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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2022

OR

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

For the transition period from _____ to _____

Commission file number: 001-36571

T2 Biosystems, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

As of May 9, 2022, the registrant had 171,725,080 shares of common stock outstanding.

T2 BIOSYSTEMS, INC.

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PART I.
FINANCIAL INFORMATION

Item 1. Financial Statements

T2 BIOSYSTEMS, INC.

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

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 9,397	$ 22,245
Marketable securities	9,989	9,996
Accounts receivable	4,361	5,134
Inventories	5,172	3,909
Prepaid expenses and other current assets	4,584	3,110
Total current assets	33,503	44,394
Property and equipment, net	4,778	4,675
Operating lease right-of-use assets	9,472	9,766
Restricted cash	1,131	1,551
Other assets	155	153
Total assets	$ 49,039	$ 60,539
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 3,385	$ 2,832
Accrued expenses and other current liabilities	8,950	8,338
Deferred revenue	338	518
Total current liabilities	12,673	11,688
Notes payable	48,257	47,790
Operating lease liabilities, net of current portion	9,060	9,359
Deferred revenue, net of current portion	47	28
Other liabilities	4,653	4,577
Commitments and contingencies (see Note 13)		
Stockholders' deficit		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; 171,412,940 and 166,400,892 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	171	166
Additional paid-in capital	462,900	459,151
Accumulated other comprehensive loss	(11)	(4)
Accumulated deficit	(488,711)	(472,216)
Total stockholders' deficit	(25,651)	(12,903)
Total liabilities and stockholders' deficit	$ 49,039	$ 60,539

See accompanying notes to condensed consolidated financial statements.

T2 BIOSYSTEMS, INC.

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

	Three Months Ended March 31,	
	2022	2021
Revenue:		
Product revenue	$ 3,844	$ 4,650
Contribution revenue	3,390	2,306
Total revenue	7,234	6,956
Costs and expenses:		
Cost of product revenue	6,205	5,790
Research and development	6,656	4,665
Selling, general and administrative	9,230	6,203
Total costs and expenses	22,091	16,658
Loss from operations	(14,857)	(9,702)
Other income (expense):		
Interest income	3	6
Interest expense	(1,650)	(1,013)
Other income, net	9	49
Total other expense	(1,638)	(958)
Net loss	$ (16,495)	$ (10,660)
Net loss per share — basic and diluted	$ (0.10)	$ (0.07)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	169,855,170	148,231,412
Other comprehensive loss:		
Net loss	$ (16,495)	$ (10,660)
Net unrealized gain (loss) on marketable securities arising during the period	(7)	9
Less: net realized gain on marketable securities included in net loss	—	(2)
Total other comprehensive (loss) income, net of taxes	(7)	7
Comprehensive loss	$ (16,502)	$ (10,653)

See accompanying notes to condensed consolidated financial statements.

T2 BIOSYSTEMS, INC.

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Deficit
	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
Unrealized gain on marketable securities	—	—	—	—	7	7
Net loss	—	—	—	(10,660)		(10,660)
Balance at March 31, 2021	148,491,673	$ 148	$ 432,905	$ (433,635)	$ 16	$ (566)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Deficit
	Shares	Amount				
Balance at December 31, 2021	166,400,892	$ 166	$ 459,151	$ (472,216)	$ (4)	$ (12,903)
Stock-based compensation expense	—	—	2,552	—	—	2,552
Issuance of common stock from vesting of restricted stock	2,002,048	2	(2)	—	—	—
Surrender of shares due to tax withholding	(539,360)	(1)	(229)	—	—	(230)
Issuance of common stock from secondary offering, net	3,549,360	4	1,428	—	—	1,432
Unrealized loss on marketable securities	—	—	—	—	(7)	(7)
Net loss	—	—	—	(16,495)	—	(16,495)
Balance at March 31, 2022	171,412,940	$ 171	$ 462,900	$ (488,711)	$ (11)	$ (25,651)

See accompanying notes to condensed consolidated financial statements.

T2 BIOSYSTEMS, INC.

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

	Three Months Ended March 31,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (16,495)	$ (10,660)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	286	383
Amortization of bond premium	—	38
Amortization of operating lease right-of-use assets	294	428
Stock-based compensation expense	2,552	1,308
Change in fair value of derivative instrument	—	(829)
Gain on sales of marketable securities	—	(2)
Non-cash interest expense	543	915
Changes in operating assets and liabilities:		
Accounts receivable	773	1,065
Prepaid expenses and other assets	(1,476)	(28)
Inventories	(1,534)	(1,426)
Accounts payable	553	1,798
Accrued expenses and other liabilities	502	(978)
Deferred revenue	(161)	27
Operating lease liabilities	(278)	(747)
Net cash used in operating activities	(14,441)	(8,708)
Cash flows from investing activities		
Proceeds from maturities of marketable securities	—	2,750
Purchases and manufacture of property and equipment	(29)	(197)
Net cash provided by investing activities	(29)	2,553
Cash flows from financing activities		
Payment of employee restricted stock tax withholdings	(230)	—
Proceeds from issuance of shares from employee stock purchase plan and stock option exercises	—	53
Proceeds from issuance of common stock in public offerings, net of offering costs	1,432	—
Net cash provided by financing activities	1,202	53
Net decrease in cash, cash equivalents and restricted cash	(13,268)	(6,102)
Cash, cash equivalents and restricted cash at beginning of period	23,796	17,344
Cash, cash equivalents and restricted cash at end of period	$ 10,528	$ 11,242
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 1,106	$ 928
Supplemental disclosures of noncash activities		
Transfer of T2 owned instruments and components (from) to inventory	$ (271)	$ (537)
Purchases of property and equipment included in accounts payable and accrued expenses	$ 134	$ 100

	March 31, 2022	March 31, 2021
Reconciliation of cash, cash equivalents and restricted cash at end of period		
Cash and cash equivalents	$ 9,397	$ 10,691
Restricted cash	1,131	551
Total cash, cash equivalents and restricted cash	$ 10,528	$ 11,242

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 has developed 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. Our technology 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.

Liquidity and Going Concern

At March 31, 2022, the Company had cash, cash equivalents, marketable securities and restricted cash of $20.5 million, an accumulated deficit of $488.7 million, stockholders' deficit of $25.7 million, and has historically experienced cash outflows from operating activities. 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), its March 2021 establishment of an Equity Distribution 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, marketing and medical and clinical affairs personnel. Although the Company did not see any material impact to accounts receivable during the period ended March 31, 2022, 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.

Since authorization from the United States Food and Drug Administration, or FDA, was obtained to market the T2Dx Instrument, T2Candida Panel, and T2Bacteria Panel, and Emergency Use Authorization, or EUA, was issued for the T2SARS-CoV-2 Panel, the Company has incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution. If the FDA rescinds EUA, the Company would be unable to sell its T2SARS-CoV-2 tests. 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.

The Company believes that its cash, cash equivalents, marketable securities and restricted cash of $20.5 million at March 31, 2022 will not be sufficient to fund its current operating plan at least one year from issuance of these financial statements, as certain elements of our operating plan cannot be considered probable. Absent any reductions in current operating expenses, the Company believes it will require additional financing during the third quarter of 2022. 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. In June 2021, the Company achieved the revenue target for the twenty-four month period ended December 31, 2021. There can be no assurances that it will continue to be in compliance with the cash covenant in future periods without additional funding. In February 2022, CRG amended the Term Loan Agreement, extending the interest only period and maturity to December 30, 2023.

The Company's stock has been trading under $1.00. On November 5, 2021, the Company received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for the Company's common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Global Market under Nasdaq Listing Rule 5450(a)(1). Under Nasdaq rules, the Company has 180 days (May 4, 2022) to regain compliance by increasing the stock price to over $1.00. On May 5, 2022, the Company received a letter from Nasdaq informing the Company that its shares of common stock have failed to comply with the $1.00 minimum bid price required for continued listing and, as a result, the Company's shares are subject to delisting. The letter further stated that the Company may appeal the Nasdaq Staff delisting determination to a Nasdaq listing qualifications hearings panel (the "Panel").

The Company has filed an appeal and hearing request to the Nasdaq Staff's determination which will stay the delisting of the Company's shares of common stock from Nasdaq pending the Panel's decision. The Nasdaq Staff has informed the Company that the delisting action has been stayed, pending a final written decision by the Panel, and the hearing date has been set for June 2, 2022. There can be no assurance that the Panel will grant the Company's request for continued listing; however, the Company intends to present a plan to regain compliance to the Panel that includes a discussion of the events that it believes will enable it to regain compliance in this timeframe and a commitment to effect a reverse stock split, if necessary.

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 contract with BARDA, 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.

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, 2021.

The accompanying interim condensed consolidated balance sheet as of March 31, 2022, the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2022 and 2021, the condensed consolidated statements of stockholders' deficit for the three months ended March 31, 2022 and 2021, the condensed consolidated statements of cash flows for the three months ended March 31, 2022 and 2021 and the related financial data and other information disclosed in these notes are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements, and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of March 31, 2022, and the results of its operations for the three months ended March 31, 2022 and 2021 and its cash flows for the three months ended March 31, 2022 and 2021. The results for the three months ended March 31, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022, 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 $1.0 million or 13% of total revenue and $0.5 million or 7% of total revenue for the three months ended March 31, 2022 and 2021, respectively.

For the three months ended March 31, 2022 and 2021, no international customer represented greater than 10% of total revenue.

The Company derived approximately 47% of its total revenue from one customer for the three months ended March 31, 2022 and 33% of its total revenue from the same customer for the three months ended March 31, 2021. The Company derived approximately 9% of its total revenue from a second customer for the three months ended March 31, 2022 and 19% of its total revenue from the same customer for the three months ended March 31, 2021.

As of March 31, 2022 and December 31, 2021, the Company had outstanding receivables of $0.7 million and $0.6 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 consist of U.S. treasury securities, which are classified as available-for-sale and included in current assets. Available-for-sale debt securities are carried at fair value with unrealized gains and losses reported as a component of stockholders' deficit in accumulated other comprehensive (loss) 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 in accumulated other comprehensive loss (income). There were no other-than-temporary unrealized losses as of March 31, 2022.

The following table summarizes the Company's marketable securities at March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities	$ 10,000	$ —	$ (11)	$ 9,989
Total	$ 10,000	$ —	$ (11)	$ 9,989

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities	10,000	—	(4)	9,996
Total	$ 10,000	$ —	$ (4)	$ 9,996

The following table summarizes the maturities of the Company's marketable securities at March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022		December 31, 2021	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Due in less than 1 year	$ 10,000	$ 9,989	$ 10,000	$ 9,996
Due in 1-2 years	—	—	—	—
Total	$ 10,000	$ 9,989	$ 10,000	$ 9,996

Guarantees

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

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

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

As of March 31, 2022 and December 31, 2021, 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.

