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 March 31, 2020

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 May 7, 2020, the registrant had 119,172,630 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)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 36,323	$ 11,033
Accounts receivable	2,454	2,825
Inventories	3,275	3,599
Prepaid expenses and other current assets	1,716	1,438
Total current assets	43,768	18,895
Property and equipment, net	4,232	5,845
Operating lease right-of-use assets	2,966	3,360
Restricted cash	180	180
Other assets	206	206
Total assets	$ 51,352	$ 28,486
Liabilities and stockholders' deficit		
Current liabilities:		
Notes payable	$ 43,400	$ 42,902
Accounts payable	1,686	3,753
Accrued expenses and other current liabilities	10,029	11,207
Derivative liability	2,314	2,425
Deferred revenue	238	285
Total current liabilities	57,667	60,572
Operating lease liabilities, net of current portion	1,350	1,873
Deferred revenue, net of current portion	32	46
Commitments and contingencies (see Note 13)		
Stockholders' deficit:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized; 119,172,630 and 50,651,535 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	119	51
Additional paid-in capital	383,310	342,121
Accumulated deficit	(391,126)	(376,177)
Total stockholders' deficit	(7,697)	(34,005)
Total liabilities and stockholders' deficit	$ 51,352	$ 28,486

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 March 31,	
	2020	2019
Revenue:		
Product revenue	$ 1,045	$ 1,314
Research revenue	—	142
Contribution revenue	1,500	329
Total revenue	2,545	1,785
Costs and expenses:		
Cost of product revenue	4,671	4,388
Research and development	4,938	3,901
Selling, general and administrative	6,497	7,055
Total costs and expenses	16,106	15,344
Loss from operations	(13,561)	(13,559)
Interest expense, net	(1,417)	(1,782)
Other income, net	29	194
Net loss and comprehensive loss	$ (14,949)	$ (15,147)
Net loss per share — basic and diluted	$ (0.22)	$ (0.34)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	68,637,322	44,282,345

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, 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, exercise of stock options and employee stock purchase plan	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)

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders' (Deficit)
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2019	50,651,535	$ 51	$ 342,121	$ (376,177)	$ (34,005)
Stock-based compensation expense	—	—	1,160	—	1,160
Issuance of common stock from vesting of restricted stock	370,417	—	—	—	—
Issuance of common stock from secondary offering, net	68,150,678	68	40,029	—	40,097
Net loss	—	—	—	(14,949)	(14,949)
Balance at March 31, 2020	119,172,630	$ 119	$ 383,310	$ (391,126)	$ (7,697)

See accompanying notes to condensed consolidated financial statements.

T2 BIOSYSTEMS, INC.

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2020	2019
Cash flows from operating activities		
Net loss	$ (14,949)	$ (15,147)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	503	557
Non-cash lease expense	394	342
Stock-based compensation expense	1,160	2,033
Change in fair value of derivative instrument	(111)	83
Impairment of property and equipment	629	—
Non-cash interest expense	621	568
Changes in operating assets and liabilities:		
Accounts receivable	371	13
Prepaid expenses and other assets	(278)	(401)
Inventories	845	(141)
Accounts payable	(2,021)	(126)
Accrued expenses and other liabilities	(1,265)	118
Deferred revenue	(61)	(31)
Operating lease liabilities	(578)	(735)
Net cash used in operating activities	(14,740)	(12,867)
Cash flows from investing activities		
Purchases and manufacture of property and equipment	(67)	(194)
Net cash used in investing activities	(67)	(194)
Cash flows from financing activities		
Proceeds from issuance of common stock in public offering, net of offering costs	40,097	—
Principal repayments of finance leases	—	(344)
Net cash provided by (used in) financing activities	40,097	(344)
Net increase (decrease) in cash, cash equivalents and restricted cash	25,290	(13,405)
Cash, cash equivalents and restricted cash at beginning of period	11,213	50,985
Cash, cash equivalents and restricted cash at end of period	$ 36,503	$ 37,580
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 906	$ 1,131
Supplemental disclosures of noncash activities		
Transfer of T2 owned instruments and components to (from) inventory	$ 521	$ (154)
Change in fair value of warrants issued and modified	$ —	$ 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	$ 50	$ 56

	March 31, 2020	December 31, 2019
Reconciliation of cash, cash equivalents and restricted cash at end of period		
Cash and cash equivalents	$ 36,323	$ 11,033
Restricted cash	180	180
Total cash, cash equivalents and restricted cash	$ 36,503	$ 11,213

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"). On February 6, 2019, the FDA granted the Company's T2Resistance Panel designation as a Breakthrough Device. On August 2, 2019, the Center for Medicare & Medicaid Services (CMS) granted approval for a New Technology Add-on Payment for the T2Bacteria Panel for fiscal year 2020. A COVID-19 test is under development that will detect the presence of the SARS-CoV-2 virus in swab samples collected from a patient's nose or mouth.

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 March 31, 2020, the Company had cash and cash equivalents of $36.3 million, an accumulated deficit of $391.1 million, a stockholders' deficit of $7.7 million, and has experienced cash outflows from operating activities over the past years. 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, its July 2019 establishment of an Equity Distribution Agreement and Equity Purchase Agreement, private placements of redeemable convertible preferred stock and through debt financing arrangements.

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

The COVID-19 pandemic may impact operations. The Company has established protocols for continued manufacturing, distribution and servicing of its products with safe social distancing and personal protective equipment measures and for remote work for employees not essential to on-site operations. To date these measures have been successful but may not continue to function should the pandemic escalate and impact personnel. The Company's hospital customers have restricted the sales team's access to their facilities and as a result, the Company significantly reduced its sales and general and administrative staffing levels to reduce expenses. The Company's customers may reduce their purchases of products. Customers may cease to comply with the terms of sales agreements and this may impact the ability to recognize revenue and hinder receivables collections. The Company has a significant development contract with a United States Government agency and should the agency reduce, cancel or not grant additional milestone projects, the Company's ability to continue its future product development may be impacted. The ability of the Company's shipping carriers to deliver products to customers may be disrupted. The Company has reviewed its suppliers and quantities of key materials and believes that it has sufficient stocks and alternate sources of critical materials including personal protective equipment should the supply chains become disrupted. As further described in Note 5., the Company believes the pandemic's impact on its sales has impacted the recoverability of the value of T2-owned instruments and components. The COVID-19 pandemic also caused the Company to reassess its build plan and evaluate its inventories accordingly, which resulted in an additional charge to cost of product revenue.

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 March 31, 2020, along with additional funding available through the Company's Equity Distribution Agreement (the "Sales Agreement") with Canaccord Genuity LLC, as agent ("Canaccord") (Note 7) in the future, will be sufficient to allow the Company to fund its current operating plan, at least a year from issuance of these financial statements, assuming availability of funds. However, as certain elements of the Company's operating plan are outside of the Company's control, including the ability to sell shares under the Sales Agreement, those elements 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. During the three months ended March 31, 2020, management implemented a cost improvement strategy which is focused on reducing operating expenses and improving our cost of goods sold. The Company reduced its total employee headcount by 22% as compared to headcount at December 31, 2019, resulting in severance of $0.4 million, of which $0.3 million is included within other accrued expenses at March 31, 2020. The Term Loan Agreement with CRG Servicing LLC ("CRG") (Note 6) requires the Company to achieve certain annual revenue targets, whereby the Company is required to pay double the amount of any shortfall as an acceleration of principal payments and maintain a minimum cash balance of $5.0 million. The Term Loan Agreement with CRG is classified as a current liability on the balance sheet at March 31, 2020, based on the Company's consideration of the probability of violating the 2020 revenue covenant primarily due to the COVID-19 pandemic's likely impact on our product sales, which in turn would trigger violation of the minimum liquidity covenant. Should the Company fall short of the revenue target, it would seek a waiver of this provision. There can be no assurances that the Company would be successful in obtaining a waiver. On April 7, 2020, the Company received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for the Company's common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Global Market under Nasdaq Listing Rule 5450(a)(1).

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 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, 2019.

The accompanying interim condensed consolidated balance sheet as of March 31, 2020, the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2020 and 2019, the condensed consolidated statements of stockholders' (deficit) equity for the three months ended March 31, 2020 and 2019, the condensed consolidated statements of cash flows for the three months ended March 31, 2020 and 2019 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 March 31, 2020, and the results of its operations for the three months ended March 31, 2020 and 2019 and its cash flows for the three months ended March 31, 2020 and 2019. The results for the three months ended March 31, 2020 are not necessarily indicative of the results to be expected for the year ending December 31, 2020, 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. Total international sales were approximately $0.4 million or 17% of total revenue and $0.6 million or 36% of total revenue for the three months ended March 31, 2020 and 2019, respectively.

