UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2021

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 August 6, 2021, the registrant had 165,845,743 shares of common stock outstanding.

T2 BIOSYSTEMS, INC.

TABLE OF CONTENTS

PART I.
FINANCIAL INFORMATION

Item 1. Financial Statements

T2 BIOSYSTEMS, INC.

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

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 32,708	$ 16,793
Marketable securities	20,080	25,396
Accounts receivable	3,979	5,099
Inventories	4,784	3,636
Prepaid expenses and other current assets	2,308	2,660
Total current assets	63,859	53,584
Property and equipment, net	4,078	3,771
Operating lease right-of-use assets	10,332	11,034
Restricted cash	551	551
Marketable securities	—	10,002
Other assets	78	136
Total assets	$ 78,898	$ 79,078
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,890	$ 2,058
Accrued expenses and other current liabilities	6,017	7,512
Deferred revenue	438	230
Total current liabilities	9,345	9,800
Notes payable	46,487	45,235
Operating lease liabilities, net of current portion	9,964	10,533
Deferred revenue, net of current portion	146	424
Derivative liability	—	1,010
Other liabilities	3,947	3,350
Commitments and contingencies (see Note 13)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized; 165,763,776 and 148,078,974 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	165	148
Additional paid-in capital	454,950	431,544
Accumulated other comprehensive income	4	9
Accumulated deficit	(446,110)	(422,975)
Total stockholders' equity	9,009	8,726
Total liabilities and stockholders' equity	$ 78,898	$ 79,078

See accompanying notes to condensed consolidated financial statements.

T2 BIOSYSTEMS, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Product revenue	$ 3,678	$ 1,041	$ 8,328	$ 2,086
Research revenue	—	11	—	11
Contribution revenue	3,016	1,500	5,322	3,000
Total revenue	6,694	2,552	13,650	5,097
Costs and expenses:				
Cost of product revenue	4,831	2,300	10,621	6,971
Research and development	5,399	3,786	10,064	8,566
Selling, general and administrative	7,244	5,305	13,447	11,960
Total costs and expenses	17,474	11,391	34,132	27,497
Loss from operations	(10,780)	(8,839)	(20,482)	(22,400)
Other income (expense):				
Interest income	6	1	12	1
Interest expense	(1,700)	(1,844)	(2,713)	(3,261)
Other income, net	(1)	(3)	48	26
Total other expense	(1,695)	(1,846)	(2,653)	(3,234)
Net loss	$ (12,475)	$ (10,685)	$ (23,135)	$ (25,634)
Net loss per share — basic and diluted	$ (0.08)	$ (0.09)	$ (0.15)	$ (0.27)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	154,885,039	120,292,543	151,576,606	94,464,933
Other comprehensive loss:				
Net loss	$ (12,475)	$ (10,685)	$ (23,135)	$ (25,634)
Net unrealized gain on marketable securities arising during the period	—	—	9	—
Less: net realized gain on marketable securities included in net loss	(12)	—	(14)	—
Total other comprehensive loss, net of taxes	(12)	—	(5)	—
Comprehensive loss	$ (12,487)	$ (10,685)	$ (23,140)	$ (25,634)

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 Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' (Deficit) Equity
	Shares	Amount				
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 public offerings, 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)
Stock-based compensation expense	—	—	994	—	—	994
Issuance of common stock from vesting of restricted stock, exercise of stock options and employee stock purchase plan	407,183	—	180	—	—	180
Issuance of common stock from secondary public offering, net	8,881,466	9	12,811	—	—	12,820
Net loss	—	—	—	(10,685)	—	(10,685)
Balance at June 30, 2020	128,461,279	$ 128	$ 397,295	$ (401,811)	$ —	$ (4,388)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' (Deficit) Equity
	Shares	Amount				
Balance at December 31, 2020	148,078,974	$ 148	$ 431,544	$ (422,975)	$ 9	$ 8,726
Stock-based compensation expense	—	—	1,308	—	—	1,308
Issuance of common stock from vesting of restricted stock and exercise of stock options	412,699	—	53	—	—	53
Other comprehensive income	—	—	—	—	7	7
Net loss	—	—	—	(10,660)	—	(10,660)
Balance at March 31, 2021	148,491,673	$ 148	$ 432,905	$ (433,635)	$ 16	$ (566)
Stock-based compensation expense	—	—	1,843	—	—	1,843
Issuance of common stock from vesting of restricted stock, exercise of stock options and employee stock purchase plan	462,679	—	251	—	—	251
Issuance of common stock from secondary offering, net	16,809,424	17	19,951	—	—	19,968
Other comprehensive loss	—	—	—	—	(12)	(12)
Net loss	—	—	—	(12,475)	—	(12,475)
Balance at June 30, 2021	165,763,776	$ 165	$ 454,950	$ (446,110)	$ 4	$ 9,009

See accompanying notes to condensed consolidated financial statements.

T2 BIOSYSTEMS, INC.

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

	Six Months Ended June 30,	
	2021	2020
Cash flows from operating activities		
Net loss	$ (23,135)	$ (25,634)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	696	905
Amortization of bond premium	76	—
Amortization of operating lease right-of-use assets	702	802
Stock-based compensation expense	3,151	2,154
Change in fair value of derivative instrument	(1,010)	(34)
Gain on sales of marketable securities	(14)	—
Gain on disposal of property and equipment	—	(2)
Impairment of operating lease asset	—	523
Impairment of property and equipment	—	636
Non-cash interest expense	1,849	1,474
Changes in operating assets and liabilities:		
Accounts receivable	1,120	1,525
Prepaid expenses and other assets	410	(4,727)
Inventories	(1,813)	19
Accounts payable	823	(1,983)
Accrued expenses and other liabilities	(573)	(2,811)
Deferred revenue	(70)	(115)
Operating lease liabilities	(1,517)	(963)
Net cash used in operating activities	(19,305)	(28,231)
Cash flows from investing activities		
Purchases of marketable securities	—	(9,247)
Proceeds from maturities of marketable securities	15,251	—
Proceeds from sale of property and equipment	—	4
Purchases and manufacture of property and equipment	(303)	(127)
Net cash provided by (used in) investing activities	14,948	(9,370)
Cash flows from financing activities		
Proceeds from issuance of shares from employee stock purchase plan and stock option exercises	304	180
Proceeds from issuance of common stock in public offerings, net of offering costs	19,968	52,917
Net cash provided by financing activities	20,272	53,097
Net increase in cash, cash equivalents and restricted cash	15,915	15,496
Cash, cash equivalents and restricted cash at beginning of period	17,344	11,213
Cash, cash equivalents and restricted cash at end of period	$ 33,259	$ 26,709
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 2,815	$ 1,820
Supplemental disclosures of noncash activities		
Transfer of T2 owned instruments and components (from) to inventory	$ (665)	$ 531
Purchases of property and equipment included in accounts payable and accrued expenses	$ 55	$ 94

	June 30, 2021	December 31, 2020
Reconciliation of cash, cash equivalents and restricted cash at end of period		
Cash and cash equivalents	$ 32,708	$ 16,793
Restricted cash	551	551
Total cash, cash equivalents and restricted cash	$ 33,259	$ 17,344

See accompanying notes to condensed consolidated financial statements.

1. Nature of Business

T2 Biosystems, Inc. and its subsidiary (the "Company," "we," or "T2") have operations based in Lexington, Massachusetts. T2 Biosystems, Inc. was incorporated on April 27, 2006 as a Delaware corporation. 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 the detection of pathogens that cause sepsis, which is an area 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 ("T2Resistance") 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 (NTAP) for the T2Bacteria Panel for fiscal year 2020 and in September 2020, CMS extended the approval for 2021. On November 20, 2019, the Company's T2Resistance Panel was granted a CE-Mark. On June 30, 2020, the Company announced the U.S. launch of its COVID-19 molecular diagnostic test, the T2SARS-CoV-2 Panel, after validation of the test meeting the FDA's requirements for an Emergency Use Authorization (EUA). In August 2020, the FDA issued EUA for the Company's T2SARS-CoV-2 Panel. The test is designed to detect the presence of the SARS-CoV-2 virus in a nasopharyngeal swab sample.