Contribution Revenue

Income under the government BARDA contract is earned under a cost-sharing arrangement in which the Company is reimbursed for direct costs incurred plus allowable indirect costs. The government contract revenue is recognized as the related reimbursable expenses are incurred. The cost reimbursement that is reported as revenue is presented gross of the related reimbursable expenses in the Company's consolidated statements of operations; the related reimbursable expenses are expensed as incurred as research and development expense. The Company accounts for these contracts as a government grant which analogizes with International Accounting Standards 20 ("IAS 20"), *Accounting for Government Grants and Disclosure of Government Assistance*.

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 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, March 31,	
	2022	2021
Product revenue		
Instruments	$ 876	$ 425
Consumables	2,950	4,206
Instrument rentals	18	19
Total product revenue	3,844	4,650
Contribution revenue	3,390	2,306
Total revenue	$ 7,234	$ 6,956

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 March 31, 2022. 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 $0.2 million as of March 31, 2022. The Company expects to recognize 86% 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 March 31, 2022 and December 31, 2021.

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 $0.4 million and $0.5 million at March 31, 2022 and December 31, 2021, respectively. Revenue recognized during the three months ended March 31, 2022 relating to contract liabilities at December 31, 2021 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 both March 31, 2022 and December 31, 2021, capitalized costs to fulfill contracts of $0.1 million was included in prepaid and other current assets and less than $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 delivering products or services associated with contribution revenue, clinical trials to evaluate the clinical utility of our product candidates, and costs associated with the enhancements of developed products. These costs include salaries and benefits, stock compensation, research-related facility and overhead costs, laboratory supplies, equipment and contract services.

Recent Accounting Standards

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

Accounting Standards Adopted

In August 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 adopted the standard as of January 1, 2022. The adoption did not have a material impact on the Company's 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 adopted this standard as of January 1, 2022. The adoption did not have a material impact on the Company's financial statements.

In November 2021, the FASB issued ASU 2021-10, *Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance*. This ASU requires certain disclosures when companies (a) have received government assistance and (b) use a grant or contribution accounting model by analogy to other accounting guidance. A company that has received government assistance must provide disclosures related to the nature of the transaction, accounting policies used to account for the transaction, and the amounts and line items on the financial statements that are affected by the transaction. This ASU is effective for fiscal years beginning after December 15, 2021, with early adoption permitted, and can be applied either prospectively or retrospectively. The Company adopted this standard as of January 1, 2022. The adoption did not have a material impact on the Company's 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 March 31, 2022 and December 31, 2021 (in thousands):

	Balance at March 31, 2022	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	$ 9,989	$ 9,989	$ —	$ —
	$ 9,989	$ 9,989	$ —	$ —

	Balance at December 31, 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	9,996	9,996	—	—
	$ 9,996	$ 9,996	$ —	$ —

The Company's cash equivalents and available-for-sale marketable securities are comprised of 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 $1.1 million at March 31, 2022 and $1.6 million at December 31, 2021 (Note 4).

4. Restricted Cash

The Company is required to maintain security deposits for its operating lease agreements for the duration of the lease agreements. At March 31, 2022, the Company had money market accounts for $1.1 million, which represented collateral as security deposits for its operating lease agreements for two facilities. At December 31, 2021, the Company had money market accounts for $1.6 million, which represented collateral as security deposits for its operating lease agreements for three 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):

	March 31, 2022	December 31, 2021
Raw materials	$ 2,400	$ 1,591
Work-in-process	1,418	953
Finished goods	1,354	1,365
Total inventories, net	$ 5,172	$ 3,909

Property and Equipment

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

	March 31, 2022	December 31, 2021
Office and computer equipment	$ 749	$ 749
Software	783	783
Laboratory equipment	5,496	5,507
Furniture	197	197
Manufacturing equipment	1,445	1,445
Manufacturing tooling and molds	478	478
T2-owned instruments and components	6,939	6,668
Leasehold improvements	3,785	3,768
Construction in progress	600	512
	20,472	20,107
Less accumulated depreciation and amortization	(15,694)	(15,432)
Property and equipment, net	$ 4,778	$ 4,675

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 March 31, 2022, there was $1.2 million of raw materials or work-in-process inventory in T2-owned instruments and components compared with $1.4 million at December 31, 2021. 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 March 31, 2022 and 2021.

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 March 31, 2022 and 2021, respectively.

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Accrued Expenses

Accrued expenses consist of the following (in thousands):

	March 31, 2022	December 31, 2021
Accrued payroll and compensation	$ 4,320	$ 3,687
Accrued research and development expenses	914	1,250
Accrued professional services	421	384
Accrued interest	1,106	974
Operating lease liabilities	1,195	1,174
Other accrued expenses	994	869
Total accrued expenses and other current liabilities	$ 8,950	$ 8,338

6. Notes Payable

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

	March 31, 2022	December 31, 2021
Term loan agreement including PIK interest, before unamortized discount and issuance costs	$ 51,140	$ 49,364
Less: unaccrued paid-in-kind interest	(2,642)	(1,287)
Less: unamortized discount and deferred issuance costs	(241)	(287)
Total notes payable	$ 48,257	$ 47,790

The Term Loan Agreement with CRG is classified as a non-current liability at March 31, 2022 and December 31, 2021 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.

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 February 2022, the entire principal payment, together with all other outstanding obligations, shall be due and payable upon maturity, December 30, 2023.

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. 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 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 maturity date, 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 March 31, 2022 and December 31, 2021 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 of $5.0 million.

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.

In February 2022, the Term Loan Agreement was amended to extend the interest-only payment period through December 30, 2023, and to extend the principal repayment to December 30, 2023. The Company did not pay or provide any consideration in exchange for this amendment. As the effective borrowing rate under the amended agreement is less than the effective borrowing rate under the previous agreement, a concession is deemed to have been granted under ASC 470-60. As a concession has been granted, the agreement was accounted for as a troubled debt restructuring under ASC 470-60. The amendment did not result in a gain on restructuring as the future undiscounted cash outflows required under the amended agreement exceed the carrying value of the debt immediately prior to the amendment.

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

Shares Authorized

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.

Equity Distribution Agreement

On March 31, 2021, the Company entered into a 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 three months ended March 31, 2022, the Company sold 3,549,360 shares for net proceeds of $1.4 million under the New Sales Agreement. The Company sold no shares under the New Sales Agreement during the three months ended March 31, 2021.

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 March 31, 2022, there were 1,415,266 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 9,625,000 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 March 31, 2022, there were 4,009,361 shares available for future grant under the Inducement Plan.

Stock Options

During the three months ended March 31, 2022 and 2021, the Company granted stock options with an aggregate fair value of $0.2 million and $0.6 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, 2021	9,868,947	$ 2.88	7.09	$ 51
Granted	578,500	0.41		
Exercised	—	—	—	—
Forfeited	(81,466)	1.01		
Cancelled	(426,205)	2.29		
Outstanding at March 31, 2022	9,939,776	$ 2.77	7.25	$ 118
Exercisable at March 31, 2022	5,688,369	$ 4.07	6.16	$ 28
Vested or expected to vest at March 31, 2022	9,321,200	$ 2.89	7.14	$ 102

There were no options exercised in the three months ended March 31, 2022 and 42,626 options exercised in the three months ended March 31, 2021. The weighted-average grant date fair values of stock options granted in the three month periods ended March 31, 2022 and 2021 were $0.33 per share and $1.33 per share, respectively, and were calculated using the following estimated assumptions:

	Three Months Ended March 31,	
	2022	2021
Weighted-average risk-free interest rate	1.67%	0.95%
Expected dividend yield	—%	—%
Expected volatility	105%	104%
Expected terms	6.0 years	6.0 years

The total fair values of options that vested during the three months ended March 31, 2022 and 2021 were $0.6 million and $0.6 million, respectively.

As of March 31, 2022, there was $3.2 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 2.4 years as of March 31, 2022.

Restricted Stock Units

During the three months ended March 31, 2022, 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 $3.6 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, 2021	7,120,475	$ 1.84
Granted	7,883,807	0.46
Vested	(2,002,048)	2.02
Forfeited	(106,849)	1.50
Nonvested at March 31, 2022	12,895,385	$ 0.97

As of March 31, 2022, there was $11.5 million of total unrecognized compensation cost related to nonvested restricted stock units granted. 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 2.1 years, as of March 31, 2022.

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 March 31, 2022 and 2021 was approximately $0.1 million and $0.1 million, respectively.

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 March 31, 2022, there were 2,623,655 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 March 31,	
	2022	2021
Cost of product revenue	$ 129	$ 47
Research and development	422	178
Selling, general and administrative	1,994	1,068
Total stock-based compensation expense	$ 2,545	$ 1,293

For the three months ended March 31, 2022 and 2021, stock-based compensation expenses capitalized as part of inventory or T2Dx instruments and components were immaterial.

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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 March 31, 2022 and December 31, 2021.

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 March 31, 2022 .

10. Net Loss Per Share

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

	Three Months Ended March 31,	
	2022	2021
Options to purchase common shares	9,939,776	8,974,627
Restricted stock units	12,895,385	6,857,896
Warrants to purchase common stock	1,097,249	1,097,249
Total	23,932,410	16,929,772

11. 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 September 2021, BARDA exercised an option valued at approximately $6.4 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.

On March 31, 2022, the Company announced that BARDA had exercised Option 2B under the existing multiple-year cost-share contract between BARDA and the Company and is providing an additional $4.4 million in funding to the Company. The additional funding under Option 2B will be used to advance the U.S. clinical trials for the T2Biothreat® Panel and T2Resistance® Panel, and to advance the development of the Company's comprehensive panel for the detection of bloodstream infections and antimicrobial resistance and next-generation instrument.

The option exercise occurred simultaneously on March 31, 2022 with a modification to the BARDA contract to make immaterial changes to, among other things, the statement of work.

The Company recorded contribution revenue of $3.4 million and $2.3 million for the three months ended March 31, 2022 and 2021, respectively, under the BARDA contract.

The Company had outstanding accounts receivable of $2.2 million and $1.9 million at March 31, 2022 and December 31, 2021, respectively, under the BARDA contract.

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 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. The lease terminated on December 31, 2021.

In November 2014, the Company entered into a lease for additional laboratory space in Lexington, Massachusetts. The lease term commenced in April 2015 and extended for six years. The rent expense, inclusive of the escalating rent payments, is recognized on a straight-line basis over the lease term. As an incentive to enter into the lease, the landlord paid approximately $1.4 million of the $2.2 million space build-out costs. 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 March 31, 2022 and December 31, 2021 and received the initial $281,000 security deposit in return.

In September 2021, the Company entered into a lease for office, research, laboratory and manufacturing space in Billerica, Massachusetts. The lease has a term of 126 months from the commencement date. The commencement date is anticipated to be in fiscal year 2022; therefore, there is no effect on the operating lease right-of-use assets and lease liability accounts at March 31, 2022. The Company opened a money market account for $1.0 million, which represents collateral as a security deposit for this lease and is classified as restricted cash at March 31, 2022.