International customers who represented 10% or more of the Company's total revenue for the three months ended March 31, 2020 and 2019 were as follows:

	Three Months Ended March 31,	
	2020	2019
Customer A	*	13%
Customer B	*	11%

*Less than 10% for the period indicated

As of March 31, 2020 and December 31, 2019, the Company had outstanding receivables of $0.6 million and $1.2 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 March 31, 2020 and December 31, 2019, 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

Pursuant to Topic 842, *Leases* ("ASC 842"), 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. 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. The exercise of lease renewal options is at our discretion and the renewal to extend the lease terms are not included in the Company's right-of-use assets and lease liabilities as they are not reasonably certain of exercise. The Company will evaluate the renewal options and when they are reasonably certain of exercise, the Company will include the renewal period in its lease term. 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 distributors in geographic regions outside the United States contain only a single performance obligation; whereas, most of the Company's contracts with direct sales customers in the United States 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 condensed 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.

Fees paid to member-owned group purchasing organizations ("GPOs") are deducted from related product revenues.

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.

Our customers may cease to comply with the terms of our sales agreements and this may impact our ability to recognize revenue and hinder receivables collections. We have a significant development contract with a United States Government agency and should the agency reduce, cancel or not grant additional milestone projects our ability to continue our future product development may be impacted.

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, March 31,	
	2020	2019
Product Revenue		
Instruments	$ 247	$ 535
Consumables	745	733
Instrument rentals	53	46
Total Product Revenue	1,045	1,314
Research Revenue	—	142
Contribution Revenue	1,500	329
Total Revenue	$ 2,545	$ 1,785

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 March 31, 2020, the aggregate amount of transaction price allocated to remaining performance obligations for contracts with an original duration greater than one year was $0.2 million. We do not disclose the value of unsatisfied performance obligations for (i) contracts with an original expected length of one year or less and (ii) contracts for which we recognize revenue at the amount to which we have the right to invoice for services performed. The Company expects to recognize revenue on the remaining performance obligations over the next 21 months.

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 March 31, 2020 and December 31, 2019.

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 $0.2 million at March 31, 2020 and December 31, 2019. Revenue recognized in the three months ended March 31, 2020 relating to contract liabilities at December 31, 2019 was $0.1 million, and related to 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 June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). This ASU requires measurement and recognition of expected credit losses for financial assets. This standard will become effective for us beginning January 1, 2020. The Company adopted ASU 2016-13 on January 1, 2020. The adoption did not have a material impact on our financial statements.

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. The Company adopted ASU 2018-13 on January 1, 2020. The results of adoption are reflected in Note 3.

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. We adopted ASU 2018-18 on January 1, 2020. The adoption did not have a material impact on our financial statements.

Accounting Standards Issued, Not Adopted

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes: Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2020, with early adoption permitted. Adoption of the standard requires certain changes to be made prospectively, with some changes to be made retrospectively. We do not expect the adoption of this standard to have a material impact on our financial position, results of operations or cash flows.

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 March 31, 2020 and December 31, 2019 (in thousands):

	Balance at March 31, 2020	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$ 726	$ 726	$ —	$ —
Restricted cash	180	180	—	—
	$ 906	$ 906	$ —	$ —
Liabilities:				
Derivative liability	$ 2,314	$ —	$ —	$ 2,314
	$ 2,314	$ —	$ —	$ 2,314

	Balance at December 31, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$ 4,301	$ 4,301	$ —	$ —
Restricted cash	180	180	—	—
	$ 4,481	$ 4,481	$ —	$ —
Liabilities:				
Derivative liability	$ 2,425	$ —	$ —	$ 2,425
	$ 2,425	$ —	$ —	$ 2,425

The Company maintains certificates of deposit, classified as restricted cash, for $0.2 million (Note 4). 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.

The fair value of the derivative at March 31, 2020 and December 31, 2019 is $2.3 million and $2.4 million, respectively, and is classified as a current liability on the balance sheet at March 31, 2020 and December 31, 2019 to match the classification of the related Term Loan Agreement (Note 6).

The estimated fair value of the derivative at March 31, 2020 was determined using a probability-weighted discounted cash flow model that includes contingent interest payments under the following scenarios:

	Range
4% contingent interest beginning in 2020	90.0%
4% contingent interest beginning in 2021	10.0%

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, 2019	$	2,425
Change in fair value of derivative liability, recorded as interest expense		(111)
Balance at March 31, 2020	$	2,314

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 March 31, 2020 and December 31, 2019, the Company had certificates of deposit for $0.2 million, 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):

	March 31, 2020	December 31, 2019
Raw materials	$ 1,232	$ 1,617
Work-in-process	1,016	1,227
Finished goods	1,027	755
Total inventories, net	$ 3,275	$ 3,599

The COVID-19 pandemic caused the Company to reassess its build plan and evaluate its inventories accordingly, which resulted in an additional $0.6 million charge to cost of product revenue for the three months ended March 31, 2020.

Property and Equipment

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

	March 31, 2020	December 31, 2019
Office and computer equipment	$ 538	$ 538
Software	762	762
Laboratory equipment	4,785	4,747
Furniture	194	194
Manufacturing equipment	672	672
Manufacturing tooling and molds	255	255
T2-owned instruments and components	5,575	6,775
Leasehold improvements	3,497	3,497
Construction in progress	1,642	1,641
	17,920	19,081
Less accumulated depreciation and amortization	(13,688)	(13,236)
Property and equipment, net	$ 4,232	$ 5,845

Construction in progress is primarily comprised of equipment that has 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 March 31, 2020 and December 31, 2019, there were $0.1 million and $0.6 million, respectively, of raw materials and work-in-process inventory in T2-owned instruments and components. 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 $0.1 million and $0.2 million for the three months ended March 31, 2020 and 2019, respectively.

The Company believes the COVID-19 pandemic will reduce product sales and impair the ability to recover the cost of the T2-owned instruments and components. The Company assessed the impact on the related cash flows of the T2-owned instruments and reduced the respective carrying values by $0.6 million as of March 31, 2020, which is recorded as cost of product revenue impairment expense.

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 $0.5 million and $0.6 million was charged to operations for the three months ended March 31, 2020 and 2019, respectively.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	March 31, 2020	December 31, 2019
Accrued payroll and compensation	$ 1,582	$ 3,193
Accrued final fee	2,568	2,445
Accrued research and development expenses	413	267
Accrued professional services	1,174	511
Accrued interest	906	908
Operating lease liabilities	2,033	1,983
Other accrued expenses	1,353	1,900
Total accrued expenses and other current liabilities	$ 10,029	$ 11,207

At March 31, 2020 and December 31, 2019, the Company classified $2.6 million and $2.4 million, respectively, related to a fee associated with the Company's Term Loan Agreement (Note 6), as accrued final fee in the table above to match the current classification of the associated debt. Included within other accrued expenses in the table above, at March 31, 2020 is $0.6 million from the Second Amendment to Employment Agreement with John McDonough (the "Transition Agreement") (Note 13). Included within

other accrued expenses and accrued payroll and compensation in the table above, at December 31, 2019 is $1.0 million and $0.2 million, respectively related to the Transition Agreement. Included within other accrued expenses in the table above at March 31, 2020 is $0.3 million of severance associated with our reduction in headcount as described in Note 1.

6. Notes Payable

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

	March 31, 2020	December 31, 2019
Term loan agreement before unamortized PIK interest, discount and issuance costs	$ 48,077	$ 48,077
Less: unamortized paid-in-kind interest	(2,888)	(3,284)
Less: unamortized discount and deferred issuance costs	(1,789)	(1,891)
Total notes payable	$ 43,400	$ 42,902

The Term Loan Agreement with CRG is classified as a current liability on the balance sheet at March 31, 2020 and December 31, 2019 based on the Company's consideration of the probability of violating the 2020 revenue covenant primarily due to the COVID-19 pandemic's likely impact on our product sales, which in turn would trigger violation of 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, as amended, require quarterly principal payments of $12.0 million commencing March 31, 2022 through maturity December 31, 2022.

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 March 31, 2020 and December 31, 2019 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 eliminate the 2018 revenue covenant. In exchange for the amendment, the Company agreed to reset the strike price of the warrants to purchase a total of 528,958 shares of the Company's common stock, issued in connection with the Term Loan Agreement, from $8.06 per share to $4.35 per share (Note 9).

In September 2019, the Term Loan Agreement was amended to extend the interest-only payment period through December 31, 2021, to extend the initial principal repayment to March 31, 2022, and to reduce the minimum product revenue target for 2019 from $9 million to $4 million, for the twenty-four month period beginning on January 1, 2019 from $95 million to $15 million and for the twenty-four month period beginning on January 1, 2020 from $140 million to $43 million. The final payment fee was increased from 8% to 10% of the principal amount outstanding upon repayment. The Company issued to CRG warrants to purchase 568,291 shares of the Company's common stock ("New Warrants") (Note 9) at an exercise price of $1.55, 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 Company also reduced the exercise price for the warrants previously issued to CRG to purchase an aggregate of 528,958 shares of the Company's common stock to $1.55. All of the New Warrants are exercisable any time prior to September 9, 2029, and all of the previously issued warrants are exercisable any time prior to December 30, 2026. The Company accounted for the March 2019 and September 2019 amendments as modifications to 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. 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.

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 was capped at a maximum of $5.0 million. Under the Credit Facility, Essex funded capital equipment purchases presented by the Company. The Company repaid 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 had 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 were 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 was included as a component of depreciation expense. During the year ended December 31, 2019, the Company repurchased the equipment for $0.3 million in accordance with the terms of the Credit Facility.