Liquidity and Going Concern

At June 30, 2021, the Company had cash, cash equivalents, marketable securities and restricted cash of $53.3 million, an accumulated deficit of $446.1 million, stockholders' equity of $9.0 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 (Note 7), private placements of redeemable convertible preferred stock and through debt financing arrangements.

The Company is subject to a number of risks similar to other early commercial stage 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 has impacted and may continue to 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 certain employees not essential to on-site operations. To date these measures have been mostly successful but may not continue to function should the pandemic escalate and impact personnel. In 2020, the Company's hospital customers restricted the sales team's access to their facilities and as a result, the Company had significantly reduced sales and general and administrative staffing levels at the beginning of the COVID-19 pandemic to reduce expenses. The Company has since hired sales and marketing personnel. Although the Company did not see any material impact to accounts receivable during the period ended June 30, 2021, the Company's exposure may increase if its customers continue to be adversely affected by the COVID-19 pandemic, including as a result of the spread of variants of the virus. Customers may reduce their purchases of products, depending on their needs and cash flow, which could negatively impact revenue. The Company has a significant development contract with BARDA and should BARDA 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, although raw materials and plastics for the manufacturing of reagents and consumables are in high demand, and interruptions in supply are difficult to predict. As further described in Note 5, at the onset of the pandemic, the Company believed the pandemic's impact on its sales would affect the recoverability of the value of T2-owned instruments and components. In early 2020, 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 for excess inventories.

Since FDA authorization was obtained to market the T2Dx Instrument, T2Candida Panel, and T2Bacteria Panel, and EUA was issued for the T2SARS-CoV-2 Panel, 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, T2SARS-CoV-2, 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.

While the Company believes that its cash, cash equivalents, marketable securities and restricted cash of $53.3 million at June 30, 2021 will be sufficient to fund its current operating plan at least one year from issuance of these financial statements, certain elements of our operating plan cannot be considered probable. Under ASC 205-40, the future receipt of potential funding from 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.

The Term Loan Agreement with CRG Servicing LLC ("CRG") (Note 6) has certain covenants which require 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. As of June 30, 2021, the Company achieved the revenue target for the twenty-four month period ended December 31, 2021. While management believes the Company can continue as a going concern for at least one year from issuance of these financial statements, there can be no assurances that it will continue to be in compliance with the cash covenant in future periods without additional funding.

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 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, 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 12 months from the date of issuance of these 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.

Reclassification

Customer service personnel provide customer product support as well as field installation, training and T2Dx system maintenance. Time spent in the field servicing customers with service maintenance contracts and for installation and training is considered services and included in cost of goods sold. Time spent providing customer support is now considered a commercial support activity and is included in selling, general and administrative expenses. Previously, customer support was considered a development phase activity and was included in research and development expense. Prior periods have been reclassified to conform to the current period presentation. The reclassification increased selling, general and administrative expenses by $0.2 million and decreased research and development expenses by $0.2 million for the three months ended June 30, 2020. The reclassification increased selling, general and administrative expenses by $0.4 million and decreased research and development expenses by $0.4 million for the six months ended June 30, 2020. The reclassification had no impact on total costs and expenses, loss from operations, net loss or net loss per share.

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, 2020.

The accompanying interim condensed consolidated balance sheet as of June 30, 2021, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2021 and 2020, the condensed consolidated statements of stockholders' (deficit) equity for the three and six months ended June 30, 2021 and 2020, the condensed consolidated statements of cash flows for the six months ended June 30, 2021 and 2020 and the related financial data and other information disclosed in these notes are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements, and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2021, and the results of its operations for the three and six months ended June 30, 2021 and 2020 and its cash flows for the six months ended June 30, 2021 and 2020. The results for the three and six months ended June 30, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021, 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 $0.5 million or 8% of total revenue and $0.3 million or 10% of total revenue for the three months ended June 30, 2021 and 2020, respectively. Total international sales were approximately $1.0 million or 7% of total revenue and $0.7 million or 15% of total revenue for the six months ended June 30, 2021 and 2020, respectively.

For the three and six months ended June 30, 2021 and 2020, no international customer represented greater than 10% of total revenue.

The Company derived approximately 45% of its total revenue from one customer for the three months ended June 30, 2021 and 59% of its total revenue from the same customer for the three months ended June 30, 2020. For the three months ended June 30, 2021, the Company derived approximately 12% of its total revenue from a second customer. For the three months ended June 30, 2020, no other customers represented greater than 10% of the Company's total revenue.

The Company derived approximately 39% of its total revenue from one customer for the six months ended June 30, 2021 and 59% of its total revenue from the same customer for the six months ended June 30, 2020. For the six months ended June 30, 2021, the Company derived approximately 16% of its total revenue from a second customer. For the six months ended June 30, 2020, no other customers represented greater than 10% of the Company's total revenue.

As of June 30, 2021 and December 31, 2020, the Company had outstanding receivables of $0.4 million and $0.5 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.

Marketable Securities

The Company's marketable securities typically consist of certificates of deposit and U.S. treasury securities, which are classified as available-for-sale and included in current and non-current assets. Available-for-sale debt securities are carried at fair value with unrealized gains and losses reported as a component of stockholders' (deficit) equity in accumulated other comprehensive income. Realized gains and losses, if any, are included in other income in the condensed consolidated statements of operations.

Available-for-sale securities are reviewed for possible impairment at least quarterly, or more frequently if circumstances arise that may indicate impairment. When the fair value of the securities declines below the amortized cost basis, impairment is indicated and it must be determined whether it is other than temporary. Impairment is considered to be other than temporary if the Company: (i) intends to sell the security, (ii) will more likely than not be forced to sell the security before recovering its cost, or (iii) does not expect to recover the security's amortized cost basis. If the decline in fair value is considered other than temporary, the cost basis of the security is adjusted to its fair market value and the realized loss is reported in earnings. Subsequent increases or decreases in fair value are reported as a component of stockholders' (deficit) equity in accumulated other comprehensive income. There were no other-than-temporary unrealized losses as of June 30, 2021.

The following table summarizes the Company's marketable securities at June 30, 2021 and December 31, 2020 (in thousands):

	June 30, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities	$ 20,076	$ 4	$ —	$ 20,080
Total	$ 20,076	$ 4	$ —	$ 20,080

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Certificates of deposit	$ 1,250	$ 1	$ —	$ 1,251
U.S. treasury securities	34,139	8	—	34,147
Total	$ 35,389	$ 9	$ —	$ 35,398

The following table summarizes the maturities of the Company's marketable securities at June 30, 2021 and December 31, 2020 (in thousands):

	June 30, 2021		December 31, 2020	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Due in less than 1 year	$ 20,076	$ 20,080	$ 25,387	$ 25,396
Due in 1-2 years	—	—	10,002	10,002
Total	$ 20,076	$ 20,080	$ 35,389	$ 35,398

Guarantees

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

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

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

As of June 30, 2021 and December 31, 2020, 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 government contributions. Pursuant to ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company determines revenue recognition through the following steps:

- Identification of a contract with a customer
- Identification of the performance obligations in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligations
- Recognition of revenue as a performance obligation is satisfied

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 or international distributor, 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 generally 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.

Revenue from the sale of consumable diagnostic tests (under instrument purchase agreements) is generally recognized upon shipment.

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. Warranty expense is recognized based on the estimated defect rates of the consumable diagnostic tests.

Pursuant to ASU No. 2018-08, *Not-For-Profit Entities – Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made* ("ASU 2018-08"), 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.

The Company has a significant development contract with BARDA and should BARDA reduce, cancel or not grant additional milestone projects, the Company's ability to continue our future product development may be impacted. Refer to Note 11 for further details regarding the development contract with BARDA.