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

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 months ended March 31, 2022 and 2021 were immaterial.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, and Section 21E of the Securities and Exchange Act of 1934, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy, prospective products and product candidates, their expected performance and impact on healthcare costs, marketing clearance from the FDA, reimbursement for our product candidates, research and development costs, timing of regulatory filings, timing and likelihood of success, plans and objectives of management for future operations, availability of 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 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 U.S. Food and Drug Administration or regulatory clearance for new product candidates in other jurisdictions;*
- *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 our technology;*
- *our ability to recruit, train and retain key personnel;*
- *our dependence on third parties;*
- *manufacturing and other product risks, including unforeseen interruptions in supply chain;*
- *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;*
- *our ability to maintain compliance with Nasdaq listing requirements;*
- *the impact of the COVID-19 pandemic on our business, results of operations and financial positions;*
- *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, 2021, 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, 2021.

Business Overview

We are an *in vitro* diagnostics company and leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes. 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 innovative products that offer a rapid, sensitive and simple alternative to existing diagnostic methodologies. We are developing a broad set of applications aimed at improving patient outcomes, reducing the cost of healthcare, and lowering mortality rates by helping medical professionals make earlier targeted treatment decisions. Our technology 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. We are currently targeting a range of critically underserved healthcare conditions, focusing initially on those for which a rapid diagnosis will serve an important dual role – saving lives and reducing costs. Our current development efforts primarily target sepsis, which is an area of significant unmet medical need in which existing therapies could be more effective with improved diagnostics.

Our primary commercial products include the T2Dx® Instrument, the T2Candida® Panel, the T2Bacteria® Panel, the T2Resistance® Panel, and the T2SARS-CoV-2™ Panel.

We have never been profitable and have incurred net losses in each year since inception. Our accumulated deficit at March 31, 2022 was $488.7 million and we have experienced cash outflows from operating activities over the past years. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations. We have incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution of our FDA-cleared products, 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 products.

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, marketing, and medical and clinical affairs personnel. Although we did not see any material impact to accounts receivable during the year ended December 31, 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, as described further below, 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.

We believe that our cash, cash equivalents, marketable securities and restricted cash of $20.5 million at March 31, 2022 will not be sufficient to fund our current operating plan at least a year from issuance of these financial statements unless additional funds are raised. Absent any reductions in current operating expenses, the Company believes it will require additional financing during the third quarter of 2022. Certain elements of our operating plan cannot be considered probable.

The Term Loan Agreement with CRG Servicing LLC ("CRG") (Note 6) has certain covenants which require us to achieve certain annual revenue targets, whereby we are required to pay double the amount of any shortfall as an acceleration of principal payments, and maintain a minimum cash balance of $5.0 million. In June 2021, we achieved the revenue covenant for the twenty-four month period beginning January 1, 2020. There can be no assurances that we will continue to be in compliance with the cash covenant in future periods without additional funding.

In February 2022, CRG amended the Term Loan Agreement extending the interest only period and maturity to December 30, 2023.

On March 31, 2022, BARDA, part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services exercised Option 2B under our existing multiple-year cost-share agreement with BARDA and the Company and is providing an additional $4.4 million in funding to the Company. The total potential BARDA funding if all contract options are exercised is $69.0 million. The additional funding under Option 2B will be used to advance the U.S. clinical trials for the T2Biothreat® Panel and T2Resistance® Panel, and to advance the development of the Company's comprehensive panel for the detection of bloodstream infections and antimicrobial resistance and next-generation instrument.

The option exercise occurred simultaneously on March 31, 2022 with a modification to the BARDA Contract to make immaterial changes to, among other things, the statement of work. The modification does not change the overall total potential value of the BARDA agreement.

On November 5, 2021, we received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Global Market under Nasdaq Listing Rule 5450(a)(1). Under Nasdaq rules, we have 180 days (May 4, 2022) to regain compliance by increasing the stock price to over $1.00. On May 5, 2022, we received a letter from Nasdaq informing us that our shares of common stock have failed to comply with the $1.00 minimum bid price required for continued listing and, as a result, our shares are subject to delisting. The letter further stated that we may appeal the Nasdaq Staff delisting determination to a Nasdaq listing qualifications hearings panel (the "Panel").

We have filed an appeal and hearing request to the Nasdaq Staff's determination which will stay the delisting of our shares of common stock from Nasdaq pending the Panel's decision. The Nasdaq Staff has informed us that the delisting action has been stayed, pending a final written decision by the Panel, and the hearing date has been set for June 2, 2022. There can be no assurance that the Panel will grant our request for continued listing; however, we intend to present a plan to regain compliance to the Panel that includes a discussion of the events that we believe will enable us to regain compliance in this timeframe and a commitment to effect a reverse stock split, if necessary.

These conditions raise substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that the financial statements are issued. Management's plans to alleviate the conditions that raise substantial doubt include raising additional funding, earning payments pursuant to our contract with BARDA, delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels for us to continue as a going concern for a period of 12 months from the date the financial statements are issued. Management has concluded the likelihood that its plan to successfully obtain sufficient funding from one or more of these sources or adequately reduce expenditures, while reasonably possible, is less than probable. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of issuance of these consolidated financial statements.

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 our 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.

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

We anticipate our overall research and development expenses remain consistent or increase in support of increased activity under the BARDA agreement. 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.

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. 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 the majority of selling, general and administrative expenses as incurred.

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, 2021 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, 2021.

Results of Operations for the Three Months Ended March 31, 2022 and 2021

	Three Months Ended March 31,		
	2022	2021	Change
	(in thousands)		
Revenue:			
Product revenue	$ 3,844	$ 4,650	$ (806)
Contribution revenue	3,390	2,306	1,084
Total revenue	7,234	6,956	278
Costs and expenses:			
Cost of product revenue	6,205	5,790	415
Research and development	6,656	4,665	1,991
Selling, general and administrative	9,230	6,203	3,027
Total costs and expenses	22,091	16,658	5,433
Loss from operations	(14,857)	(9,702)	(5,155)
Other income (expense):			
Interest income	3	6	(3)
Interest expense	(1,650)	(1,013)	(637)
Other income, net	9	49	(40)
Total other expense	(1,638)	(958)	(680)
Net loss	$ (16,495)	$ (10,660)	$ (5,835)

Product revenue

Product revenue was $3.8 million for the three months ended March 31, 2022 compared to $4.6 million for the three months ended March 31, 2021, a decrease of $0.8 million, which was driven by lower consumables sales of $1.0 million mostly due to a decrease in sales of T2SARS-CoV-2, offset by higher T2Dx sales of $0.2 million.

Contribution revenue

Contribution revenue relates to our BARDA agreement and was $3.4 million for the three months ended March 31, 2022, compared to $2.3 million for the three months ended March 31, 2021. The increase of $1.1 million was due to increased contract activity.

Cost of product revenue

Cost of product revenue was $6.2 million for the three months ended March 31, 2022, compared to $5.8 million for the three months ended March 31, 2021, an increase of $0.4 million. The increase in cost was driven by a $1.2 million increase related to a higher number of instrument sales, offset by a decrease in $0.5 million related to consumables, a $0.2 million decrease due to lower cycle count costs and $0.1 million in reduced royalties.

Research and development expenses

Research and development expenses were $6.7 million for the three months ended March 31, 2022, compared to $4.7 million for the three months ended March 31, 2021, an increase of $2.0 million. The increase was driven by an increase of $0.7 million in payroll expenses due to increased headcount, a $0.5 million increase in consulting expenses, a $0.4 million increase in lab expenses, a $0.3 million increase in clinical-related expenses, and a $0.1 million increase in project expenses.

Selling, general and administrative expenses

Selling, general and administrative expenses were $9.2 million for the three months ended March 31, 2022, compared to $6.2 million for the three months ended March 31, 2021, an increase of $3.0 million. The increase was driven by a $2.1 million increase in payroll expenses due to increased headcount, a $0.5 million increase in consulting expenses, a $0.2 million increase in marketing expenses, and a $0.2 million increase in travel expenses.

Interest income

Interest income was immaterial for the three months ended March 31, 2022 and 2021.

Interest expense

Interest expense was $1.6 million for the three months ended March 31, 2022, compared to $1.0 million for the three months ended March 31, 2021, an increase of $0.6 million. Interest expense increased primarily due to the amortization of the debt discount associated with the CRG Term Loan Agreement.

Other income, net

Other income, net, was immaterial for the three months ended March 31, 2022 and 2021.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception, and as of March 31, 2022 and December 31, 2021 we had an accumulated deficit of $488.7 million and $472.2 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), our March 2021 establishment of an Equity Distribution 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 March 31, 2021, we entered into a 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. In the second quarter of 2021, we had sold 16,809,424 shares of common stock for net proceeds of $20.0 million. During the three months ended March 31, 2022, the Company sold 3,549,360 shares for net proceeds of $1.4 million under the New Sales Agreement. We sold no shares under the New Sales Agreement during the three months ended March 31, 2021.

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.

Plan of operations and future funding requirements

As of March 31, 2022 and December 31, 2021 we had unrestricted cash and cash equivalents of approximately $9.4 million and $22.2 million, respectively. We also have marketable securities of $10.0 million, which 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 three months ended March 31, 2022, 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.

Going Concern

We believe that our cash, cash equivalents, marketable securities and restricted cash of $20.5 million at March 31, 2022 will not be sufficient to fund our current operating plan at least a year from issuance of these financial statements. Absent any reductions in current operating expenses, the Company believes it will require additional financing during the third quarter of 2022. Certain elements of our operating plan cannot be considered probable.

The Term Loan Agreement with CRG Servicing LLC ("CRG") (Note 6) has certain covenants which require us to achieve certain annual revenue targets, whereby we are required to pay double the amount of any shortfall as an acceleration of principal payments, and maintain a minimum cash balance of $5.0 million. In June 2021, we achieved the revenue covenant for the twenty-four month period beginning January 1, 2020. There can be no assurances that we will continue to be in compliance with the cash covenant in future periods without additional funding. In February 2022 CRG amended the Term Loan Agreement extending the interest only period and maturity to December 30, 2023.

On November 5, 2021, we received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Global Market under Nasdaq Listing Rule 5450(a)(1). Under Nasdaq rules, we have 180 days (May 4, 2022) to regain compliance by increasing the stock price to over $1.00. On May 5, 2022, we received a letter from Nasdaq informing us that our shares of common stock have failed to comply with the $1.00 minimum bid price required for continued listing and, as a result, our shares are subject to delisting. The letter further stated that we may appeal the Nasdaq Staff delisting determination to a Nasdaq listing qualifications hearings panel (the "Panel").