7. Stockholders' (Deficit) 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 $30.0 million from time to time through Canaccord. On March 9, 2020, the Company entered into an amendment to the Sales Agreement to increase the aggregate gross sales amount from $30.0 million to $65.0 million. On April 8, 2020, the Company entered into an amendment to the Sales Agreement to increase the aggregate gross sales amount from $65.0 million to $95.0 million. As of March 31, 2020, the Company had sold 73,237,178 shares of common stock with an aggregate gross sales amount of approximately $48.1 million, leaving approximately $46.9 million remaining under the Equity Distribution Agreement.

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, subject to shelf limitations if any, 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 an amount equal to 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. Legal and accounting fees are expected to be changed to share capital upon issuance of shares under the Sales Agreement.

During the three months ended March 31, 2020, the Company sold 67,750,678 shares for net proceeds of $39.8 million after expenses in connection with the Sales Agreement.

Purchase Agreement

On July 29, 2019, the Company entered into a $30.0 million Purchase Agreement with Lincoln Park, pursuant to which the Company was able to sell and issue to Lincoln Park, and Lincoln Park was obligated to purchase, up to $30.0 million 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. On April 7, 2020, the Company terminated the Purchase Agreement, effective April 8, 2020.

The Company was able to 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 had passed since the most recent purchase. The amount of a purchase could be increased under certain circumstances provided, however, that Lincoln Park's committed obligation under any single purchase would not exceed $2.0 million. The purchase price of shares of common stock related to the future funding was based on the then prevailing market prices of such shares at the time of sales as described in the Purchase Agreement.

In consideration for the execution and delivery of the Purchase Agreement, the Company issued 413,349 shares of common stock to Lincoln Park.

During the three months ended March 31, 2020, the Company sold 400,000 shares for proceeds of $0.3 million in connection with the Purchase Agreement.

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 vested 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, lapse 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, 2026, 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 March 31, 2020, there were 1,302,541 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 most recently, amended and restated in January 2020, provides for the granting of equity awards to new employees, including 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 5,625,000 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 March 31, 2020, there were 2,055,103 shares available for future grant under the Inducement Plan.

Stock Options

During the three months ended March 31, 2020 and 2019, the Company granted stock options with an aggregate fair value of $3.0 million and $2.0 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, 2019	6,353,330	$ 4.95	7.29	$ 229
Granted	4,011,500	0.99		
Exercised	—	—		
Forfeited	(528,087)	2.09		
Cancelled	(38,876)	10.93		
Outstanding at March 31, 2020	9,797,867	$ 3.46	8.00	$ 200
Exercisable at March 31, 2020	3,679,029	$ 6.25	5.57	$ —
Vested or expected to vest at March 31, 2020	8,534,515	$ 3.74	7.76	$ 151

There were no options exercised in the three months ended March 31, 2020 and 2019. The weighted-average grant date fair values of stock options granted in the three month periods ended March 31, 2020 and 2019 were $0.74 per share and $2.20 per share, respectively, and were calculated using the following estimated assumptions:

	Three Months Ended March 31,	
	2020	2019
Weighted-average risk-free interest rate	1.50%	2.52%
Expected dividend yield	—%	—%
Expected volatility	91%	71%
Expected terms	6.0 years	6.0 years

The total fair values of options that vested during the three months ended March 31, 2020 and 2019 were $0.8 million and $1.0 million, respectively.

As of March 31, 2020, there was $7.3 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 2.9 years as of March 31, 2020.

Restricted Stock Units

During the three months ended March 31, 2020, 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 units, excluding any restricted stock units with market conditions, vest through the passage of time, assuming continued service. Restricted stock units are not included in issued and outstanding common stock until the shares are vested and released. During the year ended December 31, 2018, an additional 73,172 restricted stock units vested but are not reflected as outstanding shares at December 31, 2019 due to a deferred release date. These restricted stock units are reflected as outstanding shares at March 31, 2020. 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 $0.5 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 March 31, 2020 are 399,437 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 immaterial for the three months ended March 31, 2020 and $0.7 million for the three months ended March 31, 2019.

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, 2019	1,295,508	4.19
Granted	917,064	0.54
Vested	(297,245)	3.72
Forfeited	(438,430)	4.10
Cancelled	—	—
Nonvested at March 31, 2020	1,476,897	2.04

As of March 31, 2020, there was $1.1 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 2.13 years, as of March 31, 2020.

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 March 31,	
	2020	2019
Cost of product revenue	$ 42	$ 50
Research and development	299	364
Selling, general and administrative	802	1,506
Total stock-based compensation expense	$ 1,143	$ 1,920

For the three months ended March 31, 2020, stock-based compensation expenses capitalized as part of inventory or T2Dx instruments and components was immaterial. For the three months ended March 31, 2019, stock-based compensation expenses capitalized as part of inventory of T2Dx instruments and components was $0.1 million.

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.

In connection with the September 2019 amendment of the Term Loan Agreement, the Company issued to CRG warrants to purchase 568,291 shares of the Company's common stock at an exercise price of $1.55, 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 Company also reduced the exercise price for the warrants previously issued to CRG to $1.55. All of the New Warrants are exercisable any time prior to September 9, 2029. 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 new and amended warrants was determined by the Black-Scholes-Merton option pricing model. The incremental fair value of the amended warrants of $0.1 million and the fair value of the New Warrants of $0.7 million were 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 Months Ended March 31,	
	2020	2019
Options to purchase common shares	9,797,867	5,092,470
Restricted stock units	1,476,897	1,656,048
Warrants to purchase common stock	1,097,249	528,958
Total	12,372,013	7,277,476

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") 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.

The Co-Development Agreement was completed in 2019 and the Company did not record any revenue for the three months ended March 31, 2020 and recorded revenue of $0.1 million for the three months ended March 31, 2019.

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 did not record any revenue for the three months ended March 31, 2020. The Company recognized the $0.9 million that was awarded under the reimbursement option in 2019, and recorded revenue of $0.3 million for the three months ended March 31, 2019, under the CARB-X Agreement. The Company will not recognize any additional revenue under the CARB-X agreement.

US Government Contract

In September 2019, the Biomedical Advanced Research and Development Authority ("BARDA") awarded the Company a milestone-based contract, with an initial value of $6.0 million, and a potential value of up to $69.0 million, if BARDA awards all contract options. BARDA operates within the Office of the Assistant Secretary for Preparedness and Response ("ASPR") at the U.S. Department of Health and Human Services' ("HHS"). If BARDA awards and the Company completes all options, the Company's management believes it will enable a significant expansion of the Company's current portfolio of diagnostics for sepsis-causing pathogen and anti-biotic resistance genes.

The Company recorded revenue of $1.5 million for the three months ended March 31, 2020. The contract began in September 2019 and the Company did not record any revenue under the US Government Contract for the three months ended March 31, 2019.

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 $160,000 in January 2018, which is recorded as restricted cash in the condensed 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 condensed 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 May 2020, the Company provided written notice of its intent to vacate this space on June 30, 2020; however, at this time, we cannot estimate the impact that this may or may not have.

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 condensed 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 reclassified 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 condensed 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.

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 three months ended March 31, 2020 and 2019 were immaterial.

Worldwide Licensing Agreement

In March 2020, the Company entered into a worldwide licensing agreement for a rapid COVID-19, novel coronavirus test developed by the Center of Discovery and Innovation at Hackensack Meridian *Health*. The licensed coronavirus assay has been used by healthcare professionals within the Hackensack Meridian *Health* network, under the U.S. Food and Drug Administration's ("FDA") Emergency Use Authorization guidance, to test and treat patients suspected of having coronavirus. Under the terms of the agreement, the Company will adapt the coronavirus test to run on its T2Dx Instrument. Hackensack Meridian *Health* will also adopt the T2Dx Instrument and test panels within its Center of Discovery and Innovation.

Transition Agreement

On July 30, 2019, the Company announced that founding CEO John McDonough was named Executive Chairman of the Board until a successor is named at which time Mr. McDonough will become non-executive Chairman of the Board. John Sperzel was named CEO in January 2020. In connection with John McDonough's transition to Non-Executive Chairman of the Board from CEO, the Company agreed to transition payments and health benefits to be paid over the 15 month period following Mr. Sperzel's start date. At December 31, 2019, included within other accrued expenses is $1.0 million related to Mr. McDonough's transition payments and health benefits and included within accrued payroll and compensation is $0.2 million related to Mr. McDonough's bonus. At March 31, 2020, included within other accrued expenses is $0.6 million related to Mr. McDonough's transition payments and health benefits.

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 are subject to numerous risks, including, without limitation, the following:

- *the impact of the COVID-19 pandemic on our business, results of operations and financial positions;*
- *our ability to continue as a going concern;*
- *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 relatively 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 cybersecurity risks, including ransomware, phishing, and data breaches on our information technology systems;*
- *the impact of short sellers on our share price;*
- *our dependence on third parties;*
- *manufacturing and other product risks;*
- *the impact of the adoption of new accounting standards;*
- *the Tax Cuts and Jobs Act of 2017 (Tax Reform);*
- *the impact of recent cost-cutting measures; and*
- *our ability to maintain compliance with NASDAQ listing requirements.*

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 Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Quarterly Report on Form 10-Q, and Part I, Item 1A and Part II, Item 7A, "Risk Factors" and "Quantitative and Qualitative Disclosures about Market Risks", respectively, in our Annual Report on Form 10-K for the year ended December 31, 2019, as updated by Part I, Item 3, "Quantitative and Qualitative Disclosures about Market Risks" and Part II, Item 1A—"Risk Factors" 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 condensed consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2019.