Disaggregation of Revenue

The Company

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

	Three Months Ended, June 30,		Six Months Ended, June 30,	
	2021	2020	2021	2020
Product Revenue				
Instruments	$ 480	$ 170	$ 905	$ 417
Consumables	3,179	853	7,385	1,598
Instrument rentals	19	18	38	71
Total Product Revenue	3,678	1,041	8,328	2,086
Research Revenue	—	11	—	11
Contribution Revenue	3,016	1,500	5,322	3,000
Total Revenue	$ 6,694	$ 2,552	$ 13,650	$ 5,097

Remaining Performance Obligations

Under ASC 606, the Company is required to disclose the aggregate amount of the transaction price that is allocated to unsatisfied or partially satisfied performance obligations as of June 30, 2021. However, the guidance provides certain practical expedients that limit this requirement, and therefore, the Company has elected to not disclose the value of unsatisfied performance obligations for contracts with an original expected length of one year or less. The nature of the excluded unsatisfied performance obligations pursuant to the practical expedient include consumable shipments, service contracts, warranties and installation services that will be performed within one year. The amount of the transaction price that is allocated to unsatisfied or partially satisfied performance obligations, that has not yet been recognized as revenue and that does not meet the elected practical expedient is $0.5 million as of June 30, 2021. The Company expects to recognize 69% of this amount as revenue within one year and the remainder within two years.

Significant Judgments

Certain contracts with customers 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 the performance obligations are determined, 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. The Company then allocates the transaction price to each performance obligation in the contract based on a relative standalone 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. The Company determines 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, the Company estimates the standalone selling price taking into account available information such as a range of selling prices, market conditions and the expected costs and margin related to the performance obligations.

Contract Assets and Liabilities

The Company did not record any contract assets at June 30, 2021 and December 31, 2020.

The Company’s contract liabilities consist of upfront payments for research and development contracts and maintenance services on instrument sales. Contract liabilities are classified in deferred revenue as current or noncurrent based on the timing of when revenue is expected to be recognized. Contract liabilities were $0.6 million and $0.6 million at June 30, 2021 and December 31, 2020, respectively. Revenue recognized during the three months ended June 30, 2021 relating to contract liabilities at December 31, 2020 was immaterial and related to straight-line revenue recognition associated with maintenance agreements. Revenue recognized during the six months ended June 30, 2021 relating to contract liabilities at December 31, 2020 was $0.2 million and related to straight-line revenue recognition associated with maintenance agreements.

Cost to Obtain and Fulfill a Contract

The Company capitalizes commission expenses paid to sales personnel that are recoverable and incremental to obtaining capital purchase agreements within the United States. These costs are classified as prepaid expenses and other current assets and other assets, based on their current or non-current nature, respectively. The Company capitalizes only those costs that are determined to be incremental and would not have occurred absent the customer contract. These capitalized costs are amortized as selling, general and administrative costs on a straight line basis over the expected period of benefit. These costs are reviewed periodically for impairment.

At June 30, 2021, capitalized costs to fulfill contracts of $0.1 million was included in prepaid and other current assets. At December 31, 2020, capitalized costs to fulfill contracts of $0.1 million was included in prepaid and other current assets and $0.1 million was included in other non-current assets.

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, related warranty and license and royalty fees. Cost of product revenue also includes depreciation on T2-owned revenue generating T2Dx instruments that have been placed with customers under reagent rental agreements; costs of materials, direct labor and manufacturing overhead costs on the T2Dx instruments sold to customers; and other costs such as customer support costs, royalties and license fees, warranty and repair and maintenance expense on the T2Dx instruments that have been placed with customers under reagent rental agreements.

Research and Development Costs

Costs incurred in the research and development of the Company's product candidates are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including activities associated with performing services under research revenue arrangements, costs associated with the enhancements 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 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 Company adopted ASU 2019-12 on January 1, 2021. The adoption did not have a material impact on the Company's financial statements.

Accounting Standards Issued, Not Adopted

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)—Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"), which simplifies accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. The standard is effective for smaller reporting companies for fiscal years beginning after December 15, 2023 and interim periods within those fiscal years. The Company is currently evaluating the impact that this new standard will have on its financial statements.

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40) Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options ("ASU 2021-04")* which clarifies and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after a modification or exchange. This standard is effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply this standard prospectively to modifications or exchanges occurring on or after the effective date of this standard. The Company is currently evaluating the impact that this new standard will have on its financial statements.

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 and

liabilities carried at fair value categorized using the lowest level of input applicable to each financial instrument as of June 30, 2021 and December 31, 2020 (in thousands):

	Balance at June 30, 2021	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
US Treasury securities	$ 20,080	$ 20,080	$ —	$ —
	$ 20,080	$ 20,080	$ —	$ —

	Balance at December 31, 2020	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Certificates of deposit	$ 1,251	$ —	$ 1,251	$ —
US Treasury securities	34,147	34,147	—	—
	$ 35,398	$ 34,147	$ 1,251	$ —
Liabilities:				
Derivative liability	$ 1,010	$ —	$ —	$ 1,010
	$ 1,010	$ —	$ —	$ 1,010

The Company's cash equivalents and available-for-sale marketable securities are comprised of certificates of deposit and government securities. Securities are classified as cash equivalents when the original maturities are within 90 days of the purchase dates. The Company also maintains money market accounts classified as restricted cash for $0.6 million at June 30, 2021 and December 31, 2020 (Note 4).

The Company has a single compound derivative related to its Term Loan Agreement with CRG (the "Term Loan Agreement") (Note 6), which is required to be re-measured at fair value on a quarterly basis.

The fair value of the derivative at December 31, 2020 is $1.0 million and is classified as a non-current liability on the balance sheet at December 31, 2020 to match the classification of the related Term Loan Agreement (Note 6). As of June 30, 2021, the Company achieved the revenue covenant for the twenty-four month period beginning January 1, 2020 and has no derivative liability.

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

Balance at December 31, 2020	$ 1,010
Change in fair value of derivative liability, recorded as interest expense	(1,010)
Balance at June 30, 2021	$ —

4. Restricted Cash

The Company is required to maintain security deposits for its operating lease agreements for the duration of the lease agreements. At June 30, 2021 and December 31, 2020, the Company had money market accounts for $0.6 million, which represented collateral as security deposits for its operating lease agreements for two facilities.

5. Supplemental Balance Sheet Information

Inventories

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

	June 30, 2021	December 31, 2020
Raw materials	$ 2,212	$ 1,496
Work-in-process	1,491	1,374
Finished goods	1,081	766
Total inventories, net	$ 4,784	$ 3,636

Property and Equipment

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

	June 30, 2021	December 31, 2020
Office and computer equipment	$ 719	$ 538
Software	783	762
Laboratory equipment	5,606	5,179
Furniture	197	197
Manufacturing equipment	1,361	672
Manufacturing tooling and molds	478	255
T2-owned instruments and components	5,666	5,001
Leasehold improvements	3,768	3,691
Construction in progress	453	1,733
	19,031	18,028
Less accumulated depreciation and amortization	(14,953)	(14,257)
Property and equipment, net	$ 4,078	$ 3,771

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 the Company's business model and forecast, and completed instruments that will be used for internal research and development, clinical studies or reagent rental agreements with customers. At June 30, 2021, there was $0.5 million of raw materials or work-in-process inventory in T2-owned instruments and components compared with $0.3 million at December 31, 2020. 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 was immaterial for the three months ended June 30, 2021 and totaled approximately $0.1 million for the three months ended June 30, 2020. 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 six months ended June 30, 2021 and 2020, respectively.

Depreciation expense for T2-owned instruments used for internal research and development and clinical studies is recorded as a component of research and development expense. Depreciation and amortization expense of $0.3 million and $0.4 million was charged to operations for the three months ended June 30, 2021 and 2020, respectively. Depreciation and amortization expense of $0.7 million and $0.9 million was charged to operations for the six months ended June 30, 2021 and 2020, respectively.

At the beginning of the COVID-19 pandemic, the Company believed the pandemic would 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 June 30, 2020, which is recorded as cost of product revenue impairment expense.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	June 30, 2021	December 31, 2020
Accrued payroll and compensation	$ 3,036	$ 3,629
Accrued research and development expenses	757	751
Accrued professional services	394	421
Accrued interest	—	940
Operating lease liabilities	1,168	1,151
Other accrued expenses	662	620
Total accrued expenses and other current liabilities	$ 6,017	$ 7,512

Included within other accrued expenses in the table above, at December 31, 2020, is $0.2 million from the Second Amendment to Employment Agreement with John McDonough (the "Transition Agreement") (Note 13) related to Mr. McDonough's transition payments and health benefits. At June 30, 2021, there were no remaining payments associated with the Transition Agreement.