We have filed an appeal and hearing request to the Nasdaq Staff's determination which will stay the delisting of our shares of common stock from Nasdaq pending the Panel's decision. The Nasdaq Staff has informed us that the delisting action has been stayed, pending a final written decision by the Panel, and the hearing date has been set for June 2, 2022. There can be no assurance that the Panel will grant our request for continued listing; however, we intend to present a plan to regain compliance to the Panel that includes a discussion of the events that we believe will enable us to regain compliance in this timeframe and a commitment to effect a reverse stock split, if necessary.

These conditions raise substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that the financial statements are issued. Management's plans to alleviate the conditions that raise substantial doubt include raising additional funding, earning payments pursuant to our contract with BARDA, delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels for us to continue as a going concern for a period of 12 months from the date the financial statements are issued. Management has concluded the likelihood that its plan to successfully obtain sufficient funding from one or more of these sources or adequately reduce expenditures, while reasonably possible, is less than probable. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of issuance of these 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:

	Three Months Ended March 31,	
	2022	2021
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (14,441)	$ (8,708)
Investing activities	(29)	2,553
Financing activities	1,202	53
Net decrease in cash, cash equivalents and restricted cash	$ (13,268)	$ (6,102)

Net cash used in operating activities

Net cash used in operating activities was approximately $14.5 million for the three months ended March 31, 2022, and consisted of a net loss of $16.5 million adjusted for non-cash items including stock-based compensation expense of $2.6 million, non-cash interest expense of $0.5 million, non-cash lease expense of $0.3 million, and depreciation and amortization expense of $0.3 million. The net change in operating assets and liabilities was primarily driven by a decrease in accounts receivable of $0.8 million, an increase in prepaid expenses and other assets of $1.5 million due to timing of payments, an increase in inventory of $1.5 million due to bulk materials purchases for favorable pricing, an increase in accounts payable of $0.6 million due to increased spend on inventory and lab

supplies, an increase in accrued expenses of $0.5 million due to increased employee costs, a decrease in deferred revenue of $0.2 million, and a decrease in operating lease liabilities of $0.3 million.

Net cash used in operating activities was approximately $8.7 million for the three months ended March 31, 2021, and consisted of a net loss of $10.7 million adjusted for non-cash items including stock-based compensation expense of $1.3 million, non-cash interest expense of $0.9 million, non-cash lease expense of $0.4 million, depreciation and amortization expense of $0.4 million, a change in fair value of the derivative of $0.8 million, and a net change in operating assets and liabilities of $0.3 million. The net change in operating assets and liabilities was primarily driven by a decrease in operating lease liabilities of $0.7 million, a decrease in accrued expenses of $1.0 million primarily from bonus and commission payments as well as payments under an employment agreement with a former executive officer, and an increase of $1.4 million in inventory to support the 2021 build plan, partially offset by an increase in accounts payable of $1.8 million due to timing of payments and increased spend related to T2SARS-CoV-2 and a decrease in accounts receivable of $1.1 million primarily due to the timing of instrument and consumable sales shipped near quarter end.

Net cash provided by (used in) investing activities

Net cash used in investing activities was immaterial for the three months ended March 31, 2022.

Net cash provided by investing activities was approximately $2.6 million for the three months ended March 31, 2021, and primarily consisted of proceeds from maturities of marketable securities of $2.8 million, partially offset by equipment purchases of $0.2 million.

Net cash provided by financing activities

Net cash provided by financing activities was approximately $1.2 million for the three months ended March 31, 2022, and consisted primarily of proceeds from sales of our common stock under the Sales Agreement, net of issuance costs, of $1.4 million, offset by payment of employee restricted stock tax withholdings of $0.2 million.

Net cash provided by financing activities was approximately $0.1 million for the three months ended March 31, 2021, and consisted of stock option exercises.

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. 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 maturity date, 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 March 31, 2022 and December 31, 2021 on the balance sheet.

The Term Loan Agreement with CRG is classified as a non-current liability at March 31, 2022 and December 31, 2021 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. 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. In June 2021, we achieved the twenty-four month revenue covenant for the period beginning January 1, 2020 and have no derivative liability. 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. We 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. We also reduced the exercise price for the warrants previously issued to CRG to purchase an aggregate of 528,958 shares of our common stock to $1.55. All of the New Warrants are exercisable any time prior to September 9, 2029, and all of the previously issued warrants are exercisable any time prior to December 30, 2026.

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.

In February 2022, the Term Loan Agreement was amended to extend the interest-only payment period through December 30, 2023, and to extend the initial principal repayment to December 30, 2023. We did not pay or provide any consideration in exchange for this amendment. As the effective borrowing rate under the amended agreement is less than the effective borrowing rate under the previous agreement, a concession is deemed to have been granted under ASC 470-60. As a concession has been granted, the agreement was accounted for as a troubled debt restructuring under ASC 470-60. The amendment did not result in a gain on restructuring as the future undiscounted cash outflows required under the amended agreement exceed the carrying value of the debt immediately prior to the amendment.

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.

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, 2021.

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 March 31, 2022. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported on a timely basis and that such information is accumulated and communicated to management, including the Chief Executive Officer and the Chief Financial Officer, as appropriate, to allow timely decisions regarding disclosure.

Based on the evaluation of our disclosure controls and procedures as of March 31, 2022, 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, 2021. Aside from the risk factors below, 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, 2021.

Our failure to meet the continued listing requirements of The Nasdaq Global Market could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of The Nasdaq Global Market, such as the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Under Nasdaq rules, the closing bid price for our common stock must remain at or above $1.00 per share to comply with Nasdaq's minimum bid requirement for continued listing.

On November 5, 2021, we received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on The Nasdaq Global Market. We were provided an initial period of 180 calendar days, or until May 4, 2022, to regain compliance. On May 5, 2022 we received a letter from Nasdaq informing us that our shares have failed to comply with the $1.00 minimum bid price required for continued listing on The Nasdaq Global Market and, as a result, our shares are subject to delisting. We filed an appeal and hearing request with Nasdaq, which has stayed the delisting of our common stock from The Nasdaq Global Market pending a Nasdaq listing qualifications hearings panel's (the "Panel") decision. The hearing date has been set for June 2, 2022. There can be no assurance that the Panel will grant our request for continued listing; however, we intend to present a plan to regain compliance to the Panel that includes a discussion of the events that we believe will enable us regain compliance in this timeframe and a commitment to effect a reverse stock split, if necessary.

The delisting of our common stock from Nasdaq may make it more difficult for us to raise capital on favorable terms in the future. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. Further, if we were to be delisted from Nasdaq, our common stock would cease to be recognized as covered securities and we would be subject to regulation in each state in which we offer our securities. Moreover, there is no assurance that any actions that we take to restore our compliance with the minimum bid price requirement would stabilize the market price or improve the liquidity of our common stock, prevent our common stock from falling below the minimum bid price required for continued listing again, or prevent future non-compliance with Nasdaq's listing requirements.

We may be adversely affected by fluctuations in demand for, and prices of, raw materials and other supplies.

We use various raw materials and other supplies in our business. Although there are currently multiple suppliers for these materials and supplies, changes in demand for, and the market price of, these raw materials and supplies could significantly affect our ability to manufacture our diagnostic instruments and, consequently, our profitability. The prices of these raw materials and supplies may fluctuate and are affected by numerous factors beyond our control such as interest rates, exchange rates, inflation or deflation, global and regional supply and demand, and the political and economic conditions of countries that produce rare earth minerals and products.

In addition, our agreements with our third party suppliers are non-exclusive. Our suppliers may dedicate more resources to other companies. We may in the future experience shortages and price fluctuations of certain key components and raw materials required in the manufacturing of our products, and the predictability of the availability and pricing of these components and raw materials may be limited. Current or future supply chain interruptions that could be exacerbated by global political tensions, such as the situation in Ukraine, or the COVID-19 pandemic and government responses could negatively impact our ability to acquire such key components or materials. Component and raw material shortages or pricing fluctuations could be material in the future. In the event of a component or raw material shortage, supply interruption or material pricing change from suppliers of these components or raw materials, we may not be able to develop alternate sources in a timely manner or at all in the case of sole or limited sources.

Developing alternate sources of supply for these components or raw materials may be time consuming, difficult, and costly and we may not be able to source these components or raw materials on terms that are acceptable to us, or at all, which may undermine our ability to meet our requirements or to fill user orders in a timely manner. Any interruption or delay in the supply of any of these parts or components, or the inability to obtain these components or raw materials from alternate sources at acceptable prices and within a reasonable amount of time, would adversely affect our ability to meet scheduled product deliveries to users. This could adversely affect our relationships with our users and could cause delays in our ability to expand our operations. Even where we are able to pass increased component or raw material costs along to our users, there may be a lapse of time before we are able to do so such that we must absorb the increased cost initially. If we are unable to buy these components or raw materials in quantities sufficient to meet our requirements on a timely basis, we will not be able to have sufficient ability to meet user demand, which may have a negative impact on our operations and financial results.

We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.

Our cash, cash equivalents, marketable securities and restricted cash at December 31, 2021 was $33.8 million, which will not be sufficient to fund our current operating plan at least a year from issuance of these financial statements. Absent any reductions in current operating expenses, the Company believes it will require additional financing during the third quarter of 2022. While we plan to raise capital there can be no assurance that any financing by us can be realized, or if realized, what the terms of any such financing may be, or that any amount that we are able to raise will be adequate.

The Term Loan Agreement with CRG Servicing LLC (“CRG”) (Note 6) has certain covenants which require us to maintain a minimum cash balance of $5.0 million. 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. We intend to continue to evaluate options to refinance the Term Loan Agreement, which becomes due on December 30, 2023. There can be no assurances that we will be able to refinance on terms favorable or at all. The amounts involved in any such transactions, individually or in the aggregate, may be material.

On November 5, 2021, we received a letter from The Nasdaq Stock Market LLC (“Nasdaq”) indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on The Nasdaq Global Market. We were provided an initial period of 180 calendar days, or until May 4, 2022, to regain compliance. On May 5, 2022 we received a letter from Nasdaq informing us that our shares have failed to comply with the $1.00 minimum bid price required for continued listing on The Nasdaq Global Market and, as a result, our shares are subject to delisting. We filed an appeal and hearing request with Nasdaq, which has stayed the delisting of our common stock from The Nasdaq Global Market pending a Nasdaq listing qualifications hearings panel’s (the “Panel”) decision. The hearing date has been set for June 2, 2022. There can be no assurance that the Panel will grant our request for continued listing; however, we intend to present a plan to regain compliance to the Panel that includes a discussion of the events that we believe will enable us regain compliance in this timeframe and a commitment to effect a reverse stock split, if necessary.

