted-average remaining lease term - operating leases (in years)	2.4
Weighted-average discount rate - finance leases	—
Weighted-average discount rate - operating leases	11.9%

The minimum lease payments for the next five years and thereafter is expected to be as follows (in thousands):

	June 30, 2019	
Maturity of lease liabilities	Operating Leases	Finance Leases
2019 (excluding the 6 months ended June 30, 2019)	$ 1,131	$ 459
2020	2,313	—
2021	1,951	—
2022	23	—
2023	—	—
Thereafter	—	—
Total lease payments	$ 5,418	$ 459
Less: effect of discounting	(681)	—
Present value of lease liabilities	$ 4,737	$ 459

The following table summarizes the presentation of the Company's operating leases in its condensed consolidated balance sheets (in thousands):

Leases	Classification	June 30, 2019
Assets		
Operating lease assets	Operating lease assets	$ 4,108
Finance lease assets	Property and equipment, net	761
Total lease assets		$ 4,869
Liabilities		
Current		
Operating	Accrued expenses and other current liabilities	$ 1,844
Finance	Notes payable	459
Noncurrent		
Operating	Noncurrent operating lease liabilities	2,893
Finance	Notes payable, net of current portion	—
Total lease liabilities		$ 5,196

Under ASC 840, future minimum non-cancelable lease payments under the Company's operating leases as of December 31, 2018 were as follows (in thousands):

Year ended December 31,	
2019	$ 2,225
2020	2,277
2021	1,926
	$ 6,428

Under ASC 840, rent expense for the years ended December 31, 2018, and 2017 was $2.0 million, and $1.9 million, respectively.

13. Commitments and Contingencies

Leases

Refer to Note 12, Leases, for discussion of the commitments associated with the Company's leases.

License Agreement

In 2006, the Company entered into a license agreement with a third party, pursuant to which the third party granted the Company an exclusive, worldwide, sublicenseable license under certain patent rights to make, use, import and commercialize products and processes for diagnostic, industrial and research and development purposes. The Company agreed to pay an annual license fee ranging from $5,000 to $25,000 for the royalty-bearing license to certain patents. The Company also issued a total of 84,678 shares of common stock pursuant to the agreement in 2006 and 2007, which were recorded at fair value at the date of issuance. The Company is required to pay royalties on net sales of products and processes that are covered by patent rights licensed under the agreement at a percentage ranging between 0.5% - 3.5%, subject to reductions and offsets in certain circumstances, as well as a royalty on net sales of products that the Company sublicenses at 10% of specified gross revenue. Royalties for the six months ended June 30, 2019 and 2018 were immaterial.

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, reimbursement for our product candidates, research and development costs, timing of regulatory filings, timing and likelihood of success, plans and objectives of management for future operations, availability of funding for such operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described under the sections in this Quarterly Report on Form 10-Q entitled "Item 1A.—Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Quarterly Report on Form 10-Q. These forward looking statements are subject to numerous risks, including, without limitation, the following:

- *our status as an early stage company;*
- *our expectation to incur losses in the future;*

- *the market acceptance of our T2MR technology;*
- *our ability to timely and successfully develop and commercialize our existing products and future product candidates;*
- *the length and variability of our anticipated sales and adoption 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;*
- *impacts of and delays caused by future federal government shutdowns;*
- *federal, state, and foreign regulatory requirements, including diagnostic product reimbursements and 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;*
- *the impact of short sellers on our share price;*
- *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, 2018, 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 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, cerebral spinal fluid 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 and T2Candida, which have the ability to rapidly identify the five clinically relevant species of *Candida*, a fungal pathogen known to cause sepsis, directly from whole blood. On May 24, 2018, we received market clearance from the FDA for T2Bacteria, which runs on the T2Dx Instrument and has the ability to rapidly identify five of the most common and deadly sepsis-causing bacteria (members of the ESKAPE pathogens, as defined in *Our T2Bacteria Panel*) directly from whole blood. We have also developed and sell a research use only *Candida auris* assay for the rapid identification of *Candida auris*, a species of *Candida* that is highly drug resistant. We have developed a T2Resistance Panel for the early and sensitive detection of carbapenemase resistance markers and multiple hospitals are testing this new panel on a "research use only" basis. The T2Resistance Panel received FDA Breakthrough Device designation in February 2019 and we believe this designation will speed our clinical trial. An additional diagnostic application in development is called T2Lyme, which is focused on the detection of the bacteria that cause Lyme disease. Diagnostic applications for additional bacteria species and resistance markers are in development as part of a collaboration with CARB-X, a public-private partnership with the U.S. Department of Health and Human Services, or HHS, and the Wellcome Trust of London, focused on combatting antibiotic resistant bacteria. We anticipate 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. 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.

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. The speed to result of T2Candida and T2Bacteria coupled with its higher sensitivity as compared to blood culture may help reduce the overuse of ineffective, or even unnecessary, antimicrobial therapy which may reduce side effects for patients, lower hospital costs and potentially counteract the growing resistance to antifungal therapy. The administration of inappropriate therapy is a driving force behind the spread of antimicrobial-resistant pathogens, which the United States Centers for Disease Control and Prevention, or the CDC, recently called "one of our most serious health threats." The addition of the use of our products, T2Bacteria and T2Candida, which both run on the T2Dx instrument, with the standard of care for the management of patients suspected of sepsis, enables clinicians to potentially treat 90% of patients with sepsis pathogen infections with the right targeted therapy within the first twelve hours of development of the symptoms of disease. Currently, high risk patients are typically initially treated with broad spectrum antibiotic drugs that typically cover approximately 60% of patients with infections. Of the remaining 40% of patients, approximately 30% of the patients typically have a bacterial infection and 10% typically have *Candida* infections. T2Candida and T2Bacteria are designed to identify pathogens commonly not covered by broad spectrum antibiotic drugs.

We compete with traditional blood culture-based diagnostic companies, including Becton Dickinson & Co. and bioMerieux, Inc., as well as companies offering post-culture species identification using both molecular and non-molecular methods, including bioMerieux, Inc. (and its affiliate, BioFire Diagnostics, Inc.), Bruker Corporation, Accelerate Diagnostics, Luminex, Genmark, Cepheid and Beckman Coulter, a Danaher company. In addition, there may be a number of new market entrants in the process of developing other post-blood culture diagnostic technologies that may be perceived as competitive with our technology. Karius, Inc. offers a lab developed culture independent diagnostic test for the identification of pathogens that has not been cleared by the FDA but may be perceived as competitive with our technology.

We have never been profitable and have incurred net losses in each year since inception. Our accumulated deficit at June 30, 2019 was $348.0 million. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations. We have incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution of our initial FDA-cleared products, T2Dx and T2Candida. In addition, we will continue to incur significant costs and expenses as we increase commercialization efforts for our most recent FDA-cleared product, T2Bacteria, and continue to develop other product candidates, improve existing products and maintain, expand and protect our intellectual property portfolio. We may seek to fund our operations through public equity or private equity or debt financings, as well as other sources. However, we may be unable to raise additional funds or enter into such

other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on our business, results of operations and financial condition and our ability to develop, commercialize and drive adoption of the T2Dx, T2Candida, T2Bacteria, and future T2MR-based diagnostics.