6. Notes Payable

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

	June 30, 2021	December 31, 2020
Term loan agreement before PIK interest, and unamortized discount and issuance costs	$ 49,364	$ 48,077
Less: paid-in-kind interest	(2,136)	(1,669)
Less: unamortized discount and deferred issuance costs	(741)	(1,173)
Total notes payable	$ 46,487	$ 45,235

The Term Loan Agreement with CRG is classified as a non-current liability at June 30, 2021 and December 31, 2020 as the Company has sufficient cash, cash equivalents and marketable securities as of the date of this filing such that the minimum liquidity covenant would not be triggered at December 31, 2021.

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. As amended in January 2021, the entire principal payment, together with all other outstanding obligations, shall be due and payable upon maturity, December 30, 2022.

The Company has assessed the classification of the note payable as non-current based on facts and circumstances as of the date of this filing, specifically as it relates to achieving the minimum liquidity and revenue covenants. As of the date of this filing, the Company achieved the revenue covenant for the twenty-four month period beginning on January 1, 2020. Management continues to reassess at each balance sheet and filing date based on facts and circumstances and can provide no assurances regarding the probability of meeting its minimum liquidity covenant in future periods.

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%, subsequently amended to 10%, of the principal outstanding upon repayment. The Company is accruing the final payment fee as interest expense and it is included as a non-current liability at June 30, 2021 and December 31, 2020 to conform to the classification of the associated debt in those periods.

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 2019, the Term Loan Agreement was amended to reduce minimum revenue targets, extend the interest-only period and extend the principal repayment. 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.

In January 2021, the Term Loan Agreement was amended to extend the interest-only payment period until the December 30, 2022 maturity, to extend the initial principal repayment until the December 30, 2022 maturity, and to significantly reduce the minimum product revenue target for the twenty-four month period beginning on January 1, 2020. The Company did not pay or provide any consideration in exchange for this amendment. The Company accounted for the January 2021 amendment as a modification 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.

7. Stockholders' (Deficit) Equity

Equity Distribution Agreement

On July 30, 2019, the Company entered into the Sales Agreement with Canaccord ("Original Sales Agreement"), 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 Original 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 Original Sales Agreement to increase the aggregate gross sales amount from $65.0 million to $95.0 million. As of December 31, 2020, the Company had sold 101,606,667 shares of common stock with an aggregate gross sales amount of $95.0 million under the Original Sales Agreement.

On March 31, 2021, the Company entered into another Sales Agreement with Canaccord ("New Sales Agreement"), as agent, pursuant to which the Company may offer and sell shares of common stock, for aggregate gross sale proceeds of up to $75.0 million from time to time from the effective date of the respective registration statement through Canaccord.

Under the New Sales 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 is able to 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 New Sales Agreement. The Company or Canaccord is able to suspend or terminate the offering of shares upon notice to the other party, subject to certain conditions. Canaccord acts 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 agrees 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 New Sales Agreement. The Company also agrees to provide Canaccord with customary indemnification for certain liabilities. Legal and accounting fees are charged to share capital upon issuance of shares under the New Sales Agreement.

During the six months ended June 30, 2020, the Company sold 76,632,144 shares under the Original Sales Agreement for net proceeds of $52.6 million after expenses.

The Company sold 16,809,424 shares under the New Sales Agreement for net proceeds of $20.0 million during the six months ended June 30, 2021.

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 8, 2020, the Company terminated the Purchase Agreement.

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 six months ended June 30, 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; provided, however, no more than 35,000,000 shares may be issued upon the exercise of incentive stock options. As of June 30, 2021, there were 2,427,598 shares available for future grant under the 2014 Plan.

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 grant 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 the grant of an award under the Inducement Plan. The payment of dividend equivalents in cash in conjunction with any outstanding award shall not be counted against the shares available for issuance under the Inducement Plan. As of June 30, 2021, there were 1,192,945 shares available for future grant under the Inducement Plan.

Stock Options

During the six months ended June 30, 2021 and 2020, the Company granted stock options with an aggregate fair value of $0.8 million and $3.0 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, 2020	8,595,929	$ 3.24	7.75	$ 1,011
Granted	642,500	1.54		
Exercised	(44,709)	1.21		
Forfeited	(42,790)	2.12		
Cancelled	(25,306)	7.39		
Outstanding at June 30, 2021	9,125,624	$ 3.12	7.42	$ 787
Exercisable at June 30, 2021	4,957,243	$ 4.44	6.42	$ 336
Vested or expected to vest at June 30, 2021	8,512,391	$ 3.25	7.32	$ 718

There were 44,709 options exercised in the six months ended June 30, 2021 and 10,000 options exercised in the six months ended June 30, 2020. The weighted-average grant date fair values of stock options granted in the six month periods ended June 30, 2021 and 2020 were $1.24 per share and $0.69 per share, respectively, and were calculated using the following estimated assumptions:

	Six Months Ended June 30,	
	2021	2020
Weighted-average risk-free interest rate	0.96%	1.40%
Expected dividend yield	—%	—%
Expected volatility	104%	95%
Expected terms	6.0 years	5.7 years

The total fair values of options that vested during the six months ended June 30, 2021 and 2020 were $1.2 million and $2.3 million, respectively.

As of June 30, 2021, there was $4.5 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 2.3 years as of June 30, 2021.

Restricted Stock Units

During the six months ended June 30, 2021, the Company awarded restricted stock units to certain employees and directors at no cost to them. 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 underlying shares are vested and released. 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 $13.4 million, which are being amortized into compensation expense over the vesting period of the restricted stock units as the services are being provided.

The following is a summary of restricted stock unit activity under the 2014 Plan:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Nonvested at December 31, 2020	1,643,779	$ 1.91
Granted	6,451,074	2.07
Vested	(551,889)	1.42
Forfeited	(412,413)	3.83
Nonvested at June 30, 2021	7,130,551	$ 1.98

As of June 30, 2021, there was $12.8 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 2.5 years, as of June 30, 2021.

Employee Stock Purchase Plan

Under the 2014 Employee Stock Purchase Plan (the “2014 ESPP”) participants may purchase the Company’s common stock during semi-annual offering periods at 85% of the lower of (i) the market value per share of common stock on the first day of the offering period or (ii) the market value per share of the common stock on the purchase date. Each participant can purchase up to a maximum of $25,000 per calendar year in fair market value as calculated in accordance with applicable tax rules. The first offering period began on August 7, 2014. Stock-based compensation expense from the 2014 ESPP for the three months ended June 30, 2021 and 2020 was approximately $0.1 million. Stock-based compensation expense from the 2014 ESPP for the six months ended June 30, 2021 and 2020 was approximately $0.2 million.

The 2014 ESPP, which was amended and restated effective August 6, 2020, provides for the issuance of up to 4,523,944 shares of the Company’s common stock to eligible employees. At June 30, 2021, there were 2,990,070 shares available for issuance under the 2014 ESPP.

Stock-Based Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Cost of product revenue	$ 71	$ 4	$ 138	$ 80
Research and development	311	224	518	512
Selling, general and administrative	1,427	716	2,475	1,543
Total stock-based compensation expense	$ 1,809	$ 944	$ 3,131	$ 2,135

For the three and six months ended June 30, 2021 and 2020, stock-based compensation expenses capitalized as part of inventory or T2Dx instruments and components were immaterial.

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 $1.55 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. These warrants remain outstanding as of June 30, 2021 and December 31, 2020.

In connection with a 2019 amendment of the Term Loan Agreement, the Company issued to CRG warrants to purchase 568,291 shares of the Company's common stock ("New Warrants") 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. All of the New Warrants are exercisable any time prior to September 9, 2029. The New Warrants remain outstanding as of June 30, 2021 and December 31, 2020.

10. Net Loss Per Share

The following shares were excluded from the calculation of diluted net loss per share applicable to common stockholders, prior to the application of the treasury stock method, because their effect would have been anti-dilutive for the periods presented:

	Three and Six Months Ended June 30,	
	2021	2020
Options to purchase common shares	9,125,624	9,684,360
Restricted stock units	7,130,551	1,426,209
Warrants to purchase common stock	1,097,249	1,097,249
Total	17,353,424	12,207,818

11. Co-Development Agreements

U.S. 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 (the "U.S. Government Contract"). 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 antibiotic resistance genes. In September 2020, BARDA exercised the first contract option valued at $10.5 million.