Business Overview

We are an in vitro diagnostics company and leader in the rapid detection of sepsis-causing pathogens, is dedicated to improving patient care and reducing the cost of care by helping clinicians effectively treat patients faster than ever before. We have developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. We are using our T2MR technology to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. T2MR enables rapid detection of pathogens, biomarkers and other abnormalities in a variety of unpurified patient sample types, including whole blood, plasma, serum, saliva, sputum and urine, and can detect cellular targets at limits of detection as low as one colony forming unit per milliliter, or CFU/mL. Our products include the T2Dx Instrument, T2Candida Panel, the T2Bacteria Panel, and the T2Resistance™ Panel, that are all powered by our proprietary T2MR technology. Our development efforts target sepsis, COVID-19, and Lyme disease, which are areas of significant unmet medical need in which existing therapies could be more effective with improved diagnostics.

On September 22, 2014, we received market clearance from the FDA for our first two products, the T2Dx® Instrument, or the T2Dx and the T2Candida® Panel, or 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 the T2Bacteria® Panel, or 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 below in *Our T2Bacteria Panel*) directly from whole blood. We have also developed and sell a research use only *Candida auris* assay, the T2Cauris™ Panel, 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, which can assist clinicians in selecting effective antibiotics. The T2Resistance Panel received FDA Breakthrough Device designation in February 2019 and was granted a CE Mark in November 2019. An additional diagnostic application in development is the T2Lyme™ Panel, or T2Lyme, which is focused on the detection of the bacteria that cause Lyme disease. Diagnostic applications for additional bacteria species and resistance markers were developed 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. On August 2, 2019, the Company's T2Bacteria Panel received a New Technology Add-on Payment (NTAP) from CMS, including a unique and stand-alone ICD-10-PCS Code. In September 2019, the Biomedical Advanced Research and Development Authority ("BARDA") awarded the Company a milestone-based contract, with an initial value of $6 million, and a potential value of up to $69 million, for the development of new direct-from-blood diagnostic panels that will run on the T2Dx. 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 a commercial team that is primarily targeting 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, T2Bacteria, T2Resistance, and T2Cauris, will redefine the standard of care in sepsis management while lowering healthcare costs by improving both the precision and the speed to 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 their 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 antimicrobial 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, T2Candida, and T2Resistance, which all 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 March 31, 2020 was $391.1 million, we had a stockholders' deficit of $7.7 million and we have experienced cash outflows from operating activities over the past years. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations. We have incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution of our FDA-cleared products, T2Dx, T2Candida and T2Bacteria. In addition, we will continue to incur significant costs and expenses as we continue to develop other product candidates, improve existing products and maintain, expand and protect our intellectual property portfolio. We may seek to fund our operations through public equity or private equity or debt financings, as well as other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on our business, results of operations and

financial condition and our ability to develop, commercialize and drive adoption of the T2Dx Instrument, T2Candida, T2Bacteria, T2Resistance, and future T2MR-based diagnostics.

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

The COVID-19 pandemic has impacted our operations. We have established protocols for continued manufacturing, distribution and servicing of our products with safe social distancing and personal protective equipment measures and for remote work for employees not essential to on-site operations. To date these measures have been successful but may not continue to function should the pandemic continue to escalate and further impact our personnel. Our hospital customers have restricted our sales team's access to their facilities and as a result, we significantly reduced our sales and general and administrative staffing levels to reduce expenses. Our customers may reduce their purchases of our products. Our customer's may cease to comply with the terms of our sales agreements and this may impact our ability to recognize revenue and hinder receivables collections. We have a significant development contract with a United States Government agency and should the agency reduce, cancel or not grant additional milestone projects our ability to continue our future product development may be impacted. Our shipping carrier's ability to deliver our products to customers may be disrupted. We have reviewed our suppliers and quantities of key materials and believe we have sufficient stocks and alternate sources of critical materials should our supply chains become disrupted. We believe the pandemic's impact on our sales has impacted the recoverability of the value of our T2-owned instruments and components. The COVID-19 pandemic also caused us to reassess our build plan and evaluate our inventories accordingly, which resulted in an additional charge to cost of product revenue.

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 our 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 March 31, 2020, along with additional funding available through the Company's Equity Distribution Agreement (the "Sales Agreement") with Canaccord Genuity LLC, as agent ("Canaccord") (Note 7) in the future, will be sufficient to allow us to fund our current operating plan, at least a year from issuance of these financial statements, assuming availability of funds. However, as certain elements of our operating plan are outside of our control, including the ability to sell shares under the Sales Agreement, those elements cannot be considered probable. 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. During the three months ended March 31, 2020, we implemented a cost improvement strategy which is focused on reducing operating expenses and improving our cost of goods sold. We reduced our total employee headcount by 22% as compared to headcount at December 31, 2019, resulting in severance of $0.4 million, of which $0.3 million is included within other accrued expenses at March 31, 2020. The Term Loan Agreement with CRG Servicing LLC ("CRG") (Note 6) requires that we 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 cash balance of $5.0 million. The Term Loan Agreement with CRG is classified as a current liability on the balance sheet at March 31, 2020, based on our consideration of the probability of violating the 2020 revenue covenant primarily due to the COVID-19 pandemic's likely impact on our product sales, which in turn would trigger violation of the minimum liquidity covenant. 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. On April 7, 2020, we received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Global Market under Nasdaq Listing Rule 5450(a)(1).

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. Our plans to alleviate the conditions that raise substantial doubt include raising additional funding, earning 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 for us to continue as a going concern for a period of twelve months from the date the financial statements are issued. We have concluded the likelihood that our 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, we have concluded that substantial doubt exists about our 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.

Our Commercial Products and the Unmet Clinical Need

The T2 Biosystems 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, our 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 when compared to conventional blood customer-based methods, 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 receiving 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 our T2 Biosystems portfolio, 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 of faster time to effective therapy include a reduction in average patient length of stay within a hospital, including the intensive care unit (ICU) 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 T2 Biosystems 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, T2 Biosystems diagnostic products enable 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 *Candida* and sepsis-causing bacteria, respectively, directly from whole blood in as few as three hours versus the one to six or more days typically required by blood culture-based diagnostics. This allows the patient to potentially receive the correct treatment in four to six hours versus 24 to 144 hours for blood culture. The T2Candida Panel and T2Bacteria Panel run on the T2Dx Instrument and offer 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 an infection with a mortality rate of approximately 30%. According to data published by HHS for 2020, the cost of sepsis was over $41 billion in the United States, building on previous data demonstrating that sepsis was responsible for approximately 5% of the total aggregate costs associated with domestic hospital stays. Sepsis is typically caused by one or more of five *Candida* species or over 25 bacterial pathogens, and effective treatment requires the early detection and identification of these specific target pathogens in a patient's bloodstream. Today, sepsis is typically diagnosed through a series of blood cultures followed by post-blood culture species identification. These methods have substantial diagnostic limitations that lead to a high rate of false negative test results, a delay of up to several days in administration of targeted treatment and the incurrence of unnecessary hospital expense. In addition, the Survey of Physicians' Perspectives and Knowledge About Diagnostic Tests for Bloodstream Infections in 2015 reported that negative blood culture results are only trusted by 36% of those physicians. Without the ability to rapidly identify pathogens, physicians typically start treatment of at-risk patients with broad-spectrum antibiotics, which can be ineffective and unnecessary and have contributed to the spread of antimicrobial resistance. According to a study published by Critical Care Medicine in 2006, in sepsis patients with documented hypotension, administration of effective antimicrobial therapy within the first hour of detection was associated with a survival rate of 79.9% and, over the ensuing six hours, each hour of delay in initiation of treatment was associated with an average decrease in survival of 7.6%.

We believe our sepsis products, which include T2Candida, T2Bacteria, T2Resistance, and T2Cauris have the potential to 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.

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

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.) The value of T2Candida as a clinical tool for aiding antimicrobial stewardship and improving timely initiation of antifungal therapy for candidemia was demonstrated in a 2017 publication in the Journal of Antimicrobial Stewardship. Results showed a reduction in median time to appropriate antifungal therapy and a reduction in candida ocular infection. In 2018 the DIRECT 2 study was published sharing data from 14 centers evaluating the clinical sensitivity of 152 hospitalized patients with candidemia. T2Candida detected 37 patients with recent candidemia missed by blood cultures, and detected Candida species in significantly more patients receiving antifungal therapy prior to the blood draw highlighting the increased sensitivity of T2Candida compared to blood culture especially in patients receiving antifungal therapy.

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."