These conditions raise substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that the financial statements are issued. Management's plans to alleviate the conditions that raise substantial doubt include raising additional funding, earning payments pursuant to our contract with BARDA, delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels for us to continue as a going concern for a period of 12 months from the date the financial statements are issued. Management has concluded the likelihood that its plan to successfully obtain sufficient funding from one or more of these sources or adequately reduce expenditures, while reasonably possible, is less than probable. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of issuance of these consolidated financial statements.

Approval, clearance and certification by the FDA and foreign regulatory authorities or notified bodies for our diagnostic tests takes significant time and requires significant research, development and clinical study expenditures and ultimately may not succeed.

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies. The regulations are very complex and are subject to rapid change and varying interpretations. Regulatory restrictions or changes could limit our ability to carry on or expand our operations or result in higher than anticipated costs or lower than anticipated sales. The FDA, other U.S. governmental agencies and foreign regulatory bodies regulate numerous elements of our business, including:

- product design and development;

- pre-clinical and clinical testing and trials;
- product safety;
- establishment registration and product listing;
- labeling and storage;
- marketing, manufacturing, sales and distribution;
- pre-market clearance, approval or certification;
- servicing and post-market surveillance;
- advertising and promotion; and
- recalls and field safety corrective actions.

Before we begin to label and market our product candidates for use as clinical diagnostics in the United States, we are required to obtain clearance from the FDA under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or FDCA, approval of a *de novo* classification request for our product, or approval of pre-market approval, or PMA, application from the FDA, unless an exemption from pre-market review applies. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. However, some devices are automatically subject to the PMA pathway regardless of the level of risk they pose because they have not previously been classified into a lower risk class by the FDA. Manufacturers of these devices may request that FDA review such devices in accordance with the *de novo* classification procedure, which allows a manufacturer whose novel device would otherwise require the submission and approval of a PMA prior to marketing to request down-classification of the device on the basis that the device presents low or moderate risk. If the FDA agrees with the down-classification, the applicant will then receive approval to market the device. This device type can then be used as a predicate device for future 510(k) submissions. The process of obtaining regulatory clearances or approvals, or completing the *de novo* classification process, to market a medical device can be costly and time consuming, and we may not be able to successfully obtain pre-market reviews on a timely basis, if at all.

The FDA and other regulators or bodies can delay, limit or deny authorization or certification of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are substantially equivalent to a predicate device or are safe and effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical studies or the interpretation of data from preclinical studies or clinical studies;
- the data from our preclinical studies and clinical studies may be insufficient to support clearance, *de novo* classification, approval or certification, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for marketing authorization or certification policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for marketing authorization or certification

Any delay in, or failure to receive or maintain, clearance or approval for our product candidates could prevent us from generating revenue from these product candidates and adversely affect our business operations and financial results.

Obtaining FDA clearance, *de novo* classification, or approval for diagnostics can be expensive and uncertain, and generally takes from several months to several years, and may require detailed and comprehensive scientific and clinical data. Notwithstanding the expense, these efforts may never result in the receipt of FDA marketing authorization. Even if we were to obtain such marketing authorizations for our products, it may not be for the uses we believe are important or commercially attractive, in which case we would not be permitted to market our product for those uses. Any delay in, or failure to receive or maintain, marketing authorization

for our products could prevent us from generating revenue from these products and adversely affect our business operations and financial results.

In order to sell our products in member states of the EU, our products must comply with the general safety and performance requirements of the EU Medical Devices Regulation (Regulation (EU) No 2017/745), which repeals and replaces the EU Medical Devices Directive (Council Directive 93/42/EEC) and the Active Implantable Medical Devices Directive (Council Directive 90/385/EEC). Compliance with these requirements is a prerequisite to be able to affix the European Conformity, or CE, mark to our products, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must meet the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and – where applicable – other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the general safety and performance requirements as a practical matter, as it creates a rebuttable presumption that the device satisfies the general safety and performance requirements.

To demonstrate compliance with the general safety and performance requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. As a general rule, demonstration of conformity of medical devices and their manufacturers with the general safety and performance requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. Except for low-risk medical devices (Class I), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the general safety and performance requirements (except for any parts which relate to sterility, metrology or reuse aspects), a conformity assessment procedure requires the intervention of an organization accredited or designated by a member state of the EU to conduct conformity assessments, or a notified body. Depending on the relevant conformity assessment procedure, the notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. If we fail to comply with applicable EU laws and regulations, and corresponding EU member state laws, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the EU.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland. Non-compliance with the above requirements would also prevent us from selling our products in these three countries.

From January 1, 2021 onwards, the Medicines and Healthcare Products Regulatory Agency, or MHRA becomes the sovereign regulatory authority responsible for Great Britain (i.e. England, Wales and Scotland) medical device market according to the requirements provided in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) that sought to give effect to the three pre-existing EU directives governing active implantable medical devices, general medical devices and in vitro diagnostic medical devices whereas Northern Ireland continues to be governed by EU rules according to the Northern Ireland Protocol. Following the end of the Brexit transitional period on January 1, 2021, new regulations require medical devices to be registered with the MHRA (but manufacturers will be given a grace period of four to 12 months to comply with the new registration process) before being placed on Great Britain market. The MHRA will only register devices where the manufacturer or their United Kingdom Responsible Person has a registered place of business in the United Kingdom. Manufacturers based outside the United Kingdom will need to appoint a U.K. Responsible Person that has a registered place of business in the United Kingdom to register devices with the MHRA in line with the grace periods. By July 1, 2023, in Great Britain, all medical devices will require a UKCA (UK Conformity Assessed) mark but CE marks issued by EU notified bodies will remain valid until this time. Manufacturers may choose to use the UKCA mark on a voluntary basis until June 30, 2023. However, UKCA marking will not be recognized in the EU. The rules for placing medical devices on the market in Northern Ireland, which is part of the United Kingdom, differ from those in the rest of the United Kingdom. Compliance with this legislation is a prerequisite to be able to affix the UKCA mark to our products, without which they cannot be sold or marketed in Great Britain. Under the terms of the Northern Ireland Protocol, Northern Ireland will follow EU rules on medical devices and devices marketed in Northern Ireland will require assessment according to the EU regulatory regime. Such assessment may be

conducted by an EU notified body, in which case a CE mark will be required before placing the device on the market in the EU or Northern Ireland. Alternatively, if a UK notified body conducts such assessment, a 'UKNI' mark will be applied and the device may only be placed on the market in Northern Ireland and not the EU.

Even if granted, a 510(k) clearance, *de novo* classification, PMA approval, or similar authorization or certification from other regulators for any future product would likely place substantial restrictions on how our device is marketed or sold, and the FDA and other regulatory authorities or bodies will continue to place considerable restrictions on our products and operations. For example, the manufacture of medical devices in the United States must comply with the FDA's Quality System Regulation, or QSR. In addition, manufacturers must register their manufacturing facilities, list the products with the FDA, and comply with requirements relating to labeling, marketing, complaint handling, adverse event and medical device reporting, reporting of corrections and removals, and import and export. The FDA monitors compliance with the QSR and these other requirements through periodic inspections. If our facilities or those of our manufacturers or suppliers are found to be in violation of applicable laws and regulations, or if we or our manufacturers or suppliers fail to take satisfactory corrective action in response to an adverse inspection, the FDA and other regulatory authorities could take enforcement action, including any of the following sanctions:

- adverse publicity, untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) clearance or PMA approvals or foreign regulatory authorizations or certifications of new products or modified products;
- withdrawing 510(k) clearances, PMA approvals or foreign regulatory authorizations or certifications that have already been granted;
- refusing to issue certificates to foreign governments needed to export products for sale in other countries;
- refusing to grant export approval for our products; or
- pursuing criminal prosecution.

Any of these sanctions could impair our ability to produce our products and product candidates in a cost-effective and timely manner in order to meet our customers' demands, and could have a material adverse effect on our reputation, business, results of operations and financial condition. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

Moreover, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced steps that the FDA intended to take to modernize the 510(k) premarket notification pathway, including plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway. In September 2019, the FDA also issued revised final guidance establishing a "Safety and Performance Based Pathway" for "manufacturers of certain well-understood device types" allowing manufacturers to rely on objective safety and performance criteria recognized by the FDA to demonstrate substantial equivalence, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA has developed and maintains a list of device types appropriate for the "safety and performance based" pathway and continues to develop product-specific guidance documents that identify the performance criteria and recommended testing methodologies for each such device type, where feasible. Some of these proposals have not yet been finalized or adopted, and the FDA announced that it would seek public feedback prior to publication of any such proposals, and may work with Congress to implement such proposals through legislation.

In addition, the EU regulatory landscape concerning medical devices is evolving and a new regulation governing in vitro diagnostic medical devices will become applicable on May 26, 2022 (*See – International Regulation - Regulation of Medical Devices in the European Union*) and these modifications may have an effect on the way we conduct our business in the EU and the EEA. The EU IVDR will fully apply on May 26, 2022 but to prevent disruption in the supply of in vitro diagnostic medical devices there will be a tiered system extending the grace period for many devices (depending on their risk classification) before they have to be fully compliant with the regulation. If any of our devices are not classified correctly, or if we cannot comply with the IVDR by the applicable deadline, our business could be adversely affected.

In addition, FDA and foreign regulations and guidance are often revised or reinterpreted by the FDA and foreign regulatory authorities in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance as a result of a changing regulatory landscape, we may lose any marketing authorizations that we have already obtained or fail to obtain new marketing approvals or clearances, and we may not be able to achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

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

On November 5, 2021, we received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on The Nasdaq Global Market. We were provided an initial period of 180 calendar days, or until May 4, 2022, to regain compliance. On May 5, 2022 we received a letter from Nasdaq informing us that our shares have failed to comply with the $1.00 minimum bid price required for continued listing on The Nasdaq Global Market and, as a result, our shares are subject to delisting. We filed an appeal and hearing request with Nasdaq, which has stayed the delisting of our common stock from The Nasdaq Global Market pending a Nasdaq listing qualifications hearings panel's (the "Panel") decision. The hearing date has been set for June 2, 2022. There can be no assurance that the Panel will grant our request for continued listing; however, we intend to present a plan to regain compliance to the Panel that includes a discussion of the events that we believes will enable us regain compliance in this timeframe and a commitment to effect a reverse stock split, if necessary.