In April 2021, BARDA agreed to accelerate product development by modifying the contract to advance future deliverables into the currently funded Option 1 of the BARDA contract for T2NxT, T2Biothreat, T2Resistance and T2AMR. The modification does not change the overall total potential value of the BARDA contract.

The Company recorded revenue of $3.0 million and $1.5 million for the three months ended June 30, 2021 and 2020, respectively, under the BARDA contract. The Company recorded revenue of $5.3 million and $3.0 million for the six months ended June 30, 2021 and 2020 respectively.

12. Leases

Operating Leases

The Company leases certain office space, laboratory space and manufacturing space. 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, 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 October 2020, the Company entered into an amendment to extend the term to December 31, 2028. In accordance with the October 2020 amendment, the Company increased its security deposit to $420,438, which is classified as restricted cash at June 30, 2021 and December 31, 2020. This amendment resulted in an increase to the operating lease right-of use assets and lease liability accounts on the balance sheet of $7.6 million and $7.7 million, respectively, at December 31, 2020.

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 October 2020, the Company entered into an amendment to extend the term to December 31, 2022. This amendment resulted in an increase to the operating lease right-of use assets and lease liability accounts on the balance sheet of $0.2 million at December 31, 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 June 2020, the Company vacated this office space and determined that subleasing it to a tenant was unlikely due to the impact of the COVID-19 pandemic on the local commercial real estate sub-lease market.

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. 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 was recorded as a component of both prepaid expenses and other current assets and other assets in the condensed consolidated balance sheets at December 31, 2019. In October 2020, the Company entered into an amendment to extend the term of the lease to October 31, 2025. In accordance with this amendment, the Company paid a replacement security deposit of $130,977, which is classified as restricted cash at June 30, 2021 and December 31, 2020 and received the initial $281,000 security deposit in return.

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 that became due under this agreement for the three and six months ended June 30, 2021 and 2020 were immaterial.

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. Accrued expenses included amounts related to Mr. McDonough’s transition payments and health benefits of $0.2 million at December 31, 2020. There were no accrued expenses related to Mr. McDonough’s transition payments and health benefits at June 30, 2021.

14. Subsequent Events

In July 2021, the Company's shareholders approved of an increase in the number of authorized shares of the Company's common stock from 200,000,000 to 400,000,000.

Additionally, in July 2021, John McDonough resigned as a director of the Company. He was a Class I director and Chairman of the Board. Upon his resignation, the Board appointed John Sperzel, the Company's CEO, as Chairman of the Board.

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 raw materials and components for our products, 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:

- *our ability to continue as a going concern;*
- *our status as an early commercial-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 ability 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 products and product candidates;*
- *our ability to protect and enforce our intellectual property rights, including our trade secret-protected proprietary rights in T2MR;*

- *our ability to recruit, train and retain key personnel;*
- *our dependence on third parties;*
- *manufacturing and other product risks;*
- *the impact of the adoption of new accounting standards;*
- *the impact of cybersecurity risks, including ransomware, phishing, and data breaches on our information technology systems;*
- *the impact of short sellers and day traders on our share price;*
- *the impact of cost-cutting measures;*
- *unforeseen interruptions in our supply chain;*
- *our ability to maintain compliance with Nasdaq listing requirements;*
- *the Tax Cuts and Jobs Act of 2017 (Tax Reform) and the impact of future tax legislation;*
- *the impact of the COVID-19 pandemic on our business, results of operations and financial positions;*
- *the impact of changes to regulatory requirements, including the adoption of the In Vitro Diagnostics Regulations (IVDR) in the European Union; and*
- *the continued market demand for SARS-CoV-2 testing and our ability to convert T2SARS-CoV-2 customers to our other test panels.*

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, 2020, 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, 2020.

Business Overview

We are an in vitro diagnostics company and leader in the rapid detection of sepsis-causing pathogens directly in the blood of patients suspected of blood stream infections. We are 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 to use alternative to existing diagnostic methodologies. We are using our T2MR technology to develop a broad set of applications aimed at providing accurate, specific and timely test results enabling medical professionals to make targeted treatment decisions earlier, thereby, lowering mortality rates, improving patient outcomes and reducing the cost of healthcare. 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, the T2Candida Panel, the T2Bacteria Panel, the T2Resistance Panel, and the T2SARS-CoV-2 Panel that are all powered by our proprietary T2MR technology. The T2Candida, T2Bacteria and T2Resistance Panels are the only rapid molecular diagnostic tests that are able to directly detect pathogens in patient blood specimens without the need for blood culture. Our ongoing development efforts target expanded detection of the pathogens associated with sepsis, an area of significant unmet medical need in which existing therapies could be more effective with more sensitive and rapid 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 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 resistance markers, which can assist clinicians in selecting effective antibiotic treatment. 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 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 Centers for Medicare & Medicaid Services, or CMS, granted approval for a New Technology Add-on Payment (NTAP) for the T2Bacteria Panel for fiscal year 2020 and in September 2020, CMS extended the approval for 2021. In September 2019, BARDA awarded us 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. In September 2020, we completed the initial phase and BARDA exercised the first contract option valued at $10.5 million. On June 30, 2020, we announced the U.S. launch of our COVID-19 molecular diagnostic test, the T2SARS-CoV-2 Panel, after validation of the test meeting the FDA's requirements for an EUA. In August 2020, the FDA issued EUA for the T2SARS-CoV-2 Panel. The test is designed to detect the presence of the SARS-CoV-2 virus in nasopharyngeal swab samples. The existing reimbursement codes support our products that detect the pathogens that cause sepsis and we anticipate the same for our Lyme disease product candidates. In 2020, CMS authorized Medicare fixed reimbursement to Clinical Laboratory Improvement Amendments, or CLIA, certified laboratories for materials and services to perform COVID testing. The T2SARS-CoV-2 Panel is covered under this reimbursement. The economic savings associated with our T2Bacteria and T2Candida products are realized directly by hospitals. In the United States, we have a commercial team that is primarily targeting acute care hospitals which treat patients at risk for sepsis-related infections. Internationally, we have partnered with distributors that target large hospitals in their respective international markets.

We believe our sepsis products, which include T2Candida, T2Bacteria, and T2Resistance, will redefine the standard of care in detection of sepsis causing pathogens and patient management, lowering healthcare costs by improving both the precision and the speed to detect sepsis-causing pathogens. 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. The speed to result of T2Candida and T2Bacteria coupled with their higher sensitivity and specificity as compared to blood culture helps clinicians escalate or confirm therapy for the identified pathogen, and deescalate treatment to 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.

According to a 2013 study published in Clinical Infectious Disease, 50% of *Candida* infections are missed by conventional blood culture techniques. In studies published in 2016, 2018, and 2020, T2Candida was able to confirm the existence of fungal infections in hours vs. days, shorten overall length of stay, and significantly reduce prescriptions of antifungal therapy in patients that tested negative. Antifungal drugs are toxic and may result in side effects and can cost over $50 per day.

A meta-analysis of 70 studies found antibiotic therapy prescribed in advance of blood culture results was inappropriate in 46.5% of patients. Reducing time to effective appropriate therapy results in significant reductions in overall length of stay of up to 8 days. A growing number of studies demonstrate clinical benefit of T2Bacteria Panel for early diagnosis of cases of blood stream infections that were being inappropriately treated with empiric antibiotics.

A meta-analysis of 14 studies published in Expert Review of Medical Devices, a peer-reviewed medical journal, confirmed the utilization of Magnetic Resonance (T2MR®) technology for identification of bloodstream infections (BSIs) provides faster time to detection, faster transition to targeted microbial therapy, faster de-escalation of empirical therapy, and shorter Intensive Care Unit (ICU) and hospital stay, and with comparable mortality rate versus the current blood culture standard. As identified by the meta-analysis, patients testing positive received targeted antimicrobial therapy 42 hours faster and patients testing negative on T2MR were de-escalated from empirical therapy 7 hours faster as compared to blood culture. Length of ICU stay and hospital stay were, on average, five days shorter in patients receiving a diagnosis with as compared to blood cultures.

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." In conjunction with empiric therapy, the addition of the use of our products, T2Bacteria, T2Candida, and T2Resistance, which all run on

the T2Dx Instrument, 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.