Pursuant to the requirements of Accounting Standards Codification (ASC) 205-40, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about our 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, 2019, along with funding available through our Sales Agreement with Canaccord and Purchase Agreement with Lincoln Park (Note 7), will be sufficient to allow us to fund our current operating plan at least a year from the issuance of these financial statements. However, because certain elements of our operating plan are outside of our control, including our ability to sell shares under the Sales Agreement and the Purchase Agreement, they cannot be considered probable according to accounting standards. Under ASC 205-40, the future receipt of potential funding from our Co-Development partners and other resources cannot be considered probable at this time because none of the plans are entirely within our control. In addition, we are required to maintain a minimum cash balance under our Term Loan Agreement with CRG (Note 6).

These conditions raise substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that the financial statements are issued. Management's plans to alleviate the conditions, should it be necessary, include raising additional funding, earning milestone payments pursuant to our Co- Development agreements, delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels to continue as a going concern for a period of 12 months from the date the financial statements are issued. Management has concluded the likelihood that its plan to obtain sufficient funding from one or more of these sources or adequately reduce expenditures will be successful, while reasonably possible, is less than probable.

Our Commercial Products and the Unmet Clinical Need

The T2Direct Diagnostics portfolio, including all current products utilizing T2MR technology that run on the T2Dx instrument, represent the only FDA-cleared products that detect and identify sepsis-causing bacterial and fungal pathogens directly from whole blood, without the need for blood culture. All other FDA-cleared products must wait for cells to divide in blood culture to achieve cell titer levels of greater than 1,000,000 CFU/mL. In contrast, the T2Direct Diagnostic products detect pathogens directly as they exist in blood, with limits of detection of 1 to 11 CFU/mL. The result is at least two days faster in time to pathogen identification, as demonstrated by two clinical trials, each including greater than 1,400 patients in addition to many clinical cases and independent studies.

The current standard of care is to treat patients suspected of a bloodstream infection using empiric antimicrobial therapy without diagnostic evidence, and then to revise therapy when diagnostic evidence is available. But as demonstrated by a meta-analysis of 70 studies, the proportion of infected patients receive effective therapy by the empiric approach is only 53.5%. However, the proportion of patients placed on effective therapy after receiving a diagnostic species identification from a blood sample is greater than 95%. We believe this is the principal value of T2Direct Diagnostics, to increase the proportion of patients on effective therapy from 55% to 95% within three to five hours, instead of days.

The benefits to clinical care outcomes from faster time to effective therapy include a reduction in average patient length of stay within a hospital, increased hospital cost savings, and reduced mortality. Across three interventional studies, the mean ratio of length of stay reduction to time to effective therapy was 2.7 hours. In other words, for every one hour faster time to effective therapy, patient length of stay was reduced by 2.7 hours. The mean reduction in length of stay from early effective therapy in these studies was up to eight days and an independent economic analysis found a $1,149 cost savings per patient tested with the T2Candida Panel. An independent economic review also found rapid, direct-from-blood diagnostics result in cost savings when sensitivity is greater than 52%, the cost of the test is less than $270, and results are returned within two to seven hours. All of these requirements are met by the T2Direct Diagnostic panels. Additionally, in septic shock patients, every hour delaying effective antimicrobial therapy decreases survival by an estimated 7.6%. In 111,816 patients given a New York State mandated sepsis bundle, the relative probability of death increased by four percent for every hour delay in the administration of effective therapy. In a retrospective analysis of 70 studies,

compared to patients given an appropriate empiric antimicrobial therapy, patients given inappropriate empiric antimicrobials showed over two-times higher probability of death. Taken together, T2Direct Diagnostics allow for a reduction in time to effective therapy by multiple days, which are realized as patient and hospital benefits in reduced length of stay, cost of care, and mortality.

Our FDA-cleared products, the T2Dx instrument, T2Candida, and T2Bacteria utilize T2MR to detect species-specific sepsis-causing bacterial and fungal pathogens, directly from whole blood in as few as three hours versus the one to five 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. T2Candida and T2Bacteria run on the T2Dx Instrument 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 HHS for 2017, the cost of sepsis was over $27 billion in the United States, building on previous data demonstrating that sepsis was responsible for approximately five percent of the total aggregate costs associated with domestic hospital stays. Sepsis is typically caused by one or more of five *Candida* species or over 25 bacterial pathogens, and effective treatment requires the early detection and identification of these specific target pathogens in a patient's bloodstream. Today, sepsis is typically diagnosed through a series of blood cultures followed by post-blood culture species identification. These methods have substantial diagnostic limitations that lead to a high rate of false negative test results, a delay of up to several days in administration of targeted treatment and the incurrence of unnecessary hospital expense. In addition, the Survey of Physicians' Perspectives and Knowledge About Diagnostic Tests for Bloodstream Infections in 2015 reported that negative blood culture results are only trusted by 36% of those physicians. Without the ability to rapidly identify pathogens, physicians typically start treatment of at-risk patients with broad-spectrum antibiotics, which can be ineffective and unnecessary and have contributed to the spread of antimicrobial resistance. According to a study published by Critical Care Medicine in 2006, in sepsis patients with documented hypotension, administration of effective antimicrobial therapy within the first hour of detection was associated with a survival rate of 79.9% and, over the ensuing six hours, each hour of delay in initiation of treatment was associated with an average decrease in survival of 7.6%.

We believe our sepsis products, which include T2Candida and T2Bacteria and the T2Resistance Panel product candidate, will redefine the standard of care in sepsis management while lowering healthcare costs by improving both the precision and the speed of detection of sepsis-causing pathogens. According to a study published in the Journal of Clinical Microbiology in 2010, targeted therapy for patients with bloodstream infections can be delayed up to 72 hours due to the wait time for blood culture results. In another study published in Clinical Infectious Diseases in 2012, the delayed administration of appropriate antifungal therapy was associated with higher mortality among patients with septic shock attributed to *Candida* infection and, on that basis, the study concluded that more rapid and accurate diagnostic techniques are needed. Our pivotal clinical trial for T2Candida demonstrated that it can deliver actionable results in as few as three hours, with an average time to result during the trial of 4.2 hours, compared to the average time to result of one to six or more days typically required for blood-culture-based diagnostics, which we believe will potentially enable physicians to make treatment decisions and administer targeted treatment to patients in four to six hours versus 24 to 144 hours for blood culture.

Data from our pivotal clinical trial for T2Bacteria, which was recently published in the Annals of Internal Medicine, demonstrated that T2Bacteria can deliver actionable results in an average of 5.4 hours, compared to an average of 60 hours for detecting the same species by blood culture. In addition, T2Bacteria identified 69 patients with bloodstream infections that were missed by the paired blood culture that was simultaneously run. The pivotal study was a study of over 1,400 patient samples collected across 11 hospital and hospital systems across the United States. The investigators concluded the following: (a) T2Bacteria demonstrated accuracy, including overall sensitivity of 90% and overall average specificity of 98%; (b) blood culture species identification results took an average of 3 days while T2Bacteria took an average of only 5.4 hours in the clinical trial, providing results more than 2.5 days faster; (c) 66% of patients in the clinical trial with a bloodstream infection confirmed by T2 and blood culture could have benefited from earlier appropriate antibiotics based on the rapid T2Bacteria result. A separate presentation on T2Bacteria at ASM Microbe 2018 by clinicians at Ochsner Medical Center found the following: (a) T2Bacteria detected 14 infections missed by a paired blood culture – but proven to be a true infection by other cultures; (b) T2Bacteria identified every infection detected by blood culture of the target species (100% sensitivity); and (c) T2Bacteria was accurate in identifying samples without an infection, with 99% average specificity. The authors concluded that the advantages of T2Bacteria over blood culture could make it a valuable tool to enable faster time to targeted antibiotic therapy and reduced use of unnecessary antibiotics. Also at ASM Microbe 2018, clinicians from Northwestern University presented its findings that T2Bacteria was more sensitive when compared to blood culture testing and detected 18 clinically important urinary and respiratory infections that were missed by blood culture. The authors concluded that T2Bacteria may improve patient care by providing clinicians rapid and actionable information for treating patients. In November 2015, the Company presented preliminary data demonstrating the ability of our T2Bacteria product candidate to provide the rapid and sensitive identification of certain sepsis-causing bacteria included in the panel, directly from whole blood. The

bacteria species included in T2Bacteria are *Staphylococcus aureus, Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, and Pseudomonas aeruginosa*. The five bacteria species in our T2Bacteria Panel are responsible for about half of all septic infections.