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*	Amendment No. 7 to Term Loan Agreement, dated February 15, 2022 between T2 Biosystems, Inc. and CRG Servicing LLC (incorporated by reference to Exhibit 10.60 of the Company's Form 10-K (File No. 001-36571) filed on March 23, 2022)
10.2*	Amendment of Solicitation/Modification of Contract, dated as of March 31, 2022 by and between the Company and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services
10.3*	Amendment of Solicitation/Modification of Contract, dated as of April 22, 2022 by and between the Company and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services
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
† 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: May 12, 2022

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

Date: May 12, 2022

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

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

11. CONTRACT ID CODE

PAGE OF PAGES: 1 | 60

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	15. PROJECT NO. (If applicable)
P00006	See Block 16C	OS292589	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	ASPR-BARDA	ASPR-BARDA US DEPT OF HEALTH & HUMAN SERVICES BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT 200 INDEPENDENCE AVE, S.W. Washington DC 20201	IASPR-BARDA

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)

T2 BIOSYSTEMS, INC. 1512719
Attn: STEPHEN HAGAN
T2 BIOSYSTEMS, INC. 101 HARTWE
101 HARTWELL AVE
LEXINGTON MA 024213125

CODE 1512719 FACILITY CODE

9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (SEE ITEM 11)

x 10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50119C00053

10B. DATED (SEE ITEM 13) 09/30/2019

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

D The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers D is extended. D is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended , by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted, or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTINGANDAPPROPRIATIONDATA(If required) Net Increase: $4,389,160.00
2022.1992022.25106

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
x	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF fAR 52.217-9 Option to Extend the Term of the Contract and fAR Part 43.10J(a) - Bilateral Modifications
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor Olsnot IR]is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contrac/ subject matter where feasible.)

Tax ID Number: 20-4827488
DUNS Number: 803126320
The purpose of this modification is to: 1) Exercise Option 2B (CLIN 0004), 2) Revise section B - Supplies or Services and Prices/Costs, 3) Revise Section F - Deliveries or Performance, 4) Section G - Contract Administration Data, 5) Add HHSAR 352.232-71 Electronic Submission of Payment Requests and instructions, 6) Revise Section J - List of Attachments, and 7) Revise Attachment 1 - Statement of Work. See Summary of Changes.

Total Base and Exercised Option Value increased by $4,389,160.00 from $22,832,147.00 to $27,221,307.00.
Total T2 Biosystems, Inc. Total Share Cost increased by $2,960,502.00 from $6,013,087 to
Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Alec J. Barclay Chief Operations Officer		RICHARD A. HALL Digitally signed by Richard A. Hall -S	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(Signature of person authorized to sign)		(Signature of Contracting Officer)	Date: 2022.03.31 16:10:56 -04'00'

Previous edition unusable

STANDARD FORM 30 (REV 1112016)
Prescribed by GSA FAR (48 CFR) 53.243

[***] – Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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NAME OF OFFEROR OR CONTRACTOR
T2 BIOSYSTEMS, INC. 1512719

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	$8,973,589.00. Total Contract Value remains unchanged at $106,922, Appr. Yr.: 2022 CAN: 1992022 Object Class: 25106 Period of Performance: 04/01/2022 to07/31/2022 Add Item 10 as follows:	207.00			
10	ASPR-22-00825- Option 2b funds Obligated Amount: $4,389,160.00				4,389,160.00

Summary of Changes

****Yellow Highlights** denotes applicable changes**

Beginning with the effective date of this modification, the Government and the Contractor mutually agree as follows:

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS,

ARTICLE B.3 OPTION PERIODS - the table included in this Article is hereby modified to reflect the following:

8.3. COST REIMBURSEMENT OPTIONS

I. The contract includes optional, cost reimbursement CLINs 0002 through 0007. The Government may exercise Option Periods in accordance with FAR 52.217-9 Option to Extend the Term of the Contract (March 2000), as set forth in Section I of the contract.

II. The contract includes optional services, cost reimbursement CLIN 0008. The Government may exercise Option Services in accordance with FAR 52.217-8 Option to Extend Services, as set forth in Section I of the contract.

III. Unless the government exercises its option pursuant to the option clause contained in ARTICLE 1.2, the contract consists only of the Base Work segment specified in the Statement of Work as defined in SECTION C and F, for the price set forth in ARTICLE B.2 of the contract.

IV. The Government may modify the contract unilaterally and require the contractor to provide supplies and services for Option Periods listed below, in accordance with FAR 52.217-9.

V. If the Government decides to exercise an option(s), the Government will provide the Contractor a preliminary written notice of its intent as referenced in the clause. Specific information regarding the time frame for this notice is set forth in the OPTION CLAUSE Article in SECTION G of this contract. The estimated cost of the contract will be increased as set forth below:

[***] – Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Option	CUN	Period of Performance	Supplies/Services	BARDA Estimated Not to Exceed	T2• Estimated Not to Exceed	Overall Total Estimated Not to Exceed
1	0002	09/14/2020 _ 10/15/2021	**Option 1 Period:**	$10,495,783	$3,925,669	$14,421,452
2A	0003	09/30/2021-03/31/2022	**Option 2A**	**$6,357,371**	**$2,087,418**	**$8,444,789**
2B	0004	**04/01/2022-[***]**	**Option 2B**	**$4,389,160**	**$2,960,502**	**$7,349,662**

[***] – Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

			Option 3 Period:			
3	0005	[****] - [****]		$[****]	$[****]	$[****]
			Option 4 Period:			
4	0006	**[****] -[****]**		$[****]	$[****]	$[****]

[***] – Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

			Option 5 Period:			
5	0007	[*****]-[****]		$[****]	$[****]	$[****]
6	0008	[****] -[****]	**Option 6 Period:**	$[****]	$[****]	$[****]

[***] – Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Optional Services	ooog	TBD- BD Exercised	as	**Option 7 Period:**		$2,625,404	$[****]
	TOTALS		**only option years**		$[****]	$[****]	$[****]
		TOTALS	**lease+ options**		$[****]	$[****]$[****]	

B.4 ESTIMATED COST - COST SHARING

This is a cost-sharing contract. The total estimated cost sharing for performing the work under this contract is $[****] (Base $[****], Option 1 $[****], Option 2A $[****], Option 2B $[****], Option 3 $[****], Option 4 $[****], Option 5 $[****], Option 6 $[****], Option 7 $[****]). For further provisions regarding the specific cost-sharing arrangement, see the ADVANCE UNDERSTANDINGS Article in SECTION B of the Contract.

SECTION F - DELIVERIES OR PERFORMANCE

F.2. DELIVERABLES

Successful performance of the final contract shall be deemed to occur upon completion of performance of the work set forth in the Statement of Work dated July 22, 2019, set forth in Section J - List of Attachments of this contract and upon delivery and acceptance, as required by the Statement of Work, by the COR, of each of the deliverables described in Section C, Section F, and Section J.

All deliverables and reporting documents listed within this Section shall be delivered electronically (as defined in Section F.3 Electronic Submission) to the CO, CS, and the COR unless otherwise specified by the CO.

Unless otherwise specified by the CO, the deliverables identified in this Section F shall also be delivered electronically to the designated eRoom along with a concurrent email notification sent to the CO, CS, COR, and Alternate COR stating delivery has been made.

Upon the written request of the CO, CS, or COR, all paper/hardcopy documents/reports submitted under this contract shall be printed or copied, doublesided, on at least 30 percent post-consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b). **Hard copies of deliverables and reports furnished to the Government under the resultant Contract shall be addressed to the Contracting Officer and Contracting Officer Representative. The address for delivery of the hard copy documents, shall be provided in the written request from the CO, CS, and/or COR**

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Contract Data Requirements List (CDRLs)

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
1	Kickoff Meeting	The Contractor shall complete a Kickoff meeting after contract award	• **Within 10 calendar** days after contract award. • Mat erials : Contractor shall provide itinerary and agenda to CO and COR at least 5 business days in advance of meeting. CO approves and the COR distributes itinerary and agenda within 3 business days. • Due out: Contractor provides meeting minutes to CO and COR within 5 business days after the meeting.
2	Quarterly Meetings	At the discretion of the government the Contractor shall hold recurring teleconference or face-to-face Project Review Meetings up to four per year either in Washington D.C or at work sites of the Contractor or subcontractors. Fac e-to-face meetings shall alternate between Washington DC and Contractor, sub-contractor sites. The meetings will be used to discuss contract progress in relation to the Program Management deliverables described below as well as study designs, technical , regulatory, and ethical aspects of the program.	• Materials: Contractor shall provide itinerary and agenda to CO and COR at least 5 business days in advance of site visit. The COR approves and distributes itinerary and agenda within 3 business days. • Due out: Contractor provides meeting minutes to the CO and the COR within 5 business days after the meeting.
3	Biweekly Teleconference Meetings	The Contractor shall participate in teleconferences every two weeks with the CO and the COR to discuss the performance of the contract.	• Materials: Contractor provides **agenda and slides** to the CO and COR no later than 2 business days in advance of meeting. The COR approves and distributes agenda prior to meeting. • Due out : Contractor provides meeting minutes to the CO and COR within 5 business days following the meeting.

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CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
4 (Monthly) 05 (Annual)	Monthly & Annual Technical Progress Reports	The Monthly and Annual Technical Progress report shall address each of the below items and be cross-referenced to the Work Breakdown Structure (WBS), Statement of Work (SOW) , Integrated Master Schedule (IMS), and Contract Performance Report (CPR). 1. An Executive Summary highlighting the progress, issues and relevant manufacturing, non- clinical, clinical and regulatory activities. The Executive Summary should highlight only critical issues for that reporting period and resolution approach; limited to 2-3 pages. 2. Progress in meeting contract milestones - broken out by subtasks within each milestone, overall project assessment, problems encountered and recommended solutions. The reports shall detail the planned and actual progress during the period covered, explaining occurrences of any differences between the two and the corrective steps. 3. The reports shall also include a three- • month rolling forecast of the key planned activities, referencing the WBS/IMS. 4. A tracking log of progress on regulatory submissions with the FDA n umber, description of sub mission, date of submission, status of submission and next st eps. 5. Estimated and Actual Exp enses. 6. This report shall also contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the% of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month . If the subcontractor(s) was not working or did not incur any costs in the previous	• Due : Monthly Reports shall be submitted on the 25th day of the month after the end of each month with an Annual Report submitted on the 30th calendar day of the final month of each contract year for the previous twelve calendar months. When the 25th or 30th falls on a weekend or a US Holiday, the reports will be due the next business day. • Monthly progress reports are not required for the periods when the Annual Report(s) and Final Report are due.

		month, then a statement to this effect should be included in this report for those respective subcontractors.	
CDRL#	**Deliverable**	**Description**	**Reporting Procedures and Due Dates**
6	Risk Management Plan	The Contractor shall provide a Risk Management Plan that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance.	• Due : Within 90 days of contract award . • Due out: Contractor provides updated Risk Management Plan in Monthly Progress Report. The COR shall provide Contractor with written comments in response submitted plan . Contractor must address, in writing, all commercially reasonable concerns raised by the COR within 20 business days of Contractor's receipt of COR's concerns for CO approval.
7	Deviation Notification and Mitigation Strategy	Process for changing IMS activities associated with cost and schedule. Contractor shall notify BARDA of significant changes the IMS defined as increases in cost above 5% or schedule slippage of more than 30 days, which would require a PoP extension. Contractor shall provide a high-level management strategy for risk mitigation .	• Due : As needed and communicated by the COR/CO.
8	Go/No-Go In Process Review (IPR) or Decision Gate Presentation	Contractor shall provide a presentation detailing technical progress made towards completion of Go/No-Go decision gate milestones following a prescribed template provided by BARDA prior to the IPR.	• Materials: Contractor shall provide presentation materials to the CO and COR 10 business days prior to the In- Process Review (IPR). Contractor shall submit written justification of progress towards satisfying Go/No-Go criteria . After reviewing, the CO and COR will provide a written response within 10 business days.