We have never been profitable and have incurred net losses in each year since inception. Our accumulated deficit at June 30, 2021 was $446.1 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, the T2Dx Instrument, T2Candida Panel and T2Bacteria Panel. 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, T2SARS-CoV-2 and future T2MR-based diagnostics.

We are subject to a number of risks similar to other early commercial stage 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 and may continue to 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 mostly successful but may not continue to function should the pandemic escalate and further impact our personnel. In 2020, our hospital customers restricted our sales team’s access to their facilities and as a result, we had significantly reduced our commercial and general and administrative staffing levels at the beginning of the COVID-19 pandemic to reduce expenses. We have since hired sales and marketing personnel. Although we did not see any material impact to accounts receivable during the period ended June 30, 2021, our exposure may increase if our customers continue to be adversely affected by the COVID-19 pandemic, including as a result of the spread of variants of the virus. Customers may reduce their purchases of products, depending on their needs and cash flow, which could negatively impact revenue. 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 BARDA and should BARDA 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, although raw materials and plastics for the manufacturing of reagents and consumables are in high demand, and interruptions in supply are difficult to predict. At the onset of the pandemic, we believed that the pandemic’s impact on our sales would affect the recoverability of the value of our T2-owned instruments and components. In early 2020, 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 for excess inventories.

While the Company believes that its cash, cash equivalents, marketable securities and restricted cash of $53.3 million at June 30, 2021 will be sufficient to fund our current operating plan at least a year from issuance of these financial statements, certain elements of our operating plan 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 year ended December 31, 2020, management implemented a cost improvement strategy which is focused on reducing operating expenses and improving cost of goods sold.

The Term Loan Agreement with CRG Servicing LLC (“CRG”) (Note 6) has certain covenants which require 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. As of June 30, 2021, the Company achieved the revenue covenant for the twenty-four month period beginning January 1, 2020. While we believe we can continue as a going concern for at least a year from issuance of these financial statements, there can be no assurances that we will continue to be in compliance with the cash covenant in future periods without additional funding.

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 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, 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 12 months from the date of issuance of these consolidated financial statements.

T2SARS-CoV-2

On March 24, 2020, we announced that we 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. On June 30, 2020, we announced the US launch of our COVID-19 molecular diagnostic test, the T2SARS-CoV-2 Panel, after validation of the test meeting the FDA's requirements for an EUA. On July 1, 2020, we submitted an EUA request to the FDA for the T2SARS-CoV-2 Panel. In August 2020, the FDA issued EUA for our T2SARS-CoV-2 Panel.

The T2SARS-CoV-2 Panel is designed to detect SARS-CoV-2, the virus that is responsible for COVID-19 infections. The T2SARS-CoV-2 Panel provides sample-to-answer results in less than two hours, utilizing a nasopharyngeal swab sample. Clinical testing on known positive and negative patient samples showed a sensitivity of 95% and specificity of 100%. The T2SARS-CoV-2 Panel runs on our FDA-cleared T2Dx Instrument, and is capable of performing seven tests simultaneously. Continued *in silico* analysis of available SARS-CoV-2 sequences have demonstrated that the T2SARS-CoV-2 assay is capable of detecting all known variants of the SARS-CoV-2 virus.

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

Financial Overview

Revenue

We generate revenue from the sale of our products, related services, reagent rental agreements and government contributions.

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.

Product revenue is generated by the sale of instruments and 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 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. 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 placed under a reagent rental agreement, our customers generally agree to fixed term agreements, which can be extended, and incremental charges on each consumable diagnostic test purchased. Shipping and handling costs are billed to customers in connection with a product sale.

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

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.

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.

Our current sales strategy is to drive adoption of our test platform installed base in hospitals, to increase test use by our existing hospital customers, and to expand T2SARS-CoV-2 customers to sepsis testing. Accordingly, we expect the following to occur:

- recurring revenue from our consumable diagnostic tests will increase; and
- become a more predictable and significant component of total revenue; and
- we will gain manufacturing economies of scale through the growth in our sales, resulting in improving gross margins and operating margins.

We believe the COVID-19 pandemic hindered our U.S. and international 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. We have a significant development contract with BARDA and should BARDA reduce, cancel or not grant additional milestone projects, our ability to continue our future product development may be impacted.

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 percentage of revenue as a result of the cost of product revenue improvement initiatives that we initiated during the year ended December 31, 2020.

At the beginning of the COVID-19 pandemic, we believed that the pandemic would 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 during the quarter ended March 31, 2020, which was recorded as cost of product revenue impairment expense. We took an additional charge to cost of product revenue during the quarter ended March 31, 2020 primarily for excess inventories as the COVID-19 pandemic also caused us to reassess our build plan and evaluate our inventories accordingly.

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 and contribution revenue. We expense all research and development costs as incurred.

We anticipate our overall research and development expenses to decrease as a percentage of revenue. 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 BARDA and should BARDA reduce, cancel or not grant additional milestone projects, our ability to continue our future product development may be impacted.

Customer service personnel provide customer product support as well as field installation, training and T2Dx system maintenance. Time spent in the field servicing customers with service maintenance contracts and for installation and training is considered services and included in cost of goods sold. Time spent providing customer support is now considered a commercial support activity and is included in selling, general and administrative expenses. Previously, customer support was considered a development phase activity and was included in research and development expense. Prior periods have been reclassified to conform to the current period presentation. The reclassification increased selling, general and administrative expenses by $0.2 million and decreased research and development expenses by $0.2 million for the three months ended June 30, 2020. The reclassification increased selling, general and administrative expenses by $0.4 million and decreased research and development expenses by $0.4 million for the six months ended June 30, 2020. The reclassification had no impact on total costs and expenses, loss from operations, net loss or net loss per share.

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 as a percentage of revenue in future periods. 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.

As noted under research and development expenses, the reclassification of customer support increased selling, general and administrative expenses by $0.2 million and decreased research and development expenses by $0.2 million for the three months ended June 30, 2020 and increased selling, general and administrative expenses by $0.4 million and decreased research and development expenses by $0.4 million for the six months ended June 30, 2020.

Interest income

Interest income consists of interest earned on our cash and cash equivalents.

Interest expense

Interest expense consists primarily of interest expense on our notes payable, changes in fair value of our derivative liability and the amortization of deferred financing costs and debt discount.

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, 2020 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, 2020.

Results of Operations for the Three Months Ended June 30, 2021 and 2020

	Three Months Ended June 30,		
	2021	2020	Change
	(in thousands)		
Revenue:			
Product revenue	$ 3,678	$ 1,041	$ 2,637
Research revenue	—	11	(11)
Contribution revenue	3,016	1,500	1,516
Total revenue	6,694	2,552	4,142
Costs and expenses:			
Cost of product revenue	4,831	2,300	2,531
Research and development	5,399	3,786	1,613
Selling, general and administrative	7,244	5,305	1,939
Total costs and expenses	17,474	11,391	6,083
Loss from operations	(10,780)	(8,839)	(1,941)
Other income (expense):			
Interest income	6	1	5
Interest expense	(1,700)	(1,844)	144
Other income, net	(1)	(3)	2
Total other expense	(1,695)	(1,846)	151
Net loss	$ (12,475)	$ (10,685)	$ (1,790)

Product revenue

Product revenue was $3.7 million for the three months ended June 30, 2021 compared to $1.1 million for the three months ended June 30, 2020, an increase of $2.6 million, which was driven by higher consumables sales of $2.4 million primarily from our T2SARS-CoV-2 Panel which we started selling in the third quarter of 2020, as well as higher sales from our T2Bacteria and T2Candida Panels. We also had higher other revenue of $0.2 million mostly attributable to service and freight.

Research revenue

Research revenue was immaterial for the three months ended June 30, 2021 and June 30, 2020.

Contribution revenue

Contribution revenue relates to our BARDA agreement and was $3.0 million for the three months ended June 30, 2021, compared to $1.5 million for the three months ended June 30, 2020. The increase of $1.5 million was primarily due to increased contract activity.