At the 2019 ECCMID conference, several clinical presentations were made on our products. These include a poster and podium presentation by Dr. Tom Walsh from New York Presbyterian / Cornell Hospital highlighting the clinical utility of T2Bacteria in the hematologic malignancy and stem cell transplant patient population. Within his institution, T2Bacteria showed a 75% positive predictive agreement with blood culture and 98% negative predictive agreement and covered 80% of significant species detected by blood culture. T2Bacteria could have potentially influenced care and provided an opportunity to place patients with infections that were diagnosed by T2Bacteria but missed by blood culture on effective therapy faster than with culture dependent methods. Another study presented by Maiken Arendrup from Rigshospitalet, Denmark evaluated the performance of T2Candida, Mannan Ag and blood culture for diagnosis of invasive candidiasis infections across 126 patients. The sensitivity for invasive candidiasis was higher for T2Candida compared to blood culture and Mannan Ag and the positive predictive value was highest for T2Candida. A group from Bambino Gesu Pediatrics Hospital in Rome, Italy presented a comparison of T2Candida, SeptiFast and blood culture in pediatric and neonatal patients showing an 89% concordance between blood culture and T2MR. Data were also presented on the new T2Carba Resistance+ Panel (for research use only or "RUO") by clinicians at Gemelli Hospital in Rome Italy and by scientists from our company. This data shows that T2MR can be used for detection of resistance genes KPC, NDM, OXA-48, VIM, IMP, and AmpC (CMY-2/DHA) in spiked human whole blood at 5 CFU/mL, as well as in clinical samples from patients with bloodstream infections. The clinical data shows that T2MR results for resistance markers can be available on average 25 hours faster than conventional methods and the T2Carba Resistance Panel has a positive predictive agreement with conventional methods greater than 95%.

There are currently eight interventional studies ongoing and four interventional studies scheduled to begin this year, as well as many observational studies ongoing that are evaluating the clinical impact of our tests. In total, we have over two dozen investigator-initiated clinical studies currently running on our direct-from-blood tests for the purposes of demonstrating their clinical utility.

Our T2Candida Panel

Candida is the fourth leading hospital-acquired bloodstream infection, afflicting more than 135,000 patients per year in the United States, and the most lethal form of common bloodstream infections that cause sepsis, with an average mortality rate of approximately 40%. This high mortality rate is largely due to a delay in providing targeted therapy to the patient due to the elapsed time from *Candida* infection to positive diagnosis. According to a study published in Antimicrobial Agents and Chemotherapy, the *Candida* mortality rate can be reduced to 11% with the initiation of targeted therapy within 12 hours of presentation of symptoms. Additionally, a typical patient with a *Candida* infection averages 40 days in the hospital, including nine days in intensive care, resulting in an average cost per hospital stay of more than $130,000 per patient. In a study published in the American Journal of Respiratory and Critical Care Medicine, providing targeted antifungal therapy within 24 hours of the presentation of symptoms decreased the length of hospital stay by approximately ten days and decreased the average cost of care by approximately $30,000 per patient.

Our DIRECT pivotal clinical trial was designed to evaluate the sensitivity and specificity of T2Candida on the T2Dx instrument. The DIRECT trial consisted of two patient arms: a prospective arm with 1,501 samples from patients with a possible infection and a seeded arm with 300 samples, also obtained from patients with a possible infection. T2Candida and the T2Dx instrument demonstrated a sensitivity of 91.1 percent and a specificity of 99.4 percent. In addition, the speed to a species-specific positive result with T2Candida was 4.4 hours versus 129 hours with blood culture. A negative result from T2Candida was obtained in just 4.2 hours versus greater than 120 hours with blood culture. The data and other information from the DIRECT pivotal clinical trial was published in January 2015 in Clinical Infectious Diseases.

In April 2015, Future Microbiology published the results of an economic study regarding the use of T2Candida conducted by IMS Health, a healthcare economics company. In that economic study, IMS demonstrated that an average hospital admitting 5,100 patients at risk for *Candida* infections could save approximately $5.8 million annually due to decreased hospital stays for patients, reduction in use of antifungal drugs, and other associated savings. The economic study further showed T2Candida can potentially reduce the costs of care by $26,887 per *Candida* patient and that rapid detection of *Candida* reduces patient deaths by 60.6%. Results from a data analysis of T2Candida for the detection and monitoring of *Candida* infection and sepsis were published comparing aggregated results from the use of T2Candida to blood culture-based diagnostics for the detection of invasive candidiasis and candidemia. The analysis included samples acquired from more than 1,900 patients. Out of 55 prospective patient cases that were tested with T2Candida and blood culture and determined to be positive or likely to be positive for a *Candida* infection, T2Candida detected 96.4% of the patients (53 cases) compared to detection of 60% of the patients (33 cases) with blood culture. During 2016, a number of T2Candida users presented data on their experiences with T2Candida which demonstrated both the clinical and economic benefits of use of T2Candida in the diagnostic regimen. The Henry Ford Health System in Detroit, Michigan reported data on a pre- and post-T2Candida implementation analysis that covered 6 months of clinical experience. The data showed a statistically significant ($p = 0.009$) seven day reduction in median Intensive Care Unit ("ICU") length of stay per positive patient that was identified as

positive for *Candida* after implementation of T2Candida and a trend (p = 0.164) of total hospital length of stay reduction of four days. The data also showed significant reductions in use of antifungal drugs for negative patients tested with T2Candida. The overall economic savings resulting from these clinical benefits was projected to be approximately $2.3 million on an annualized basis. The Lee Health System in Fort Myers, Florida compared patient and economic experience before and after T2Candida implementation. The data demonstrated that in the post-T2Candida cohort, median length of stay for patients with *Candida* infections was reduced by 7 days when detected by T2Candida while unnecessary antifungal therapy was avoided in 41% of patients tested and was discontinued after one dose in another 15% of patients tested. The average economic savings derived solely from reduction in antifungal drug use was $195 per patient tested, net of the cost of T2Candida. Huntsville Hospital in Huntsville, Alabama, reported that the use of T2Candida resulted in a reduction in the duration of therapy and time to de-escalation in patients that tested negative for *Candida* on T2Candida, yielding net pharmacy savings of approximately $280 per patient tested. T2Candida also detected 56% more positive patients than blood culture. Finally, Riverside Community Hospital in Riverside, California, demonstrated improvements in time to appropriate therapy, increased sensitivity, and rapid discontinuation of antifungal therapy when using T2Candida. Specifically, 83% of patients who tested positive with T2Candida received appropriate therapy within six hours of the blood draw and 100% of patients received appropriate therapy in under nine hours. None of the patients who tested positive had been identified to have been treated with antifungals prior to T2Candida testing. In addition, antifungal therapy was discontinued for 100% of the patients who tested negative with T2Candida.