Data published in 2019 in Diagnostic Mircobiology and Infectious Disease compared T2Candida to beta-D-glucan to facilitate antifungal discontinuation in the intensive care unit. The investigators found that T2Candida testing supports safe, early discontinuation of empiric antifungal therapy in ICU patients with suspected candidemia. Patients tested with T2Candida had significantly more early antifungal discontinuation and significantly shorter duration of empiric antifungal therapy compared to patients tested with beta-D-glucan.

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.

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.

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. The T2Bacteria Panel is designed to identify five species of bacteria directly from human whole blood specimens: *Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa*, and *Staphylococcus aureus.* Outside of the United States, the CE-marked T2Bacteria panel identifies all 5 of these species along with a 6th species, *Acinetobacter baumannii*.

The 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.

The results from our pivotal clinical trial for T2Bacteria, which was published on May 14, 2019 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 the T2Bacteria Panel 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.

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%. At IDWeek 2019, data was presented from a prospective, interventional evaluation of the clinical impact of the T2Bacteria panel on patients with suspected blood stream infections in Vienna, Austria. Forty-four patients were evaluated and T2Bacteria detected more pathogens than blood culture with a faster time to species ID and targeted antibiotic therapy.

November 23, 2019 data on the performance of T2Bacteria in the emergency department of Ochsner Medical Center and Tampa General Hospital was accepted for publication in Clinical Laboratory in Emergency Medicine. 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.

At the Transplant and Cellular Therapies conference in 2020, data was presented evaluating the utility of the T2Bacteria Panel for Antimicrobial Stewardship in patients undergoing hematopoietic stem cell transplantation. This prospective evaluation of 39 HSCT patients with febrile neutropenia sought to evaluate the use of T2Bacteria Panel for early de-escalation of anti-pseudomonal therapy. The investigators found early de-escalation of anti-pseudomonal therapy in 49% of patients for a total of 124 days of therapy saved (5.2 per patient).

On August 2, 2019, the United States Centers for Medicare & Medicaid Services (CMS) granted approval for a New Technology Add-on Payment (NTAP) for the T2Bacteria Panel for FY 2020. In its FY 2020 inpatient prospective payments system final rule, CMS explained: "the T2Bacteria Test Panel represents a substantial clinical improvement over existing technologies because it reduces the proportion of patients on inappropriate therapy, thus reducing the rate of subsequent diagnostic or therapeutic intervention as well as length of stay and mortality rates caused by sepsis causing bacterial infections." With this designation, hospitals in the United States treating Medicare inpatients with sepsis will now be eligible for a NTAP, in addition to the standard payment amount. In the final rule, CMS determined a maximum NTAP amount of $97.50 for the T2Bacteria Panel in addition to the diagnosis-related group (MS-DRG)-based reimbursement that hospitals receive under the Medicare Hospital Inpatient Prospective Payment System (IPPS). Hospitals will be eligible for the NTAP for any in-patient T2Bacteria Panel tests performed on Medicare patients beginning October 1, 2019. The maximum NTAP reimbursement for a qualifying case involving the use of the T2Bacteria Panel is $97.50, (65 percent of the list price of one T2Bacteria Panel test) in addition to standard hospital payment under the appropriate sepsis MS-DRG codes. According to CMS there are more than 30 million Medicare patients in the United States enrolled in Medicare fee-for-service.

Our T2Cauris Panel

On September 6, 2017, we announced that the CDC has agreed to validate the T2Dx Instrument and the T2Cauris investigational use only panel in their laboratory for potentially testing and monitoring the emergence and outbreaks of the superbug *Candida auris* in hospitals around the country. *Candida auris* is a multi-drug resistant pathogen recognized by the CDC as a "serious global health threat" because it can be resistant to "all three major classes of antifungal drugs" and difficult to identify. The CDC has also reported that more than one in three patients with *Candida auris* infections have died. Unlike most other species of Candida, *Candida auris* can spread quickly in a hospital making rapid identification and hospital environment surveillance a critical component of containing these outbreaks. Existing laboratory methods that detect *Candida auris*, including blood culture, suffer from prolonged detection times and low accuracy, which exacerbates the challenge in the fight to contain the superbug. Recently, reported cases have surged internationally, and the CDC has reported a significant increase in infected patients in the United States. According to the European Centre for Disease Prevention and Control, hospital outbreaks have occurred in the United Kingdom and Spain. Because *Candida auris* can be resistant to most treatment options and can spread so quickly, these hospital outbreaks have been difficult to contain by even the most enhanced control measures. Multiple hospitals and labs in the Middle East and Africa are conducting evaluations to demonstrate the ability to detect *Candida auris* directly in patient blood specimens. The T2Cauris panel is currently available in the US and international geographies, as a Research Use Only (RUO) test, which can be used to monitor environmental contamination or used in studies to detect colonization of *Candida auris* on patient's skin or to detect the presence of *Candida auris* in whole blood samples. Since demand is driven by infrequent occasional regional outbreaks, we expect customers will either stockpile or order in large bulk quantities as required. RUO product can be used without licensure to test for contaminated surfaces or as a laboratory developed test (LDT) depending on sample preparation.

The T2Cauris Panel demonstrated significantly shorter time to detection (<5 hours) compared to blood culture, that took multiple days. Other methods using skin swabs take up to 14 days and are unable to detect low levels of C.auris. The T2Cauris Panel can detect levels as low as <5 CFU/ml which is greater than a 100-fold increase in sensitivity compared to other molecular diagnostic tests for C. auris. Other detection methods currently available utilize real-time PCR or conventional PCR techniques that are very time-consuming and laborious. 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.

Our T2 Resistance Panel

The T2Resistance Panel is the only direct-from-blood diagnostic assay for the detection of antibiotic resistance genes associated with sepsis causing pathogens. The T2Resistance Panel identifies many of the most serious resistance genes on the antibiotic resistance threat list published by the CDC including genes indicating resistance to common empiric antibiotic therapies such as carbapenems, vancomycin and more. A recent study was conducted in which 26 patients were enrolled based on having symptoms consistent with bloodstream infection. The data showed that the T2Resistance Panel has a clinical sensitivity and specificity of 100% and that the average time to result was 4.1 hours which was 53.2 hours faster than with standard blood culture methods. We believe this panel will be beneficial to patients with risk factors for, or colonization with, antimicrobial resistant organisms, as well as those with positive blood culture or T2Bacteria results.

The T2 Resistance panel has received CE Mark and is currently marketed and sold internationally. The first routine use of T2 Resistance was implemented in Greece, and subsequent sales have occurred elsewhere in Europe. The panel still requires clinical validation and FDA clearance in the US prior to being available for clinical use.

Our T2 Biosystems Portfolio

We believe our T2 Magnetic Resonance technology, or T2MR, delivers what no conventional technology currently available can: a rapid, sensitive and simple diagnostic platform to enable sepsis applications that can identify specific sepsis pathogens directly from an unpurified blood sample in hours instead of days at a level of accuracy equal to or better than blood culture-based diagnostics. The addition of the use of our products, T2Bacteria and T2Candida, which both run on the T2Dx, with the standard of care for the management of patients suspected of sepsis enables clinicians to potentially treat 90% of patients with sepsis pathogen infections with the right targeted therapy within the first twelve hours of developing the symptoms of disease. Currently, high risk patients are typically initially treated with broad spectrum antibiotic drugs that typically cover approximately 60% of patients with infections. Of the remaining 40% of patients, approximately 30% of the patients have a bacterial infection and 10% have *Candida* infections. T2Candida and T2Bacteria are designed to identify pathogens commonly not covered by broad spectrum antibiotic drugs.

We believe our products provide a pathway for more rapid and targeted treatment of infections, potentially reducing the mortality rate by as much as 75% if a patient is treated within 12 hours of suspicion of infection and significantly reducing the cost

burden of sepsis. Each year, approximately 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 T2 Biosystems Portfolio 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. Based on feedback from the FDA and the dynamics of the Lyme disease testing market, we currently believe that the most expeditious path for commercializing the T2Lyme panel is to offer the test with a single partner as a lab developed test. Our current goal is to have T2Lyme validated in a partner's lab for commercial launch. Due to the outbreak of the recent COVID-19 pandemic, we are not certain as to the timing of when this may be achieved.

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

US Government Contract

In September 2019, the Biomedical Advanced Research and Development Authority (“BARDA”) awarded the Company a milestone-based contract, with an initial value of $6 million, and a potential value of up to $69 million, if BARDA awards all contract options. BARDA operates within the Office of the Assistant Secretary for Preparedness and Response (“ASPR”) at the U.S. Department of Health and Human Services’ (“HHS”).” If BARDA awards and the Company completes all options, management believes it will enable a significant expansion of the Company’s current portfolio of diagnostics for sepsis-causing pathogen and anti-biotic resistance genes.

COVID-19

On March 24, 2020, the Company announced that it had licensed certain technology for the development of a rapid test for COVID-19 from the Center for Discovery and Innovation (CDI) at Hackensack Meridian Health. Under this license agreement, T2 Biosystems is authorized to use the CDI technology and adapt the CDI-developed COVID-19 test to the T2 Biosystems platform, and market and distribute the test in places of need amid the expanding pandemic. We believe the test will be capable of running on the T2Dx Instrument, the same instrument which runs the FDA-cleared T2Bacteria and T2Candida Panels and believe the test will detect the SARS-CoV-2 virus directly in patient swab samples in a fully automated sample-to-answer manner.