Cost of product revenue

Cost of product revenue was $4.8 million for the three months ended June 30, 2021, compared to $2.3 million for the three months ended June 30, 2020, an increase of $2.5 million. The increase in cost was driven by $1.2 million from higher consumable sales primarily from T2SARS-CoV-2, $0.6 million of higher service and repair costs, $0.6 million of increased costs due to the effect of the change in build plan partially offset by manufacturing efficiencies, $0.1 million of higher shipping related expenses and $0.1 million of royalties, partially offset by $0.1 million of decreased quality control testing.

Research and development expenses

Research and development expenses were $5.4 million for the three months ended June 30, 2021, compared to $3.8 million for the three months ended June 30, 2020, an increase of $1.6 million. The increase was driven by $0.5 million of higher payroll related expenses due to increased headcount, $0.3 million of increased BARDA consulting expenses, $0.3 million of increased IT support, increased lab and facility expenses of $0.2 million primarily for our BARDA agreement, partially offset by a decrease in T2SARS-CoV-2 expenses, $0.2 million higher of materials cost, and $0.1 million of increased clinical related expenses for assay development.

Selling, general and administrative expenses

Selling, general and administrative expenses were $7.2 million for the three months ended June 30, 2021, compared to $5.3 million for the three months ended June 30, 2020, an increase of $1.9 million. The increase was driven by an increase in payroll related expenses of $1.6 million and an increase in stock based compensation expenses of $0.7 million due to increased headcount, $0.1 million of increased travel due to less domestic COVID-19 travel restrictions, $0.2 million of increased IT support, $0.1 million of increased marketing research. These increases are partially offset by a $0.5 million impairment charge of a vacated operating lease that was recorded in 2020 and $0.3 million of lower consulting expenses primarily driven by less temporary help related to final cyber-recovery efforts in early 2020 and less work incurred for Section 404 of the Sarbanes-Oxley Act and a Board members search.

Interest income

Interest income was immaterial for the three months ended June 30, 2021 and 2020.

Interest expense

Interest expense, was $1.7 million for the three months ended June 30, 2021, compared to $1.8 million for the three months ended June 30, 2020. Interest expense decreased by $0.1 million primarily due to the 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 June 30, 2021 and 2020.

Results of Operations for the Six Months Ended June 30, 2021 and 2020

	Six Months Ended June 30,		
	2021	2020	Change
	(in thousands)		
Revenue:			
Product revenue	$ 8,328	$ 2,086	$ 6,242
Research revenue	—	11	(11)
Contribution revenue	5,322	3,000	2,322
Total revenue	13,650	5,097	8,553
Costs and expenses:			
Cost of product revenue	10,621	6,971	3,650
Research and development	10,064	8,566	1,498
Selling, general and administrative	13,447	11,960	1,487
Total costs and expenses	34,132	27,497	6,635
Loss from operations	(20,482)	(22,400)	1,918
Other income (expense):			
Interest income	12	1	11
Interest expense	(2,713)	(3,261)	548
Other income, net	48	26	22
Total other expense	(2,653)	(3,234)	581
Net loss	$ (23,135)	$ (25,634)	$ 2,499

Product revenue

Product revenue was $8.3 million for the six months ended June 30, 2021 compared to $2.1 million for the six months ended June 30, 2020, an increase of $6.2 million. The increase was driven primarily by higher consumables revenue of $5.8 million primarily from our T2SARS-CoV-2 Panel which we started selling in the third quarter of 2020, as well as higher sales from our T2Bacteria and T2Candida Panels, higher other revenue of $0.2 million mostly attributable to service and freight, and higher T2Dx instrument sales of $0.1 million.

Research revenue

Research revenue was immaterial for the six months ended June 30, 2021 and June 30, 2020.

Contribution revenue

Contribution revenue relates to our BARDA agreement and was $5.3 million for the six months ended June 30, 2021 compared to $3.0 million for the six months ended June 30, 2020. The increase of $2.3 million is primarily due to increased contract activity.

Cost of product revenue

Cost of product revenue was $10.6 million for the six months ended June 30, 2021, compared to $7.0 million for the six months ended June 30, 2020, an increase of $3.6 million. The increase in cost was driven by $2.7 million from higher consumable sales primarily from T2SARS-CoV-2, $0.7 million of increased costs due to the effect of the change in build plan partially offset by manufacturing efficiencies, $0.3 million of higher service and repair costs, $0.2 million of royalties, $0.2 million from higher instrument sales, $0.1 million of increased quality control testing and $0.1 million of higher shipping related expenses. These increases are partially offset by the $0.6 million COVID-19 related impairment charge of our T2-owned instruments and components recorded in early 2020, and $0.1 million of lower T2-owned instrument depreciation primarily as a result of a lower carrying value of T2-owned instruments subsequent to the impairment charge in the first quarter of 2020.

Research and development expenses

Research and development expenses were $10.1 million for the six months ended June 30, 2021, compared to $8.6 million for the six months ended June 30, 2020, an increase of $1.5 million. The increase was driven by increased lab and facility expenses of $0.6 million primarily related to our BARDA agreement, partially offset by a decrease in T2SARS-CoV-2 expenses, $0.5 million of increased IT support, $0.3 million of higher payroll related expenses due to increased headcount and $0.2 million of increased consulting expenses primarily related to our BARDA agreement. These increases are partially offset by decreased clinical related expenses for assay development of $0.1 million.

Selling, general and administrative expenses

Selling, general and administrative expenses were $13.4 million for the six months ended June 30, 2021, compared to $11.9 million for the six months ended June 30, 2020, an increase of $1.5 million. The increase was driven by a higher payroll related expenses of $1.8 million and higher stock based compensation expenses of $1.0 million due to increased headcount, $0.4 million of increased IT support, and $0.1 million of increased marketing research. These increases were partially offset by $0.8 million of lower consulting expenses primarily driven by less temporary help related to final cyber-recovery efforts in early 2020 and less work incurred for Section 404 of the Sarbanes-Oxley Act and a Board members search, a decrease of $0.5 million related to an impairment charge of a vacated operating lease that was recorded in 2020, $0.4 million of less legal expenses related to financings and the CEO transition and $0.1 million of less travel expenses.

Interest income

Interest income was immaterial for the six months ended June 30, 2021 and 2020.

Interest expense

Interest expense was $2.7 million for the six months ended June 30, 2021, compared to $3.3 million for the six months ended June 30, 2020. Interest expense decreased by $0.6 million primarily due to the change in fair value of the derivative associated with the CRG Term Loan Agreement.

Other income, net

Other income, net, was immaterial for the six months ended June 30, 2021 and 2020.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception, and as of June 30, 2021 and December 31, 2020 we had an accumulated deficit of $446.1 million and $423.0 million, respectively. Having obtained clearance from the FDA and a CE mark in Europe to market the T2Dx Instrument, T2Candida Panel, and T2Bacteria Panel, 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, T2SARS-CoV-2 and other product candidates.

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 (Note 7), private placements of redeemable convertible preferred stock and debt financing arrangements.

In July 2021, our shareholders approved of an increase in the number of authorized shares of our common stock from 200,000,000 to 400,000,000.

Equity Distribution Agreement

On July 30, 2019, we entered into an Equity Distribution Agreement (the "Original 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 Original 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 Original Sales Agreement to increase the aggregate gross sales amount from $65.0 million to $95.0 million. As of December 31, 2020, we had sold 101,606,667 shares of common stock with an aggregate gross sales amount of $95.0 million.

On March 31, 2021, we entered into another Sales Agreement with Canaccord ("New Sales Agreement"), as agent, pursuant to which we may offer and sell shares of common stock, for aggregate gross sale proceeds of up to $75.0 million from time to time from the effective date of the respective registration statement through Canaccord. As of June 30, 2021, we had sold 16,809,424 shares of common stock for net proceeds of $20.0 million.