A study presented at ASM Microbe 2018 found that the T2MR technology provided accurate diagnostic results from patient skin samples for *Candida auris*. The study concluded that T2MR could be used to provide a more rapid detection of Candida auris in patient skin swabs.

Recent publications and presentations continue to demonstrate the clinical utility of T2Candida to assess the presence of disease, and continuation of antifungal therapy and resolution of disease despite negative blood cultures. (Ahuja et al. “Combination Antifungal Therapy for Treatment of Candida Parapsilosis Prosthetic Valve Endocarditis and utility of T2Candida Panel: A Case Series” ID Cases 2019; Chaudhry “Tales from the trenches” ID Week 2018.) Additionally, the Open Forum of Infectious Diseases recently published online “Diagnostic performance of T2Candida among ICU patients with risk factors for invasive candidiasis” by Maiken C. Arendrup reported on a multi-center study on 126 intensive care patients with high risk of invasive candidiasis and sepsis testes with T2Candida, blood culture and Candida Mannan Antigen. In this study the best diagnostic performance was observed for a combination of T2Candida and blood culture. Additionally, the authors note that “T2Candida was superior to blood culture and mannan-antigen and may improve diagnosis of patients with invasive candidiasis.”

Our T2Bacteria Panel

On May 24, 2018, we received market clearance from the FDA for T2Bacteria, a multiplex diagnostic panel that runs on the T2Dx and detects five major bacterial pathogens (members of the ESKAPE pathogens, as defined below) associated with sepsis and, in conjunction with T2Candida and standard empiric therapy regimens, may enable the early, appropriate treatment of 90% of sepsis patients. T2Bacteria addresses the same approximately 6.75 million symptomatic high-risk patients as T2Candida and also a new population of patients who are at increased risk for bacterial infections, including an additional two million patients presenting with symptoms of infection in the emergency room setting.

On August 4, 2017 we completed a pivotal clinical study of T2Bacteria, which is a qualitative T2MR assay designed for the direct detection of bacterial species in human whole blood specimens from patients with suspected bacteremia. T2Bacteria is designed to identify five species of bacteria directly from human whole blood specimens: *Enterococcus faecium*, *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Staphylococcus aureus.* Outside of the United States, the CE-marked T2Bacteria identifies all 5 of these species along with a 6th species, *Acinetobacter baumannii*.

The performance characteristics of T2Bacteria were evaluated through a series of analytical studies as well as a multi-center clinical study. The clinical study evaluated the performance of T2Bacteria in comparison to the current standard of care, blood culture. All of the data generated in the analytical studies and the clinical study were submitted to the United States Food and Drug Administration, or FDA, in a 510(k) premarket notification on September 8, 2017. T2Bacteria was cleared by the FDA on May 24, 2018.

The clinical study consisted of two arms, a prospective arm and a seeded arm. In the prospective arm, a total of 1,427 subjects were tested at eleven geographically dispersed and demographically diverse sites in the United States. In the seeded arm, 300 specimens of known bacterial composition were evaluated at three sites. Seeded specimens were prepared by spiking whole blood with multiple strains of the bacterial species detected by T2Bacteria at defined concentrations (CFU/mL). Fifty negative blood samples also were evaluated as part of the seeded arm of the study. In total, 1,777 (1,427 prospective specimens and 350 seeded and negative) clinical samples were tested to evaluate the clinical performance of T2Bacteria.

Recently, poster presentations by Dr. Christopher Voigt at ECCMID 2019 and EIM 2019 reported on the performance of T2Bacteria in the emergency department of Ochsner Medical Center and Tampa General Hospital. Data from 137 emergency department patients were evaluated and relative to blood culture, T2Bacteria showed 100% positive percent agreement and 99.2% negative percent agreement. In addition, for species on T2Bacteria, the T2Bacteria assay detected 4 more positive results associated with infection than blood culture, the average time to identification was 56.6 hours faster than blood culture and T2Bacteria covered 70.5% of all species detected by blood culture. A review of the 16 positive results identified by T2Bacteria records revealed, relative to actual care, T2Bacteria could have potentially allowed for focused therapy in 8 patients, potentially reduced time to a species-directed therapy in 4 patients, and potentially reduced time to effective therapy in 4 patients. In this emergency department population, T2Bacteria appeared to be a more rapid and sensitive detector of bacteremia for the most common ESKAPE pathogens (*E. coli*, *E. faecium*, *S. aureus*, *K. pneumoniae*, and *P. aeruginosa*) and showed the theoretical potential to influence subsequent patient therapy, ranging from antibiotic de-escalation to faster time to effective therapy.

Our T2Direct Diagnostics

We believe our T2MR delivers what no conventional technology currently available can: a rapid, sensitive and simple diagnostic platform to enable sepsis applications that can identify specific sepsis pathogens directly from an unpurified blood sample in hours instead of days at a level of accuracy equal to or better than blood culture-based diagnostics. The addition of the use of our products, T2Bacteria and T2Candida, which both run on the T2Dx Instrument, with the standard of care for the management of patients suspected of sepsis enables clinicians to potentially treat 90% of patients with sepsis pathogen infections with the right targeted therapy within the first twelve hours of developing the symptoms of disease. Currently, high risk patients are typically initially treated with broad spectrum antibiotic drugs that typically cover approximately 60% of patients with infections. Of the remaining 40% of patients, approximately 30% of the patients have a bacterial infection and 10% have *Candida* infections. T2Candida and T2Bacteria are designed to identify pathogens commonly not covered by broad spectrum antibiotic drugs.

We believe our products provide a pathway for more rapid and targeted treatment of infections, potentially reducing the mortality rate by as much as 50-75% if a patient is treated within 12 hours of suspicion of infection and significantly reducing the cost burden of sepsis. Each year, approximately 250,000 patients in the United States die from sepsis. According to a study published by *Critical Care Medicine* in 2006, in sepsis patients with documented hypotension, administration of effective antimicrobial therapy within the first hour of detection was associated with a survival rate of 79.9% and, over the ensuing six hours, each hour of delay in initiation of treatment was associated with an average decrease in survival of 7.6%. According to such study, the survival rate for septic patients who remained untreated for greater than 36 hours was approximately 5%. The toll of sepsis on a patient's health can be severe: more than one-in-five patients die within two years as a consequence of sepsis. Sepsis is also the most prevalent and costly cause of hospital readmissions.

We believe our T2Direct Diagnostics addresses a significant unmet need in *in vitro* diagnostics by providing:

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

Our T2Dx Instrument

Our FDA-cleared T2Dx instrument is an easy-to-use, fully-automated, benchtop instrument utilizing T2MR for use in hospitals and labs for a broad range of diagnostic tests. To operate the system, a patient's sample tube is snapped onto a disposable test cartridge, which is pre-loaded with all necessary reagents. The cartridge is then inserted into the T2Dx instrument, which automatically processes the sample and then delivers a diagnostic test result. Test results are displayed on screen and printed out.

By utilizing our proprietary T2MR technology for direct detection, the T2Dx instrument eliminates the need for sample purification and analyte extraction, which are necessary for other optical-detection devices. Eliminating these sample processing steps increases diagnostic sensitivity and accuracy, enables a broad menu of tests to be run on a single platform, and greatly reduces the complexity of the consumables. The T2Dx instrument incorporates a simple user interface and is designed to efficiently process up to seven specimens simultaneously.