Clinical data from Wuhan, China showed that for COVID-19 patients, bacterial and fungal co-infections are a significant burden with 71% of patients being treated for bacterial infections and 15% treated for fungal infections Given the high incidence of bacterial and fungal co-infections and the SARS-CoV-2 test in development, we believe the T2 Biosystems technology has the potential to address the diagnostic needs of COVID-19 patients by helping identify bacterial and fungal secondary infections associated with coronavirus and detecting the virus directly. Taken together, these capabilities have the potential to enable clinicians to target therapy for patients with secondary bacterial or fungal infections associated with primary COVID-19 infections.

The Company believes that the COVID-19 test may be fully automated on the T2Dx as soon as the end of the quarter. The Company plans to launch this test under the Emergency Use Authorization (EUA) FDA pathway for use in the United States.

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 and government contributions.

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 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.

Product revenue is derived from the sale of our instruments and related consumable diagnostic tests, predominantly through our direct sales force in the United States, and distributors in geographic regions outside the United States. We do not offer product return or exchange rights (other than those relating to defective goods under warranty) or price protection allowances to our customers, including our distributors. Payment terms granted to distributors are the same as those granted to end-user customers and payments are not dependent upon the distributors' receipt of payment from their end-user customers. We either sell instruments to customers and international distributors or retain title and place the instrument at the customer site pursuant to a reagent rental agreement. When the instrument is directly purchased by a customer, we recognize 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, our 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, Leases ("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. We will recognize the revenue allocated to the extended Maintenance Services performance obligation straight-line over the service delivery period. We warrant 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, we provide replacement product free of charge. Accordingly, we accrue warranty expense associated with the estimated defect rates of the consumable diagnostic tests.

Our current sales strategy is focused on driving adoption of our technology within the hospital market, increasing test utilization amongst our existing installed based on T2Dx Instruments, and opportunistically increasing the installed based. Accordingly, 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.

However, we believe the COVID-19 pandemic will hinder our near term sales growth. Our customers may cease to comply with the terms of our sales agreements and this may impact our ability to recognize revenue and hinder receivables collections.

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 decrease as a result of a cost of product revenue improvement plan that we initiated during the three months ended March 31, 2020.

We believe the COVID-19 pandemic will reduce product sales and impair our ability to recover the cost of our T2-owned instruments and components. We assessed the impact on the related cash flows of the instruments and reduced their carrying values by $0.6 million as of March 31, 2020, which was recorded as cost of product revenue impairment expense. The COVID-19 pandemic also caused us to reassess our build plan and evaluate our inventories accordingly, which resulted in an additional $0.6 million charge to cost of product revenue.

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 decrease due to our cost improvement strategy which is focused on reducing operating expenses. We expect to continue developing additional product candidates, improving existing products, and conducting ongoing and new clinical trials. We have a significant development contract with a United States Government agency and should the agency reduce, cancel or not grant additional milestone projects our ability to continue our future product development may be impacted.

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 decrease in future periods as we have decided to focus our resources on growing adoption at existing customers and to significantly reduce the overall size of our U.S. sales and sales management teams. 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, the amortization of deferred financing costs and debt discount, and interest earned on our cash and cash equivalents.

Other income, net

Other income, net, consists of dividend and other investment 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, 2019 remained materially consistent. For a description of those critical accounting policies, please refer to our Annual Report on Form 10-K filing for the year ended December 31, 2019.

Results of Operations for the Three Months Ended March 31, 2020 and 2019

	Three Months Ended March 31,		
	2020	2019	Change
	(in thousands)		
Revenue:			
Product revenue	$ 1,045	$ 1,314	$ (269)
Research revenue	—	142	(142)
Contribution revenue	1,500	329	1,171
Total revenue	2,545	1,785	760
Costs and expenses:			
Cost of product revenue	4,671	4,388	283
Research and development	4,938	3,901	1,037
Selling, general and administrative	6,497	7,055	(558)
Total costs and expenses	16,106	15,344	762
Loss from operations	(13,561)	(13,559)	(2)
Interest expense, net	(1,417)	(1,782)	365
Other income, net	29	194	(165)
Net loss	$ (14,949)	$ (15,147)	$ 198

Product revenue

Product revenue was $1.0 million for the three months ended March 31, 2020 compared to $1.3 million for the three months ended March 31, 2019, a decrease of $0.3 million. The decrease was driven by less T2Dx instrument sales of $0.4 million, partially offset by higher consumables and other revenue of $0.1 million.

Research revenue

We did not record any research revenue for the three months ended March 31, 2020, compared to $0.1 million for the three months ended March 31, 2019, a decrease of $0.1 million. Research revenue for the three months ended March 31, 2019 relates to our Co-Development Agreement with Canon US Life Sciences, which completed in 2019.

Contribution revenue

Contribution revenue was $1.5 million for the three months ended March 31, 2020, compared to $0.3 million for the three months ended March 31, 2019, an increase of $1.2 million. Contribution revenue for the three months ended March 31, 2020 relates to our U.S. Government Contract, which began in September 2019. Contribution revenue for the three months ended March 31, 2019 relates to our cost-sharing agreement with CARB-X, which completed in 2019.

Cost of product revenue

Cost of product revenue was $4.7 million for the three months ended March 31, 2020, compared to $4.4 million for the three months ended March 31, 2019, an increase of $0.3 million. The increase in cost was driven by a COVID-19 related impairment charge of $0.6 million of our T2-owned instruments and components, a $0.6 million increase primarily from excess instrument raw material as a result of a COVID-19 related reduction in the instrument build plan and an increase of $0.2 million from higher Bacteria sales, partially offset by $0.8 million from less instrument sales and $0.3 million in repairs under service agreements.

Research and development expenses

Research and development expenses were $4.9 million for the three months ended March 31, 2020, compared to $3.9 million for the three months ended March 31, 2019, an increase of $1.0 million. The increase was driven by consulting fees for our US Government Contract of $0.4 million, higher materials cost of $0.3 million and higher internal usage of our products of $0.1 million, both due to increased activity, and increased clinical related expenses of $0.1 million. Research and development expenses also increased $0.1 million from higher lab expenses primarily associated with our US Government Contract.

Selling, general and administrative expenses

Selling, general and administrative expenses were $6.5 million for the three months ended March 31, 2020, compared to $7.1 million for the three months ended March 31, 2019, a decrease of $0.6 million. The decrease was driven by a decrease in stock compensation expense of $0.7 million primarily from the restricted stock units with market conditions, a decrease in payroll related expenses and travel of $0.5 million and $0.1 million, respectively, due to a lower headcount, and a decrease in tradeshow expenses of $0.2 million. These decreases were partially offset by an increase of $0.4 million for work incurred primarily related to the Sarbanes-Oxley Act Section 404, a $0.3 million increase in legal fees related to financings and the CEO transition, and a $0.2 million increase in D&O insurance premiums.

Interest expense, net

Interest expense, net, was $1.4 million for the three months ended March 31, 2020, compared to $1.8 million for the three months ended March 31, 2019. Interest expense, net, decreased by $0.4 million primarily due to a $0.2 million change in interest expense from a change in fair value of the derivative associated with the CRG Term Loan Agreement.

Other income, net

Other income, net, was immaterial for the three months ended March 31, 2020 compared to $0.2 million for the three months ended March 31, 2019, a decrease of $0.2 million, primarily from decreased dividend and other investment income.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception, and as of March 31, 2020 and December 31, 2019 we had an accumulated deficit of $391.1 million and $376.2 million respectively. Having obtained clearance from the FDA and a CE mark in Europe to market the T2Dx, T2Candida, and T2Bacteria, we have incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We may seek to continue 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 and commercialize T2Dx, T2Candida, T2Bacteria, and other product candidates.

The COVID-19 pandemic may impact our operations. We have established protocols for continued manufacturing, distribution and servicing of our products with safe social distancing and personal protective equipment measures and for remote work for employees not essential to on-site operations. To date these measures have been successful but may not continue to function should the pandemic escalate and impact our personnel. Our hospital customers have restricted our sales team's access to their facilities and as a result, we significantly reduced our sales and general and administrative staffing levels to reduce expenses. Our customers may reduce their purchases of our products. Our customers may cease to comply with the terms of our sales agreements and this may impact our ability to recognize revenue and hinder receivables collections. We have a significant development contract with a United States Government agency and should the agency reduce, cancel or not grant additional milestone projects our ability to continue our future product development may be impacted. Our shipping carriers' ability to deliver our products to customers may be disrupted. We have reviewed our suppliers and quantities of key materials and believe we have sufficient stocks and alternate sources of critical materials including personal protective equipment should our supply chains become disrupted. As further described in Note 5, we believe the pandemic's impact on our sales has impacted the recoverability of the value of our T2-owned instruments and components. The COVID-19 pandemic also caused us to reassess our build plan and evaluate our inventories accordingly, which resulted in an additional charge to cost of product revenue.