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

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, we 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 June 30, 2021 and December 31, 2020 we had unrestricted cash and cash equivalents of approximately $32.7 million and $16.8 million respectively. Currently, the majority of our cash and cash equivalents, along with our marketable securities of $20.1 million, are held in U.S. treasury 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 has impacted and may continue to 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 mostly successful but may not continue to function should the pandemic escalate and further impact our personnel. In 2020, our hospital customers restricted our sales team's access to their facilities and as a result, we had significantly reduced our commercial and general and administrative staffing levels at the beginning of the COVID-19 pandemic to reduce expenses. We have since hired sales and marketing personnel. Although we did not see any material impact to accounts receivable during the period ended June 30, 2021, our exposure may increase if our customers continue to be adversely affected by the COVID-19 pandemic, including as a result of the spread of variants of the virus. Customers may reduce their purchases of products, depending on their needs and cash flow, which could negatively impact revenue. 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 BARDA and should BARDA 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, although raw materials and plastics for the manufacturing of reagents and consumables are in high demand, and interruptions in supply are difficult to predict. At the onset of the pandemic, we believed that the pandemic's impact on our sales would affect the recoverability of the value of our T2-owned instruments and components. In early 2020, 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 for excess inventories.

Going Concern

While the Company believes that its cash, cash equivalents, marketable securities and restricted cash of $53.3 million at June 30, 2021 will be sufficient to fund our current operating plan at least a year from issuance of these financial statements, certain elements of our operating plan 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 year ended December 31, 2020, management implemented a cost improvement strategy which is focused on reducing operating expenses and improving cost of goods sold.

The Term Loan Agreement with CRG Servicing LLC ("CRG") (Note 6) has certain covenants which require 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. As of June 30, 2021, the Company achieved the revenue covenant for the twenty-four month period beginning January 1, 2020. While we believe we can continue as a going concern for at least a year from issuance of these financial statements, there can be no assurances that we will continue to be in compliance with the cash covenant in future periods without additional funding.

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 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, 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 12 months from the date of issuance of these 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.

Cash flows

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

	Six Months Ended June 30,	
	2021	2020
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (19,305)	$ (28,231)
Investing activities	14,948	(9,370)
Financing activities	20,272	53,097
Net increase in cash, cash equivalents and restricted cash	$ 15,915	$ 15,496

Net cash used in operating activities

Net cash used in operating activities was approximately $19.3 million for the six months ended June 30, 2021, and consisted of a net loss of $23.1 million adjusted for non-cash items including stock-based compensation expense of $3.2 million, non-cash interest expense of $1.8 million, non-cash lease expense of $0.7 million, depreciation and amortization expense of $0.7 million, a change in fair value of the derivative of $1.0 million, and a net change in operating assets and liabilities of $1.6 million. The net change in operating assets and liabilities was primarily driven by an increase of $1.8 million in inventory to support the 2021 build plan, a decrease in operating lease liabilities of $1.5 million, a decrease in accrued expenses of $0.6 million primarily from bonus, payments related to the Transition Agreement and accrued interest and a decrease of $0.1 million in deferred revenue due to timing of service agreements, partially offset by a decrease in accounts receivable of $1.1 million primarily due to the timing and volume of instrument and consumable sales shipped near quarter end partially offset by an increase in accounts receivable for our BARDA agreement and an increase in accounts payable of $0.8 million due to timing of payments.

Net cash used in operating activities was approximately $28.2 million for the six months ended June 30, 2020, and consisted of a net loss of $25.6 million adjusted for non-cash items including stock-based compensation expense of $2.2 million, non-cash interest expense of $1.5 million, depreciation and amortization expense of $0.9 million, non-cash lease expense of $0.8 million, COVID-19 related impairment charge of $0.6 million of our T2-owned instruments and components, an impairment of one of our operating lease assets of $0.5 million, and a net change in operating assets and liabilities of $9.1 million, primarily related to a decrease in accounts payable of $2.0 million due to timing of payments, a decrease in accrued expenses of $2.8 million primarily from bonus and commission payments as well as payments related to the Second Amendment to the Employment Agreement with John McDonough, a decrease in operating lease liabilities of $1.0 million, an increase in prepaid expenses and other assets of $4.7 million primarily related to a receivable from the Sales Agreement and order deposits with our contract manufacturer, and a decrease in deferred revenue of $0.1 million, partially offset by a decrease in accounts receivable of $1.5 million from timing of collections from our U.S. Government Contract and lower instrument sales.

Net cash provided by (used in) investing activities

Net cash provided by investing activities was approximately $14.9 million for the six months ended June 30, 2021, and primarily consisted of proceeds from maturities of marketable securities of $15.2 million, partially offset by equipment purchases of $0.3 million.

Net cash used in investing activities was approximately $9.4 million for the six months ended June 30, 2020, and primarily consisted of purchases of marketable securities of $9.3 million and equipment purchases of $0.1 million.

Net cash provided by financing activities

Net cash provided by financing activities was approximately $20.3 million for the six months ended June 30, 2021, and consisted primarily of proceeds from sales of our common stock under the Sales Agreement, net of issuance costs, of $20.0 million, and of proceeds from issuance of shares under our 2014 Employee Stock Purchase Plan and stock option exercises of $0.3 million.

Net cash provided by financing activities was approximately $53.1 million for the six months ended June 30, 2020, and consisted of primarily of proceeds from sales of our common stock under the Sales Agreement, net of issuance costs, of $52.9 million and proceeds from issuance of shares under our 2014 Employee Stock Purchase Plan and stock option exercises of $0.2 million.

Borrowing Arrangements

Term Loan Agreement

In December 2016, we entered into a 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%, subsequently amended to 10%, of the principal outstanding upon repayment. We are accruing the final payment fee as interest expense and it is included as a non-current liability at June 30, 2021 and December 31, 2020 on the balance sheet.

The Term Loan Agreement with CRG is classified as a non-current liability at June 30, 2021 and December 31, 2020 as we have sufficient cash, cash equivalents and marketable securities as of the date of this filing that the minimum liquidity covenant would not be triggered at December 31 2021. We have assessed the classification of the note payable as non-current based on facts and circumstances as of the date of this filing, specifically as it relates to achieving the minimum liquidity and revenue covenants. As of June 30, 2021, we achieved the twenty-four month revenue covenant for the period beginning January 1, 2020. Management continues to reassess at each balance sheet and filing date based on facts and circumstances and can provide no assurances regarding the probability of meeting its minimum liquidity covenant in future periods.

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 2019, the Term Loan Agreement was amended to reduce minimum revenue targets, extend the interest-only period and extend the principal repayment. 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.

In January 2021, the Term Loan Agreement was amended to extend the interest-only payment period through December 30, 2022, to extend the initial principal repayment to December 30, 2022, and to significantly reduce the revenue covenant for the 24-month period beginning on January 1, 2020. We did not pay or provide any consideration in exchange for this amendment. We accounted for the January 2021 amendment as a modification 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 December 31, 2020 is $1.0 million and is classified as a non-current liability on the balance sheet at December 31, 2020 to match the classification of the related Term Loan Agreement. As of June 30, 2021, we achieved the revenue covenant for the twenty-four month period beginning January 1, 2020 and have no derivative liability.

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, 2020.

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

As a smaller reporting company, we are not required to provide this information.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

Management of the Company, with the participation of the Chief Executive Officer and the Chief Financial Officer, evaluated the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of June 30, 2021. 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 June 30, 2021, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, the Company's disclosure controls and procedures were effective.

(b) Changes in Internal Control over Financial Reporting

There have been no changes to the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f)) 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, 2020. 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, 2020.

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

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits, Financial Statement Schedules

Exhibit Number	Exhibit Description
3.1	Restated Certificate of Incorporation of the Company, as amended (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36571) filed on August 12, 2014)
3.2	Certificate of Amendment of Restated Certificate of Incorporation of the Company dated July 23, 2021 (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36751) filed on July 23, 2021)
3.3	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	T2 Biosystems, Inc. 2014 Incentive Award Plan, as amended and restated (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on June 28, 2021)
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
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith
** Furnished herewith
# Indicates management contract or compensatory plan
† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, or the Securities Act.

SIGNATURES

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

T2 BIOSYSTEMS, INC.

Date: August 9, 2021

By: /s/ JOHN SPERZEL
John Sperzel
President, Chief Executive Officer and Chairman of the Board
(principal executive officer)

Date: August 9, 2021

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: August 9, 2021

Exhibit 31.2

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

I, John M. Sprague, certify that:

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

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

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

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

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

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

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

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

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

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

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

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

Date: August 9, 2021

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of T2 Biosystems, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2021 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: August 9, 2021

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

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

Exhibit 32.2

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of T2 Biosystems, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John M. Sprague, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

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

Date: August 9, 2021

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.