Our T2MR Platform

T2MR is a miniaturized, magnetic resonance-based approach that measures how water molecules react in the presence of magnetic fields. For molecular and immunodiagnostics targets, T2MR utilizes advances in the field of magnetic resonance by deploying particles with magnetic properties that enhance the magnetic resonance signals of specific targets. When particles coated with target-specific binding agents are added to a sample containing the target, the particles bind to and cluster around the target. This clustering changes the microscopic environment of water in that sample, which in turn alters the magnetic resonance signal, or the T2 relaxation signal that we measure, indicating the presence of the target.

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

We have also developed the T2Resistance Panel, a product candidate that detects 13 resistance genes from both gram-positive and gram-negative pathogens. These targets include the most clinically important carbapenem resistance genes (KPC, OXA-48, NDM, VIM, IMP), which are listed on the CDC Urgent Threat list for antibiotic resistance; CTXM-14 and CTXM-15, a major source of extended spectrum beta lactamases (ESBLs); AmpC beta-lactamase genes (CMY, DHA); detection of *vanA/B* resistance genes, which are responsible for vancomycin resistant gram-positive enterococcus; and the detection of the methicillin resistance genes *mecC* and *mecA*, which cause methicillin resistant Staphylococcus aureus (MRSA). Initial clinical performance data demonstrates the carbapenemase targets on the T2Resistance Panel identify these resistance genes with an average time of 5.3 hours compared to an average of 30 hours (and up to 95 hours) with conventional methods. Antibiotic resistance is recognized by the WHO as 'one of the biggest threats to global health, food security, and development today'. We believe the T2Resistance Panel has the potential to prevent the spread of multidrug-resistant organisms and improve patient outcomes by enabling rapid identification of the genes and species associated with antibiotic resistance – enabling the reduction of unnecessary antibiotic use which is the primary cause of antibiotic resistance. Most importantly, these tests can enable more patients to get on the right targeted therapy quicker, potentially reducing mortality and hospitalization cost. Finally, these tests could also be used to accelerate clinical trials for new antibiotics and reduce the time to commercial availability. We expect the T2Resistance Panel to be available for research use only in the United States and receive a CE mark for commercial availability in Europe by the end of 2019.

The T2Dx Instrument also has the ability to ability to enable high-sensitivity, culture-independent detection of pathogens at ultra-high sensitivity in ultra-low concentrations for five biothreat pathogens, including *Bacillus anthracis (anthrax)*, *Burkholderia spp.*, *Rickettsia prowazekii*, *Francisella tularensis* and *Yersinia pestis*. The U.S. Department of Homeland Security has defined these as biothreat pathogens because they require quick antibiotic treatment and can be difficult to diagnose due to non-distinguishing symptoms, making the development and availability of rapid, high-throughput, high-sensitivity diagnostics for these biothreat pathogens a national priority. Rapid, ultra-high sensitivity diagnosis with T2MR will help discriminate the infected from the non-infected, reducing the spread of disease and impact of a bioweapon event.

In addition, we now have data that demonstrates potential support for a T2MR test panel that could potentially report greater than 40 reported results covering greater than 99% of infections caused by blood-borne bacterial and fungal pathogens. This panel includes "pan-level" channels that detect greater than 250 pathogen species with detection at less than or equal to 10 CFU/mL. Additionally, this panel provides coverage for all blood-borne antibiotic resistance threats identified by the CDC.

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

Financial Overview

Revenue

We generate revenue from the sale of our products, related services, reagent rental agreements and from activities performed pursuant to research and development agreements.

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

Grants received, including cost reimbursement agreements, are assessed to determine if the agreement should be accounted for as an exchange transaction or a contribution. An agreement is accounted as a contribution if the resource provider does not receive commensurate value in return for the assets transferred. Contribution revenue is recognized when all donor-imposed conditions have been met.

Product revenue is derived from the sale of our instruments and related consumable diagnostic tests, predominantly through our direct sales force in the United States, and distributors in geographic regions outside the United States. We do not offer product return or exchange rights (other than those relating to defective goods under warranty) or price protection allowances to our customers, including our distributors. Payment terms granted to distributors are the same as those granted to end-user customers and payments are not dependent upon the distributors' receipt of payment from their end-user customers. The Company either sells instruments to customers and international distributors, or retains title and places the instrument at the customer site pursuant to a reagent rental agreement. When the instrument is directly purchased by a customer, the Company recognizes revenue when the related performance obligation is satisfied (i.e. when the control of an instrument has passed to the customer; typically, at shipping point). When the instrument is placed under a reagent rental agreement, the Company's customers generally agree to fixed term agreements, which can be extended, certain of which may include minimum purchase commitments and/or incremental charges on each consumable diagnostic test purchased, which varies based on the volume of test cartridges purchased. Revenue from the sale of consumable diagnostic tests (under a reagent rental agreement), which includes the incremental charge, is recognized upon shipment. Revenue associated with reagent rental consumable purchases is currently classified as variable consideration and constrained until a purchase order is received and related performance obligations have been satisfied (or partially satisfied). The transaction price from consumables purchases is allocated between the lease of the instrument (under a contingent rent methodology as provided for in ASC 842), and the consumables when related performance obligations are satisfied as a component of lease and product revenue.

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

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

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

Cost of Product Revenue

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

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

Research and development expenses

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

We anticipate our overall research and development expenses to be flat to a slight increase due to the anticipation of additional research partnerships. Research and development costs include costs to support research partnerships, clinical trials and new product development. We have committed, and expect to commit, significant resources toward developing additional product candidates, improving existing products, conducting ongoing and new clinical trials and expanding our laboratory capabilities.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of costs for our sales and marketing, finance, legal, human resources, business development and general management functions, as well as professional services, such as legal, consulting and accounting services. We expect selling, general and administrative expenses to increase in future periods as we commercialize products and future product candidates and as our needs for sales, marketing and administrative personnel grow. Other selling, general and administrative expenses include facility-related costs, fees and expenses associated with obtaining and maintaining patents, clinical and economic studies and publications, marketing expenses, and travel expenses. We expense all selling, general and administrative expenses as incurred.

Interest expense, net

Interest expense, net, consists primarily of interest expense on our notes payable, changes in fair value of our derivative liability and the amortization of deferred financing costs and debt discount, partially offset by interest earned on our cash and cash equivalents.

Other income, net

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

Critical Accounting Policies and Use of Estimates

We have prepared our condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States. Our preparation of these condensed consolidated financial statements requires us to make estimates, assumptions,

and judgments that affect the reported amounts of assets, liabilities, expenses, and related disclosures at the date of the condensed consolidated financial statements, as well as revenue and expenses recorded during those periods. We evaluated our estimates and judgments on an ongoing basis. We based our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions.

The items that we disclosed as our critical accounting policies and estimates in Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2018 remained materially consistent, other than the January 1, 2019 adoption of ASC 842, *Leases* ("ASC 842") (Note 2). For a description of those critical accounting policies, please refer to our Annual Report on Form 10-K filing for the year ended December 31, 2018.