Historically, we have funded our operations primarily through our August 2014 initial public offering, our December 2015 public offering, our September 2016 private investment in public equity ("PIPE") financing, our September 2017 public offering, our June 2018 public offering, our July 2019 establishment of an Equity Distribution Agreement and Equity Purchase Agreement, private placements of redeemable convertible preferred stock and debt financing arrangements.

Equity Distribution Agreement

On July 30, 2019, we entered into an Equity Distribution Agreement (the "Sales Agreement") with Canaccord Genuity LLC, as agent ("Canaccord"), pursuant to which we may offer and sell shares of common stock in an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act, for aggregate gross sale proceeds of up to $30.0 million from time to time through

Canaccord. On March 9, 2020, we entered into an amendment to the Sales Agreement to increase the aggregate gross sales amount from $30.0 million to $65.0 million. On April 8, 2020, we entered into an amendment to the Sales Agreement to increase the aggregate gross sales amount from $65.0 million to $95.0 million. As of March 31, 2020, the Company had sold 73,237,178 shares of common stock with an aggregate gross sales amount of approximately $48.1 million, leaving approximately $46.9 million remaining under the Equity Distribution Agreement.

We have 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. Legal and accounting fees are reclassified to share capital upon issuance of shares under the Sales Agreement.

Purchase Agreement

On July 29, 2019, we entered into a $30.0 million purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which we were able to sell and issue to Lincoln Park, and Lincoln Park was obligated to purchase, up to $30.0 million 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. On April 7, 2020, the Company terminated the Purchase Agreement, effective April 8, 2020.

In consideration for the execution and delivery of the Purchase Agreement, we issued 413,349 shares of common stock to Lincoln Park.

Plan of operations and future funding requirements

As of March 31, 2020 and December 31, 2019 we had unrestricted cash and cash equivalents of approximately $36.3 million and $11.0 million respectively. Currently, a portion of our funds are 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.

The COVID-19 pandemic may impact our operations. We have established protocols for continued manufacturing, distribution and servicing of our products with safe social distancing and personal protective equipment measures and for remote work for employees not essential to on-site operations. To date these measures have been successful but may not continue to function should the pandemic escalate and impact our personnel. Our hospital customers have restricted our sales team's access to their facilities and as a result, we significantly reduced our sales and general and administrative staffing levels to reduce expenses. Our customers may reduce their purchases of our products. Our customers may cease to comply with the terms of our sales agreements and this may impact our ability to recognize revenue and hinder receivables collections. We have a significant development contract with a United States Government agency and should the agency reduce, cancel or not grant additional milestone projects our ability to continue our future product development may be impacted. Our shipping carriers' ability to deliver our products to customers may be disrupted. We have reviewed our suppliers and quantities of key materials and believe we have sufficient stocks and alternate sources of critical materials including personal protective equipment should our supply chains become disrupted. As further described in Note 5, we believe the pandemic's impact on our sales has impacted the recoverability of the value of our T2-owned instruments and components. The COVID-19 pandemic also caused us to reassess our build plan and evaluate our inventories accordingly, which resulted in an additional charge to cost of product revenue.

Going Concern

At March 31, 2020, we had an accumulated deficit of $391.1 million, and a stockholders' deficit of $7.7 million. We have experienced cash outflows from operating activities over the past years and are required to maintain a minimum cash balance under our Term Loan Agreement with CRG Servicing LLC ("CRG") (Note 6). The Term Loan Agreement with CRG is classified as a current liability on the balance sheet at March 31, 2020, based on our consideration of the probability of violating the 2020 revenue covenant primarily due to the COVID-19 pandemic's likely impact on our product sales, which in turn would trigger violation of the minimum liquidity covenant. 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.

Management believes that the existing cash and cash equivalents at March 31, 2020, along with funding available through our Equity Distribution Agreement (the "Sales Agreement") with Canaccord Genuity LLC, as agent ("Canaccord") (Note 7) in the future, will be sufficient to allow us to fund our current operating plan, at least a year from issuance of these financial statements, assuming availability of funds. However, because certain elements of our operating plan are outside of our control, including our ability to sell shares under the Sales Agreement, those elements cannot be considered probable. 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. During the three months ended March 31, 2020, management implemented a cost improvement strategy which is focused on reducing operating expenses and improving our cost of goods sold. We reduced our total employee headcount by 22% as compared to headcount at December 31, 2019, resulting in severance of $0.4 million, of which $0.3 million is included within other accrued expenses at March 31, 2020. Should our current operating plan not materialize, management's plans to alleviate the conditions that raise substantial doubt include raising additional funding, earning payments pursuant to our Co-Development agreements, delaying certain research projects and capital expenditures and eliminating additional future operating expenses in order to fund operations at reduced levels in order 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 successfully obtain sufficient funding from one or more of these sources or adequately reduce expenditures, while reasonably possible, is less than probable. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of issuance of these 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. The Term Loan Agreement with CRG requires us to achieve certain annual revenue targets, whereby we are required to pay double the amount of any shortfall as an acceleration of principal payments, and maintain a minimum liquidity amount of $5.0 million (Note 6). The Term Loan Agreement with CRG is classified as a current liability on the balance sheet at March 31, 2020, based on our consideration of the probability of violating the 2020 revenue covenant primarily due to the COVID-19 pandemic's likely impact on our product sales, which in turn would trigger violation of the minimum liquidity covenant. 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.

On April 7, 2020, we received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Global Market under Nasdaq Listing Rule 5450(a)(1).

Cash flows

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

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (14,740)	$ (12,867)
Investing activities	(67)	(194)
Financing activities	40,097	(344)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 25,290	$ (13,405)

Net cash used in operating activities

Net cash used in operating activities was approximately $14.7 million for the three months ended March 31, 2020, and consisted of a net loss of $14.9 million adjusted for non-cash items including stock-based compensation expense of $1.2 million, COVID-19 related impairment charge of $0.6 million of our T2-owned instruments and components, depreciation and amortization expense of $0.5 million, non-cash interest expense of $0.6 million, non-cash lease expense of $0.4 million, a reduction in the fair value of the derivative instrument of $0.1 million, and a net change in operating assets and liabilities of $3.0 million, primarily related to a decrease in accounts payable of $2.0 million due to timing of payments, a decrease in accrued expenses of $1.3 million primarily from bonus and commission payments as well as payments related to the Second Amendment to the Employment Agreement with John McDonough, partially offset by increased legal expenses associated with financings and the CEO transition and increased severance

associated with the headcount reduction, a decrease in operating lease liabilities of $0.6 million, an increase in prepaid expenses and other assets of $0.3 million primarily related to order deposits with our contract manufacturer, and a decrease in deferred revenue of $0.1 million, and partially offset by a $0.9 million decrease in inventories primarily as a result of a COVID-19 related reduction in the build plan, and a decrease in accounts receivable of $0.4 million from timing of instrument invoice collections coupled with less product sales, partially offset by an increase in receivables for our U.S. Government Contract.

Net cash used in operating activities was approximately $12.9 million for the three months ended March 31, 2019, and consisted of a net loss of $15.1 million adjusted for non-cash items including stock-based compensation expense of $2.0 million, depreciation and amortization expense of $0.6 million, non-cash interest expense of $0.6 million, amortization of operating lease right-of-use assets of $0.3 million, a change in the fair value of the derivative instrument of $0.1 million, partially offset by a net change in operating assets and liabilities of $1.4 million, primarily related to an increase in prepaid expenses and other assets of $0.4 million primarily due to expected landlord reimbursements, an increase in inventories of $0.2 million, a decrease in operating lease liabilities of $0.7 million, and a decrease in deferred revenue of $0.1 million.

Net cash used in investing activities

Net cash used in investing activities was approximately $0.1 million for the three months ended March 31, 2020, and consisted of equipment purchases.

Net cash used in investing activities was approximately $0.2 million for the three months ended March 31, 2019, and consisted of equipment purchases.

Net cash used in / provided by financing activities

Net cash provided by financing activities was approximately $40.1 million for the three months ended March 31, 2020, and consisted of primarily of proceeds from sales of our common stock under the Sales Agreement, net of issuance costs.

Net cash used in financing activities was approximately $0.3 million for the three months ended March 31, 2019, and consisted of repayments of the Equipment Lease Credit facility.

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 three years (through December 30, 2019) of interest-only payments, which period was extended to four years (through December 30, 2020) upon achieving the Approval Milestone, after which quarterly principal and interest payments would be due through the December 30, 2022 maturity date. Interest on the amounts borrowed under the Term Loan Agreement accrues at an annual fixed rate of (a) prior to the Approval Milestone, 12.50%, 4.0% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount and (b) following the Approval Milestone, 11.50%, 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% 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 March 31, 2020 and December 31, 2019 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 certain prepayment fee during the first five years of the term and no prepayment fee thereafter. As security for our obligations under the Term Loan Agreement, we entered into a security agreement with CRG whereby we granted a lien on substantially all of its assets, including intellectual property. The Term Loan Agreement also contains customary affirmative and negative covenants for a credit facility of this size and type, including a requirement to maintain a minimum cash balance of $5.0 million. 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 eliminate the 2018 revenue covenant. In exchange for the amendment, we agreed to reset the strike price of the warrants to purchase 528,958 shares of our common stock, issued in connection with the Term Loan Agreement, from $8.06 per share to $4.35 per share.