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CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
9	Incident Report	Contractor shall communicate and document all critical programmatic concerns, risks, or potential risks with the CO and COR.	• Due out: Contractor shall submit, within 5 business days, a Corrective Action Plan (if deemed necessary by either party) to address any potential issues. If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by the CO, within 5 business days of receiving such concerns in writing. • Due: Within 48 hours of activity or incident or within 24 hours for a security activity or incident via email or telephone, with written follow- up to the CO and COR. Additional updates due within 48 hours of additional developments.
10	Draft and Final Reports for Clinical and Non Clinical Studies	Contractor shall provide Draft and Final Clinical/Non-Clinical Study Reports to the CO and COR for review and comment.	• Draft - within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA. Subcontractor prepared reports received by the Contractor shall be submitted to the CO and COR for review and comment no later than 5 business days after receipt by Contractor. The CO shall provide written comments to the Draft Final Report for Clinical and Non-Clinical Studies within 15 business days after the submission. • Final - due 30 calendar days after receiving comments on the Draft Final Report for Clinical and Non-Clinical Studi es. If corrective action is recommended, Contractor must address, in writing, all reasonable concerns raised by the CO in writing. Contractor shall consider revising reports to address CO' s recommendations prior to FDA submission . • Final FDA submissions shall be provided to the CO and COR concurrently or no later than 5 business days after submission to the FDA .

[***] – Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
11	Standard Operating Procedures	The Contractor shall make internal and , to the extent possible, subcontractor Standard Operating Procedures (SOPs) available for review electronically .	Upon request from the CO.
12	FDA Correspondence	The Contractor shall memorialize any correspondence between Contractor and FDA and submit to the CO and COR. All documents shall be duly marked as either "Draft" or "Final".	• Due : Contractor shall provide written summary of any FDA correspondence within 5 business days of correspondence .
13	FDA Meetings	The Contractor shall forward the dates and times of any meeting with the FDA to the CO and COR and make arrangements for appropriate government staff to attend the FDA meetings. Government staff shall include up to a maximum of four people (COR, CO and up to 2 subject matter experts).	• Contractor shall schedule upcoming FDA meetings, so at a minimum the CO, COR, and RQA persons from BARDA can attend. Additionally, a pre-meeting needs to be held with BARDA to review slides and discuss meeting strategies. • Contractor shall notify the CO and COR of upcoming FDA meeting within 24 hours of sch eduling. • The Contractor shall forward initial Contractor and FDA- issued draft minutes and final minutes of any meeting with the FDA to the CO and COR within 5 business days of receipt . All documents shall be duly marked as either "Draft" or "Final " .
14	FDA Submissions	The Contractor shall provide the CO and COR the opportunity to review and comment upon all draft submissions before submission to the FDA. Contractor shall provide the CO and COR with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft " or "Final" .	• Due : Contractor shall submit draft FDA submissions to the CO and COR at least 15 business days prior to FDA submission . The CO and COR will provide feedback to Contractor within 10 business days of receipt . • Due out: If corrective action is recommended , the Contractor must address, in writing, its consideration of all concerns raised by the CO. • The Contractor shall consider revising their documents to address CO' s concerns and/or recommendations prior to FDA submission. • Final FDA submissions shall be submitted to the CO and COR concurrently or no later than 5 calendar day of its submission to CDER.

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CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
15	FDA Audits	In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the Government with an exact copy (non- redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.	• Contractor shall notify the CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice. • Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA or third party. • Within 10 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.
16	QA Audit Reports	BARDA Quality group and /or their qualified representatives reserves the right to participate in QA audits.Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor . If action is requested of the subcontractor, detailed concerns for addressing areas of non- conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to the CO and COR. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.	• Contractor shall notify the CO and COR 10 days in advance of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications. • Contractor shall notify the CO and COR within 5 business days of report completion.

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CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
17	BARDA Audit	Contractor shall accommodate periodic or ad hoc site visits by the CO and COR. Contractor shall also accommodate any ' for cause' audit if and when there are potential issues identified in the program during the period of performance. Such issues include but are not limited to stability failures, GLP issues etc. If the CO, COR, Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the CO and COR.	• If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and corrective action(s) within 10 business days of the audit. • Due out: The CO and COR will review the report and provide a response to the Contractor with 10 business days. Once corrective action is completed, the Contractor will provide a final report to the CO and COR.
18	Technical Documents	Upon request, Contractor shall provide CO and COR with deliverables from the following contract funded activities : process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/ Report , Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government .	• Contractor shall provide technical document within 10 business days of COR's request. Contractor can request additional time on an as needed basis. • If corrective action is recommended by the COR, the Contractor must address, in writing, concerns raised by the COR to the COR and CO in writing.
19	Raw Data or Data Analysis	Contractor shall provide raw data and/or data analysis to the CO and COR upon request. Contractor shall address and adjudicate all concerns from BARDA review of the data/analysis and amend the reports as req uired.	• Contractor shall provide data or data analysis to the CO and COR within 20 business days of request. • Contractor shall amend the reports if required and adjudicate all comments.
20	Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to the CO and COR for review prior to submission.	• Contractor must submit all manuscript or scientific meeting abstract to the CO and COR within 30 days for manuscripts and 15 days for abstracts. • Contractor must address in writing all concerns raised by the CO and COR in writing. • Final submissions shall be submitted to the CO and COR concurrently or no later than five (5) calendar days after its submission.

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CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
21	Press Releases	Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases.	• With the exception of ad-hoc press releases required by applicable law or regulations, Contractor shall ensure that the CO and COR has received and approved an advanced copy of any draft press release to this contract not less than **10 business days** prior to the issuance of the press release. • If corrective action is required, the Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. • Any final press releases shall be submitted to the CO and COR no later than 1 (one) calendar day prior to its release.
22	Integrated Master Schedule (IMS) Gantt	The Contractor shall provide an IMS including WBS, critical path, and milestones.	• Due: Contractor shall provide the draft IMS-Gantt within **15 days of contract award with final due 30 days after award** and updated monthly as part of the Monthly Progress Report. • Contractor must address , in writing, all concerns raised by the COR in writing and provide response to the CO and COR.

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CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
23	Draft and Final Technical Progress Report	A Draft Final Technical Progress Report containing a summation of the work performed and the results obtained for the entire contract PoP. The draft report shall be duly marked as 'Draft' . The Final Technical Progress Report incorporating feedback received from the CO and COR and containing a summation of the work performed and the results obtained for the entire contract PoP. The final report shall document the results of the entire contract. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. The final report shall be duly marked as 'Final '.	• Due : Contractor shall provide a draft Technical Progress **Report 30 calendar days** before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP. • Subcontractor prepared reports received by the Contractor shall be submitted to the CO and COR for review and comment no later than 5 business days after receipt by the Contractor . • Due out: the CO shall provide feedback on draft report within 15 calendar days of receipt , which the Contractor shall consider incorporating into the Final Report. • Contractor shall submit, with the Final Technical Progress Report , a summary (not to exceed 200 words) of salient results achieved during the performance of the contract .
24	Draft and Final Study Protocols	Contractor shall provide all Draft and Final Study Protocols to the COR for evaluation. (The CO and COR reserves the right to request within the period of performance a n on-propriet ary Study Protocol for distribution within the US Government.	• The Contractor will submit all proposed protocols to the CO and COR at least 10 business days prior to study start. If corrective action is required, the Contractor must address in writing all concerns raised by the CO and COR to the satisfaction of the COR before study execution and provide the CO and COR a revised draft protocol that addresses the CO's comments and requested changes. • After receiving the revised Study Protocol that satisfies the COR, the CO will approve the revised Study Protocol and will provide a written approval to the Contractor that provides authorization to the Contractor to execute the specific study. • Contractor shall not proceed with any study protocol until the COR gives its approval and the Contractor has provided the CO

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			and COR with a final and approved Study Protocol.
CDRL#	**Deliverable**	**Description**	**Reporting Procedures and Due Dates**
25	Clinical Study Status Update	Contractor shall provide COR with a status update of clinical studies that are actively enrolling patients to include by study site : cumulative enrollment; new enrollments; screen failures; patients dropped from study; AE and SAEs; activation or inactivation of study sites; investigator appointments or changes; and status of IRB/IEC review/approval/renewal. Contractor will provide proposed format for the COR's review and approval.	• Update will be submitted by e-mail or other electronic format to be provided by the COR by the end of the 25th business day of each new month. • When the 25th falls on a weekend or US Holiday, the update will be due the next business day. • Updates, to the extent they are available, will be presented during biweekly teleconferences. • If no changes have occurred since the prior update only a simple statement that there is no new data is required .

SECTION G - CONTRACT ADMINISTRATION DATA

G.1. CONTRACTING OFFICER

The following Contracting Officers (CO) will represent the Government for the purpose of this contract

R. Anthony Hall (Tony)
U.S. Department of Health & Human Services
Office of the Assistant Secretary for Preparedness and Response (ASPR) Biomedical Advanced Research and Development Authority (BARDA) Contract Management and Acquisition (CMA)
(202) 578.8547
Richard.hall@hhs.gov

1) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public fund s. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.
2) The Contracting Officer is the only person with the authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimburse to the Contractor of

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any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this cont ract .

3) No information other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the US Government, other otherwise, shall be considered grounds for deviation from any stipulation of this contract.

4) The Government may unilaterally change its CO designat io n, after which it will notify the Contractor in writing of such change.

NOTE: An unauthorized commitment is an agreement that is not binding solely because the Government representative who made it lacked the authority to enter into that agreement on behalf of the Gove rnment. An unauthorized commitment (UC) usually results in the receipt of goods or services on behalf of the Government by someone with apparent authority, but that lacks the authority to obligate the Government; it can be intentional or unintentional. Only a warranted contracting officer has authority to obligate government funds and contractually bind the government for supplies and services within their warrant authority.

G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this cont ract:

Dr. Molly Mclendon
U.S. Department of Health & Human Services
Office of the Assistant Secretary for Preparedness and Response Biomedical Advanced Research & Development Authority (BARDA)
(202) 507-0331

Molly.M clend on@hhs.gov

The COR is responsible for:

1) Monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;
2) Assisting the Contracting Officer in interpreting the statement of work and any other technical performance requirements;
3) Performing technical evaluation as required;
4) Performing technical inspections and acceptances required by this contract; and
5) Assisting in the resolution of technical problems encountered during performance . The Government may unilaterally change its COR designation, after which it will notify Contractor in writing of such change.