Results of Operations for the Three Months Ended June 30, 2019 and 2018

	Three Months Ended June 30,		
	2019	2018	Change
	(in thousands)		
Revenue:			
Product revenue	$ 1,274	$ 1,220	$ 54
Research revenue	71	2,711	(2,640)
Contribution revenue	459	—	459
Total revenue	1,804	3,931	(2,127)
Costs and expenses:			
Cost of product revenue	4,820	3,458	1,362
Research and development	4,048	3,749	299
Selling, general and administrative	6,722	7,611	(889)
Total costs and expenses	15,590	14,818	772
Loss from operations	(13,786)	(10,887)	(2,899)
Interest expense, net	(2,000)	(1,506)	(494)
Other income, net	139	69	70
Net loss	$ (15,647)	$ (12,324)	$ (3,323)

Product revenue

Product revenue was $1.3 million for the three months ended June 30, 2019 compared to $1.2 million for the three months ended June 30, 2018, an increase of $0.1 million. The increase was driven by higher consumable sales, mostly from T2Bacteria.

Research revenue

Research revenue was $0.1 million for the three months ended June 30, 2019, compared to $2.7 million for the three months ended June 30, 2018, a decrease of $2.6 million. The decrease was the result of $1.2 million less revenue from services delivered under our Co-Development Agreement with Canon Life Sciences, a result of achieving a $2.0 million milestone during the quarter ended June 30, 2018, and $0.9 million less of revenue recognized related to our Co-Development Agreement with Allergan Sales, which completed in October 2018. Research revenue for the three months ended June 30, 2018 included $0.5 million from our cost-sharing agreement with CARB-X. Revenue from our cost-sharing agreement with CARB-X, for the three months ended June 30, 2019, is recorded as contribution revenue, a result of adopting a new accounting standard.

Contribution revenue

Contribution revenue of $0.5 million, for the three months ended June 30, 2019, relates to our cost-sharing agreement with CARB-X. Revenue related to our cost-sharing agreement with CARB-X, for the three months ended June 30, 2018, was recorded as research revenue.

Cost of product revenue

Cost of product revenue was $4.8 million for the three months ended June 30, 2019, compared to $3.5 million for the three months ended June 30, 2018, an increase of $1.3 million. The increase in cost was driven by $0.5 million from materials, which increased as a result of higher inventory balances required to meet anticipated demand, $0.3 million of repair costs associated with refurbishing and redeploying T2 owned instruments, $0.3 million from service related activity due to an increased customer base and $0.2 million of higher consumable materials due to T2Bacteria, which was not capitalized prior to FDA approval.

Research and development expenses

Research and development expenses were $4.0 million for the three months ended June 30, 2019, compared to $3.7 million for the three months ended June 30, 2018, an increase of $0.3 million, related to payroll expenses. The increase was driven by higher headcount.

Selling, general and administrative expenses

Selling, general and administrative expenses were $6.7 million for the three months ended June 30, 2019, compared to $7.6 million for the three months ended June 30, 2018, a decrease of $0.9 million. The decrease was attributed to lower stock compensation expense of $2.1 million due to the vesting of restricted stock units with market conditions, causing acceleration of expense, during the three months ended June 30, 2018. The decrease was partially offset by increased payroll expenses of $0.9 million and travel expenses of $0.1 million associated with additional medical affairs personnel, professional fees of $0.1 million, and tradeshow costs of $0.1 million.

Interest expense, net

Interest expense, net, was $2.0 million for the three months ended June 30, 2019, compared to $1.5 million for the three months ended June 30, 2018, an increase of $0.5 million due to the change in fair value of the derivative.

Other income, net

Other income, net, was $0.1 million for the three months ended June 30, 2019 and 2018.

Results of Operations for the Six Months Ended June 30, 2019 and 2018

	Six Months Ended June 30,		
	2019	2018	Change
	(in thousands)		
Revenue:			
Product revenue	$ 2,588	$ 2,268	$ 320
Research revenue	213	3,974	(3,761)
Contribution revenue	788	—	788
Total revenue	3,589	6,242	(2,653)
Costs and expenses:			
Cost of product revenue	9,208	6,731	2,477
Research and development	7,949	8,467	(518)
Selling, general and administrative	13,776	13,366	410
Total costs and expenses	30,933	28,564	2,369
Loss from operations	(27,344)	(22,322)	(5,022)
Interest expense, net	(3,782)	(3,074)	(708)
Other income, net	332	159	173
Net loss	$ (30,794)	$ (25,237)	$ (5,557)

Product revenue

Product revenue was $2.6 million for the six months ended June 30, 2019 compared to $2.3 million for the six months ended June 30, 2018, an increase of $0.3 million. The increase was driven by higher T2Dx instrument sales.

Research revenue

Research revenue was $0.2 million for the six months ended June 30, 2019, compared to $4.0 million for the six months ended June 30, 2018, a decrease of $3.8 million. The decrease was the result of $2.2 million less of revenue recognized related to our Co-Development Agreement with Allergan Sales, which completed in October 2018, and $1.1 million less of revenue recognized under our Co-Development Agreement with Canon US Life Sciences, a result of achieving a $2.0 million milestone during the six months ended June 30, 2018. Research revenue for the six months ended June 30, 2018 included $0.5 million from our cost-sharing agreement with CARB-X. Revenue from our cost-sharing agreement with CARB-X, for the six months ended June 30, 2019, is recorded as contribution revenue, a result of adopting a new accounting standard.

Contribution revenue

Contribution revenue of $0.8 million, for the six months ended June 30, 2019, relates to our cost-sharing agreement with CARB-X. Revenue related to our cost-sharing agreement with CARB-X, for the six months ended June 30, 2018, was recorded as research revenue.

Cost of product revenue

Cost of product revenue was $9.2 million for the six months ended June 30, 2019, compared to $6.7 million for the six months ended June 30, 2018, an increase of $2.5 million. The increase in cost was driven by an increase of $0.9 million from materials, which increased as a result of higher inventory balances required to meet anticipated demand, $0.5 million of repair costs associated with refurbishing and redeploying T2 owned instruments, $0.5 million from T2Dx increased instrument sales, $0.4 million from service related activity due to an increased customer base and $0.2 million of higher consumable materials due to T2Bacteria, which was not capitalized prior to FDA approval.

Research and development expenses

Research and development expenses were $7.9 million for the six months ended June 30, 2019, compared to $8.5 million for the six months ended June 30, 2018, a decrease of $0.6 million. Research and development expenses decreased by $0.8 million related to FDA clearance of T2Bacteria, after which T2Bacteria costs are capitalized in inventory. Stock compensation expense decreased by $0.2 million due to the vesting of restricted stock units with market conditions, causing acceleration of expense, during the six months ended June 30, 2018. The decrease in research and development expenses were partially offset by a $0.4 million increase in payroll related expenses due to higher headcount.

Selling, general and administrative expenses

Selling, general and administrative expenses were $13.8 million for the six months ended June 30, 2019, compared to $13.4 million for the six months ended June 30, 2018, an increase of $0.4 million. The increase was attributed to increased payroll expenses of $1.6 million and increased travel expenses of $0.3 million due to an increase in medical affairs personnel. The increase was partially offset by a $1.5 million decrease in stock compensation expense due to the vesting of restricted stock units with market conditions, causing acceleration of expense, during the six months ended June 30, 2018.

Interest expense, net

Interest expense, net, was $3.8 million for the six months ended June 30, 2019, compared to $3.1 million for the six months ended June 30, 2018, an increase of $0.7 million, primarily due to the change in fair value of the derivative.

Other income, net

Other income, net, was $0.3 million for the six months ended June 30, 2019 and $0.2 million for the six months ended June 30, 2018, an increase of $0.1 million.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception, and as of June 30, 2019 and December 31, 2018 we had an accumulated deficit of $348.0 million and $317.2 million respectively. Having obtained clearance from the FDA and a CE mark in Europe to market the T2Dx, T2Candida, and T2Bacteria, the Company has incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution. The Company may seek to fund its operations through public equity or private equity or debt financings, as well as other sources. However, the Company may be unable

to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. The Company's failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on the Company's business, results of operations and financial condition and the Company's ability to develop and commercialize T2Dx, T2Candida, T2Bacteria, and other product candidates.