In September 2019, the Term Loan Agreement was amended to extend the interest-only payment period through December 31, 2021, to extend the initial principal repayment to March 31, 2022, and to reduce the minimum product revenue target for 2019 from $9 million to $4 million, for the twenty-four month period beginning on January 1, 2019 from $95 million to $15 million and for the twenty-four month period beginning on January 1, 2020 from $140 million to $43 million. The final payment fee was increased from 8% to 10% of the principal amount outstanding upon repayment. We issued to CRG warrants to purchase 568,291 shares of our common stock ("New Warrants") (Note 9) at an exercise price of $1.55, with typical provisions for termination upon a change of control or a sale of all or substantially all of our assets. We also reduced the exercise price for the warrants previously issued to CRG to purchase an aggregate of 528,958 shares of our common stock to $1.55. All of the New Warrants are exercisable any time prior to September 9, 2029, and all of the previously issued warrants are exercisable any time prior to December 30, 2026. We accounted for the March 2019 and September 2019 amendments as modifications to 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. 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.

We assessed the terms and features of the Term Loan Agreement, including the interest-only period dependent on the achievement of the Approval Milestone and the acceleration of the obligations under the Term Loan Agreement under an event of default, of the Term Loan Agreement in order to identify any potential embedded features that would require bifurcation. In addition, under certain circumstances, a default interest rate of an additional 4.0% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default, we 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 March 31, 2020 and December 31, 2019 is $2.3 million and $2.4 million respectively. We classified the derivative liability as a current liability on the balance sheet at March 31, 2020 and December 31, 2019 to match the classification of the related Term Loan Agreement.

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 was capped at a maximum of $5.0 million. Under the Credit Facility, Essex funded capital equipment purchases presented by us. We repaid 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 had 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 were treated as capital leases and were included in property and equipment on the balance sheet. The amortization of the assets conveyed under the Credit Facility was included as a component of depreciation expense. During the year ended December 31, 2019, we repurchased the equipment for $0.3 million in accordance with the terms of the Credit Facility.

Contractual Obligations and Commitments

There were no other material changes to our contractual obligations and commitments from those described under Management's Discussion and Analysis of Financial Condition and Results of Operations in the Annual Report on Form 10-K for the year ended December 31, 2019.

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 March 31, 2020 and December 31, 2019, we had cash and cash equivalents of $36.3 million and $11.0 million, respectively, with a portion held 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 March 31, 2020 and December 31, 2019, we had no outstanding debt exposed to variable market interest rates. Our ability to invest our cash and cash equivalents may be impacted by market fluctuations caused by the COVID-19 pandemic.

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 March 31, 2020. 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 on the evaluation of our disclosure controls and procedures as of March 31, 2020, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, the Company's disclosure controls and procedures were not effective due to the material weakness in our internal control over the quality, frequency and periodic testing of the backup of the Company's IT data that was included in Form-10-Q for the quarterly period ended September 30, 2019 and continued to exist at December 31, 2019.

As described in Form 10-Q for the quarterly period ended September 30, 2019, the Company historically backed up IT data monthly to a tape system and stored the tapes offsite in a secure location for use in data recovery. However, management determined that the frequency of the backup, monthly, presented a potential loss of data that takes an inordinate amount of time to recover. This prevented the Company from timely filing its report on Form 10-Q for the quarterly period ended September 30, 2019 without filing an extension. Furthermore, management determined that semi-annual data recovery testing to a secure environment to ensure the integrity and recoverability of the data was not performed. Because these tests were not performed, the Company did not detect flaws in the backup data timely and this flawed data required a lengthy data recovery process which delayed the Company's ability to prepare timely and accurate financial statements.

The Company took actions to remediate the deficiencies in its internal controls over financial reporting and implemented additional processes and controls designed to address the underlying causes associated with the above-mentioned material weakness. We upgraded our tape backup system during the third quarter of 2019. Backups to tapes occur monthly. We implemented redundant cloud-based backup processes during April 2020 and are currently refining the system. After updating cloud-based backup processes, we expect to perform daily backups to minimize data loss. We expect to implement a semi-annual data recovery process to a secure environment to ensure data integrity. Our first instance of this activity is expected to occur in the second quarter of 2020. Management will monitor the progress of the remediation plan and report regularly to the audit committee on the progress and results of the remediation plan, including the identification, status and resolution of internal control deficiencies. The Company believes these actions will be effective in remediating the material weakness described above. As the Company continues to evaluate and work to improve its internal control over financial reporting, management may determine to take additional measures to address the material weakness or determine to modify the remediation plan described above. Until the remediation steps set forth above are fully implemented and operating for a sufficient period of time, the material weakness described above will continue to exist.

Management has taken steps to ensure the continued effectiveness of the Company's controls and procedures during the COVID-19 pandemic including procedures for ensuring effective controls for securely accessing the Company's systems and for financial record keeping by personnel working remotely via secure virtual private network ("VPN") connection. We do not believe the pandemic has negatively impacted our ability to produce accurate and timely financial reports or SEC filings.

(b) Changes in Internal Control over Financial Reporting

Except as noted above, 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, 2019, and the following risk, 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, 2019 other than as set forth below.

The COVID-19 pandemic has had, and may continue to have, an adverse impact on our business, including our marketing and research activities.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China and on March 11, 2020 was declared by the World Health Organization as a global pandemic. The global outbreak of COVID-19 continues to rapidly evolve and has had adverse effects on general commercial activity and the global economy, including research, manufacturing and distributions. The COVID-19 pandemic could lead to a global economic downturn and, at this point in time, there is significant uncertainty relating to its potential effect on our business, operating and research activities, including but not limited to:

- delays, difficulties or postponement in expanding the range of hospitals utilizing our T2Dx Instrument, T2Candida and T2Bacteria panels;
- diversion of healthcare resources away from our products for COVID-19 testing;
- interruption of marketing and research activities due to limitations on travel related to COVID-19;
- limitations in employee resources that would otherwise be focused on the conduct of our research activities, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- inability to obtain additional financing or access the financial markets; and
- manufacturing challenges, such as scarcity of the components required to produce our products or contamination of our manufacturing facility, could harm our ability to manufacture and assemble our current and proposed products in sufficient quantities and on a timely basis so as to meet consumer demand.

As a result of COVID-19, we may experience a reduction in product sales and have experienced an impaired ability to recover the cost of instruments and components, and we may experience further reductions in the future. The extent to which COVID-19 may continue to impact our business, research and development programs and operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and manage the disease. In addition, if we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted, which could have a material adverse effect on our business and our financial results.

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

The Company's Board of Directors (the "Board") has determined that it intends to hold the Company's next Annual Meeting of Stockholders (the "2020 Annual Meeting") on approximately July 31, 2020 or shortly thereafter, at a time and location to be specified in the Company's proxy statement for the 2020 Annual Meeting (the "Proxy Statement"). The record date for determining stockholders eligible for notice of, and to vote at, the 2020 Annual Meeting will be included in the Proxy Statement.

Because the date of the 2020 Annual Meeting has been changed by more than 30 calendar days from the date of the previous year's annual meeting, pursuant to Rule 14a-8 of the Securities Exchange Act of 1934, as amended, stockholders of the Company who wish to have a proposal considered for inclusion in the Company's proxy materials for the 2020 Annual Meeting pursuant to Rule 14a-8 must ensure that their proposal is received by the Secretary of the Company, at 101 Hartwell Ave., Lexington, MA 02421, Attention: Corporate Secretary, by May 21, 2020, which the Company has determined to be a reasonable time before it expects to begin to print and send its proxy materials. Rule 14a-8 proposals must also comply with the requirements of Rule 14a-8 and other applicable laws in order to be eligible for inclusion in the Company's proxy materials for the 2020 Annual Meeting.

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	Employment Agreement, dated as of January 8, 2020, by and between the Company and John Sperzel (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (001-36571) filed on January 9, 2020)
10.2	T2 Biosystems, Inc. Inducement Award Plan, as amended, and forms of award agreements thereunder, dated as of January 8, 2020, by and between the Company and John Sperzel (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K (001-36571) filed on January 9, 2020)
10.3	Amendment No. 1 to Equity Distribution Agreement dated as of March 9, 2020 by and between T2 Biosystems, Inc. and Canaccord Genuity LLC) (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (001-36571) filed on March 9, 2020)
10.4	Amendment No. 2 to Equity Distribution Agreement dated as of April 8, 2020 by and between T2 Biosystems, Inc. and Canaccord Genuity LLC) (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (001-36571) filed on April 8, 2020)
31.1*	Certification of principal 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.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.4*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* 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: May 11, 2020

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

Date: May 11, 2020

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 Sperzel, 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 Sperzel
John Sperzel
President, Chief Executive Officer and Director
(principal executive officer)

Date: May 11, 2020

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: May 11, 2020

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 March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John Sperzel, 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 Sperzel
John Sperzel
President and Chief Executive Officer
(principal executive officer)

Date: May 11, 2020

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 March 31, 2020 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: May 11, 2020

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.