Historically, 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 debt financing arrangements.

Equity Distribution Agreement

On July 30, 2019, the Company entered into an Equity Distribution Agreement (the "Sales Agreement") with Canaccord Genuity LLC, as agent ("Canaccord"), pursuant to which the Company may offer and sell shares of common stock, for aggregate gross sale proceeds of up to $30,000,000 from time to time through Canaccord.

Sales of the shares pursuant to the Sales Agreement, if any, may be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act, including sales made directly on or through The Nasdaq Global Market or any other existing trading market for the Shares, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices and/or any other method permitted by law. The Company intends to use the net proceeds from the offering for working capital and general corporate purposes, which may include, among other things, commercialization and research and development expenses and capital expenditures. The Company is not obligated to make any sales of Shares under the Sales Agreement. The Company or Canaccord may suspend or terminate the offering of Shares upon notice to the other party, subject to certain conditions. Canaccord will act as sales agent on a commercially reasonable efforts basis consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of Nasdaq.

The Company has agreed to pay Canaccord for its services of acting as agent 3% of the gross proceeds from the sale of the Shares pursuant to the Sales Agreement. The Company has also agreed to provide Canaccord with customary indemnification and contribution rights. At June 30, 2019, legal and accounting fees associated with the Sales Agreement were immaterial. Legal and accounting fees are expected to be reclassified to share capital upon issuance of shares under the Sales Agreement.

This Quarterly Report on Form 10-Q shall not constitute an offer to sell or a solicitation of an offer to buy any securities, nor shall there be any sale of these securities in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

Purchase Agreement

On July 29, 2019, the Company entered into a $30,000,000 purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which the Company may sell and issue to Lincoln Park, and Lincoln Park is obligated to purchase, up to $30,000,000 in value of its shares of common stock from time to time over a 36-month period starting from the effective date of the respective registration statement.

The Company may direct Lincoln Park, at its sole discretion, and subject to certain conditions, to purchase up to 200,000 shares of common stock on any business day, provided that at least one business day has passed since the most recent purchase. The amount of a purchase may be increased under certain circumstances provided, however, that Lincoln Park's committed obligation under any single purchase shall not exceed $2,000,000. The purchase price of shares of common stock related to the future funding will be based on the then prevailing market prices of such shares at the time of sales as described in the Purchase Agreement.

Plan of operations and future funding requirements

As of June 30, 2019 and December 31, 2018 we had unrestricted cash and cash equivalents of approximately $28.4 million and $50.8 million respectively. Currently, our funds are primarily held in money market funds invested in U.S. government agency securities. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, costs related to our products, clinical trials, laboratory and related supplies, supplies and materials used in manufacturing, legal and other regulatory expenses and general overhead costs.

Until such time as we can generate substantial product revenue, we expect to finance our cash needs, beyond what is currently available or on hand, through a combination of equity offerings, debt financings and revenue from existing and potential research and

development and other collaboration agreements. If we raise additional funds in the future, we may need to relinquish valuable rights to our technologies, future revenue streams or grant licenses on terms that may not be favorable to us.

Going Concern

Our ability to continue operations after June 30, 2019 will depend on our ability to obtain additional funding, as to which no assurances can be given. These conditions raise substantial doubt about our ability to continue as a going concern. There can be no assurance that any financing by us can be realized, or if realized, what the terms of any such financing may be, or that any amount that we are able to raise will be adequate.

We believe that our existing cash and cash equivalents at June 30, 2019, along with funding available through our Sales Agreement with Canaccord and Purchase Agreement with Lincoln Park, will be sufficient to allow us to fund our current operating plan at least a year from the issuance of these financial statements. Should our current operating plan not materialize, Management's plans include raising additional funding, earning milestone payments pursuant to the Company's Co- Development agreements, delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels for the Company to continue as a going concern for a period of 12 months from the date the financial statements are issued. Management has concluded the likelihood that its plan to obtain sufficient funding from one or more of these sources or adequately reduce expenditures will be successful, while reasonably possible, is less than probable. The Term Loan Agreement requires us to achieve certain annual revenue targets, whereby we are required to pay double the amount of any shortfall as an acceleration of principal payments, and maintain a minimum liquidity amount. Should we fall short of the revenue target we would seek a waiver of this provision. There can be no assurances that we would be successful in obtaining a waiver. We are also required to maintain a minimum cash balance under our Term Loan Agreement with CRG.

Cash flows

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

	Six Months Ended June 30,	
	2019	2018
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (21,707)	$ (20,356)
Investing activities	(444)	(599)
Financing activities	(232)	49,786
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (22,383)	$ 28,831

Net cash used in operating activities

Net cash used in operating activities was approximately $21.7 million for the six months ended June 30, 2019, and consisted of a net loss of $30.8 million adjusted for non-cash items including stock-based compensation expense of $3.3 million, depreciation and amortization expense of $1.2 million, non-cash interest expense of $1.1 million, amortization of operating lease right-of-use assets of $0.7 million, a change in the fair value of the derivative instrument of $0.4 million, and a net change in operating assets and liabilities of $2.4 million, primarily related to an increase in accounts payable of $2.0 million due to timing of payments, an increase in accrued expenses of $1.2 million due to timing of interest payments, a decrease in accounts receivable of $0.6 million due to less outstanding instrument invoices and a decrease in prepaid expenses and other assets of $0.6 million primarily related to tradeshows and insurance, partially offset by a decrease in operating lease liabilities of $1.1 million, and a $0.9 million increase in instrument inventories to meet anticipated demand.

Net cash used in operating activities was approximately $20.4 million for the six months ended June 30, 2018, and consisted of a net loss of $25.2 million adjusted for non-cash items including stock-based compensation expense of $5.3 million, depreciation and amortization expense of $1.2 million, non-cash interest expense of $1.1 million, an impairment charge of $0.2 million, offset by a change in the fair value of the derivative instrument of $0.4 million, deferred rent of $0.1 million, and a net change in operating assets and liabilities of $2.5 million, primarily related to an increase in accounts receivable of $1.2 million from increased instrument sales and our cost-sharing agreement with CARB-X, a decrease in accrued expenses and accounts payable of $0.6 million due to clinical, bonus and professional fees, a decrease in deferred revenue of $0.6 million primarily from our Co-Development Agreement with Allergan Sales, LLC, and an increase in prepaid expenses and other assets of $0.1 million.

Net cash used in investing activities

Net cash used in investing activities was approximately $0.4 million for the six months ended June 30, 2019, and consisted of costs to acquire property and equipment.

Net cash used in investing activities was approximately $0.6 million for the six months ended June 30, 2018, and consisted of costs to acquire property and equipment.

Net cash used in / provided by financing activities

Net cash used in financing activities was approximately $0.2 million for the six months ended June 30, 2019, and consisted of repayments of finance leases of $0.5 million, partially offset by proceeds from issuance of common stock of $0.3 million.

Net cash provided by financing activities was approximately $49.8 million for the six months ended June 30, 2018, and consisted primarily of the net proceeds from the June 2018 public offering of $49.4 million and proceeds from the exercise of stock options of $1.1 million which were partially offset by $0.7 million of repayments of notes payable.

Borrowing Arrangements

Term Loan Agreement

In December 2016, we entered into a Term Loan Agreement (the "Term Loan Agreement") with CRG. We borrowed $40.0 million pursuant to the Term Loan Agreement, which has a six-year term with four years of interest-only payments (through December 30, 2020), 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 11.5%, 3.5% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount. In addition, if we achieve certain financial performance metrics, the loan will convert to interest-only until the December 30, 2022 maturity, at which time all unpaid principal and accrued unpaid interest will be due and payable. We are required to pay CRG a financing fee based on the loan principal amount drawn. We are also required to pay a final payment fee of 8.0% of the principal outstanding upon repayment. We are accruing the final payment fee as interest expense and it is included as a current liability at June 30, 2019 and December 31, 2018 on the balance sheet.

We may prepay all or a portion of the outstanding principal and accrued unpaid interest under the Term Loan Agreement at any time upon prior notice subject to a prepayment fee during the first five years of the term and no prepayment fee thereafter. As security for our obligations under the Term Loan Agreement we entered into a security agreement with CRG whereby we granted a lien on substantially all of our assets, including intellectual property. The Term Loan Agreement also contains customary affirmative and negative covenants for a credit facility of this size and type. The Term Loan Agreement also requires us to achieve certain revenue targets, whereby we are required to pay double the amount of any shortfall as an acceleration of principal payments. In March 2019, the Term Loan Agreement was amended to reduce the 2019 minimum revenue target to $9.0 million and delete the 2018 revenue covenant. In exchange for the amendment, we agreed to reset the strike price of the warrants, issued in connection with the Term Loan Agreement, from $8.06 per share to $4.35 per share. The Term Loan Agreement includes a subjective acceleration clause whereby an event of default, including a material adverse change in the business, operations, or conditions (financial or otherwise), could result in the acceleration of the obligations under the Term Loan Agreement. Under certain circumstances, a default interest rate of an additional 4.0% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default. CRG has not exercised its right under this clause, as there have been no such events. We believe the likelihood of CRG exercising this right is remote.

We assessed the terms and features of the Term Loan Agreement, including the interest-only period and the acceleration of the obligations under the Term Loan Agreement under an event of default, in order to identify any potential embedded features that would require bifurcation. In addition, under certain circumstances, a default interest rate of an additional 4.0% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default. We concluded that these features are not clearly and closely related to the host instrument, and represent a single compound derivative that is required to be re-measured at fair value on a quarterly basis.

The fair value of the derivative at June 30, 2019 and December 31, 2018 is $2.5 million and $2.1 million, respectively. We classified the derivative liability as accrued expenses and other current liabilities on the balance sheet at June 30, 2019 and December 31, 2018 to match the classification of the related Term Loan Agreement.

In connection with the Term Loan Agreement entered into in December 2016, we issued to CRG warrants to purchase a total of 528,958 shares of common stock. The warrants are exercisable any time prior to December 30, 2026 at a price of $4.35 per share, with typical provisions for termination upon a change of control or sale of all or substantially all of our assets. The strike price was reduced, by a March 2019 amendment, from an original strike price of $8.06 per share. 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 amended warrants was $0.9 million. The incremental fair value of the modified instrument of $0.1 million was recorded as additional debt discount and additional paid-in-capital.

Equipment Lease Credit Facility

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

In April 2016 and June 2016, we completed the first two draws under the Credit Facility of $2.1 million and $2.5 million, respectively. We made 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 finance leases and are included in property and equipment on the balance sheet. The amortization of the assets conveyed under the Credit Facility is included as a component of depreciation expense.

Contractual Obligations and Commitments

There were no material changes to our contractual obligations and commitments from those described under Management's Discussion and Analysis of Financial Condition and Results of Operations in the Annual Report on Form 10-K for the year ended December 31, 2018.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk related to changes in interest rates. As of June 30, 2019 and December 31, 2018, we had cash and cash equivalents of $28.4 million and $50.8 million, respectively, held primarily in money market funds consisting of U.S. government agency securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate one percent change in interest rates would not have a material effect on the fair market value of our portfolio. As of June 30, 2019 and December 31, 2018, we had no outstanding debt exposed to variable market interest rates.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

Management of the Company, with the participation of the Chief Executive Officer and the Chief Financial Officer, evaluated the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of June 30, 2019. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported on a timely basis and that such information is accumulated and communicated to management, including the Chief Executive Officer and the Chief Financial Officer, as appropriate, to allow timely decisions regarding disclosure. Based upon this evaluation, the Chief Executive Officer and the Chief Financial Officer have concluded that the Company's disclosure controls and procedures were effective as of June 30, 2019.

(b) Changes in Internal Control over Financial Reporting

There have been no changes to the Company’s internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

PART II.
OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2018, which could materially affect our business, financial condition or future results. There have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018.

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

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None

Item 6. Exhibits, Financial Statement Schedules

Exhibit Number	Exhibit Description
3.1	Restated Certificate of Incorporation of the Company, as amended (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36571) filed on August 12, 2014)
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 of the Company's Form 8-K (File No. 001-36571) filed on August 12, 2014)
10.1	Equity Distribution Agreement dated as of July 30, 2019 by and between T2 Biosystems, Inc. and Canaccord Genuity LLC (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on July 30, 2019)
10.2	Purchase Agreement dated as of July 29, 2019 by and between T2 Biosystems, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K (File No. 001-36571) filed on July 30, 2019)
10.3	Second Amendment to Employment Agreement dated as of July 30, 2019 by and between T2 Biosystems, Inc. and John McDonough (incorporated by reference to Exhibit 10.3 of the Company's Form 8-K (File No. 001-36571) filed on July 30, 2019)
31.1*	Certification of principle executive officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of principal financial officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.1*	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, formatted in XBRL: (i) Condensed Consolidated Balance Sheets (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited), (iii) Condensed Consolidated Statements of Cash Flows (unaudited), and (v) Notes of Condensed Consolidated Financial Statements.

* Filed herewith
** Furnished herewith

SIGNATURES

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

T2 BIOSYSTEMS, INC.

Date: August 2, 2019

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

Date: August 2, 2019

By: /s/ JOHN M. SPRAGUE
John M. Sprague
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 31.1

CERTIFICATION
PURSUANT TO 17 CFR 240.13a-14
PROMULGATED UNDER
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John McDonough, certify that:

1. I have reviewed this quarterly report on Form 10-Q of T2 Biosystems, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ John McDonough
John McDonough
President, Chief Executive Officer and Director
(principal executive officer)

Date: August 2, 2019

Exhibit 31.2

CERTIFICATION
PURSUANT TO 17 CFR 240.13a-14
PROMULGATED UNDER
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John M. Sprague, certify that:

1. I have reviewed this quarterly report on Form 10-Q of T2 Biosystems, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ John M. Sprague
John M. Sprague
Chief Financial Officer
(principal accounting and financial officer)

Date: August 2, 2019

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of T2 Biosystems, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John McDonough, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ John McDonough
John McDonough
President and Chief Executive Officer
(principal executive officer)

Date: August 2, 2019

This certification accompanies each Report pursuant to §906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of §18 of the Securities Exchange Act of 1934, as amended.

A signed original of this written statement required by §906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of T2 Biosystems, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John M. Sprague, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ John M. Sprague
John M. Sprague
Chief Financial Officer
(principal accounting officer and financial officer)

Date: August 2, 2019

This certification accompanies each Report pursuant to §906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of §18 of the Securities Exchange Act of 1934, as amended.

A signed original of this written statement required by §906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.