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G.10. **INVOICE SUBMISSION**

(a) The Contractor shall submit invoices electronically in accordance with HHSAR 352.232- 71. As prescribed in HHSAR 332.7003, use the following clause:

Electronic Submission of Payment Requests

(a) Definitions. As used in this clause-

(1) "Payment request" means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform **(IPP)** or successor system. Information regarding **IPP,** including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(End of Clause)

(b) The Contractor agrees to include (as a minimum) the following information on each invoice:

(1) Contractor's Name & Address
(2) Contractor's Tax Identification Number (TIN)
(3) Requisition Number per CUN or Task or as appropriate (4) Contract Number
(5) Invoice Number
(6) Invoice Date
(7) Contract Line-Item Number (8) Quantity
(9) Unit Price & Extended Amount for each line item
(10) Total Amount of Invoice
(11) Name, title and telephone number of the person(s) to be notified in the event of a defective invoice
(12) Payment Address, if different from the information in (b)(I).

(c) The invoice shall be signed by a person authorized to bind the Contractor.

(d) The Contractor shall not submit an invoice prior to delivery of goods or services.

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PART II - **CONTRACT CLAUSES SECTION**

I - **CONTRACT CLAUSES**

1.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text availa ble. Also, the full text of a clause may be accessed electronically at: http://www.acquisition.gov/far. HHSAR clauses at http://www.hhs.gov/policies/hhsar/subpart352.html

General Clauses for Cost-Reimbursement Research and Development Contract

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLA USES:

Reg	Clause	Date	Clause Title
FAR52.202-1Nov 2013Definitions			
FAR	52.203-3	Apr1984	Gratuities
FAR	52.203-5	May 2014	Covenant Against Contingent Fees
FAR	52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	May 2014	Anti-Kickback Procedures
FAR	52.203-8	May 2014	Cancellation, Rescission , and Recovery of Funds for Illegal orImproper Activity
FAR	52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-11	Sept 2007	Certification and Disclosure Regarding Payments to InfluenceCertain Federal Transactions
FAR	52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Oct 2015	Contractor Code of Business Ethics and Conduct
FAR	52.203-14	Oct 2015	Display of Hotline Poster(s)
FAR	52.203-17	Apr2014	Contractor Employee Whistleblower Rights and Requirement ToInform Employees of Whistleblower Rights
FAR	52.204-1	Dec 1989	Administrative Matters Provisions and Clauses
FAR	52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
FAR	52.204-5	Oct 2014	Women -Owned Business (Other Than Small Business)
FAR	52.204-7	Oct 2016	System for Award Management
FAR	52.204-10	Oct 2016	Reporting Executive Compensation and First -Tier SubcontractAwards
FAR	52.204-13	Oct 2016	System for Award Management Maintenance
FAR	52.204-16	Jul2016	Commercial and Government Entity Code Reporting
FAR	52.204-17	Jul2016	Ownership of Control or Offeror
FAR	52.204-18	Jul2015	Commercial and Government Entity Code Maintenance
FAR	52.207-1	May 2006	Notice of Standard Competition
FAR	52.209-5	Oct 2015	Certification Regarding Responsibility Matters

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FAR	52.209-6	Oct 2015	Protecting the Government's Interests When Subcontracting WithContractors Debarred, Suspended, or Proposed for Debarment
FAR	52.209-9	Jul 2013	Updates of Publicly Available Information RegardingResponsibility Matters
FAR	52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations
FAR	52.210-1	Apr 2011	Market Research
FAR	52.211-5	Aug 2000	Material Requirements
FAR	52.215-2	Oct 2010	Audit and Records - Negotiation
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR	52.215-10	Aug 2011	Price Reduction for Defective Cost or Pricing Data
FAR	52.215-11	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data -Modifications.
FAR	52.215-12	Oct 2010	Subcontractor Certified Cost or Pricing Data
FAR	52.215-13	Oct 2010	Subcontractor Certified Cost or Pricing Data-Modifications
FAR	52.215-14	Oct 2010	Integrity of Unit Prices (Over the Simplified Acquisition Threshold
FAR	52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
FAR	52.215-16	June 2003	Facilities Capital Cost of Money
FAR	52.215-17	Oct 1997	Waiver of Facilities Capital Cost of Money
FAR	52.215-18	Jul2005	Reversion or Adjustment of Plans for Postretirement Benefits(PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-20	Oct 2010	Requirements for Certified Cost or Pricing Data and Data OtherThan Certified Cost or Pricing Data
FAR	52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data OtherThan Certified Cost or Pricing Data - Modifications
FAR	52.215-22	Oct 2009	Limitations on Pass-Through Charges-Identification of Subcontract Effort
FAR	52.215-23	Oct 2009	Limitations on Pass-Through Charges
FAR	52.216-7	Aug 2018	Allowable Cost and Payment
FAR	52.216-8	Jun 2011	Fixed Fee
FAR	52.219-8	Nov 2018	Utilization of Small Business Concerns
FAR	52.219-9	Aug 2016	Small Business Subcontracting Plan
FAR	52.219-10	Oct 2014	Incentive Subcontracting Program
FAR	52.219-14	Jan 2017	Limitations on Subcontracting
FAR	52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan
FAR	52.219-28	Jul 2013	Post-Award Small Business Program Representation
FAR	52.222-3	Jun 2003	Convict Labor
FAR	52.222-21	Apr2015	Prohibition of Segregated Facilities
FAR	52.222-24	Feb 1999	Pre-award On-Site Equal Opportunity Compliance Evaluation
FAR	52.222-25	Apr1984	Affirmative Action Compliance
FAR	52.222-26	Sept 2016	Equal Opportunity
FAR	52.222-35	Oct 2015	Equal Opportunity for Veterans ($150,000 or more)
FAR	52.222-36	Jul2014	Equal Opportunity for Workers with Disabilities
FAR	52.222-37	Feb 2016	Employment Reports on Veterans
FAR	52.222-38	Feb 2016	Compliance with Veterans' Employment Reporting Requirements
FAR	52.222-40	Dec 2010	Notification of Employee Rights Under the National LaborRelations Act

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FAR	52.222-50	Mar 2015	Combating Trafficking in Persons
FAR	52.222-54	Oct 2015	Employment Eligibility Verification
FAR	52.222-59	Dec 2016	Compliance With Labor Laws (Executive Order 13673)
FAR	52.222-60	Oct 2016	Paycheck Transparency (Executive Order 13673)
FAR	52.222-61	Dec 2016	Arbitration of Contractor Employee Claims (Executive Order 13673)
FAR	52.222-62	Jan 2017	Paid Sick Leave Under Executive Order 13706
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-18	Aug 2011	Encouraging Contractor Policy to Ban Text Messaging While Driving
FAR	52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
FAR	52.225-25	Aug 2018	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran-Representation and Certifications
FAR	52.226-1	Jun 2000	Utilization of Indian Organizations and Indian-Owned Economic Enterprises.
FAR	52.227-1	Dec 2007	Authorization and Cons ent, Alternate 1 (APR 1984)
FAR	52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-3	Apr1984	Patent Indemnity
FAR	52.227-11	May 2014	Patent Rights - Ownership by the Contractor
FAR	52.227-14	May 2014	Rights in Data - General
FAR	52.227-14 Alt . II	Dec 2007	Rights in Data - General - Limited Rights Notice
FAR	52.227-15	Dec 2007	Representation of Limited Rights Data and Restricted Computer Software
FAR	52.227-16	June 1987	Additional Data Requirements
FAR	52.228-7	Mar 1996	Insurance - Liability to Third Persons
FAR	52.230-2	Oct 2015	Cost Accounting Standards
FAR	52.230-3	Oct 2015	Disclosure and Consistency of Cost Accounting Practices
FAR	52.230-6	Jun 2010	Administration of Cost Accounting Standards
FAR	52.230-7	Apr2005	Proposal Disclosure-Cost Accounting Practice Changes
FAR	52.232-9	Apr1984	Limitation on Withholding of Payments
FAR	52.232-17	May 2014	Interest
FAR	52.232-20	Apr1984	Limitation of Cost
FAR	52.232-23	May 2014	Assignment of Claims
FAR	52.232-25	Jan 2017	Prompt Payment
FAR	52.232-33	Jul 2013	Payment by Electronic Funds Transfer-System for Award Management
FAR	52.232.39	Jun 2013	Unenforceability of Unauthorized Obligations
FAR	52.232-40	Dec 2013	Providing Accelerated Payments to Small Business Subcontractors
FAR	52.233-1	May 2014	Disputes
FAR	52.233-3	Aug 1996	Protest After Award, Alternate 1 (Jun 1985)
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr1984	Notice of Intent to Disallow Costs
FAR	52.242-3	May 2014	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.243-2	Aug 1987	Changes - Cost-Reimbursement Alternate V (Apr 1984)
FAR	52.244-2	Oct 2010	Subcontracts, Alternate 1 (Jun 2007)
FAR	52.244-5	Dec 1996	Competition in Subcontracting
FAR	52.244-6	Aug 2018	Subcontracts for Commercial Items

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FAR	52.245 -1	Apr 2012	Government Property
FAR	52.245-9	Apr2012	Use and Charges
FAR	52.246-23	Feb 1997	Limitation of Liability
FAR	52.249-6	May 2004	Termination (Cost-Reimbursement)
FAR	52.249-14	Apr1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR	352.203 -70	Dec 2015	Anti-Lobbying
HHSAR	352.208-70	Dec 2015	Printing and Duplication
HHSAR	352 .211-3	Dec 2015	Paperwork Reduction Act
HHSAR	352.219-70	Dec 2015	Mentor-Protege Program
HHSAR	352.219-71	Dec 2015	Mentor-Protege Program Reporting Requirements
HHSAR	352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
HHSAR	352 .223-70	Dec 2015	Safety and Health
HHSAR	352 .224-70	Dec 2015	Privacy Act
HHSAR	352.224-71	Dec 2016	Confidential Information
HHSAR	352.227-70	Dec 2015	Publications and Publicity
HHSAR	352.231-70	Dec 2015	Salary Rate Limitation
HHSAR	352.233-71	Dec 2015	Litigation and Claims
HHSAR	352 .237-75	Dec 2015	Key Personnel
HHSAR	352 .239 -7	Dec 2015	Electronic and Information Technology Accessibility
HHSAR	352.270-9	Dec 2015	Non-discrimination for Conscience
HHSAR	**352.232-71**	**Feb 2022**	**Electronic Submission of Payment Requests**

PART Ill - **LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS SECTION J** - **LIST OF ATTACHMENTS**

The following documents are attached and incorporated in this contract:

1. **Statement of Work**

2. **Reserved**

3. **Sample Invoice, 1 page**

4. **Financial Report of Individual Project/Contract, 1 page**

5. **Instructions for Completing Financial Report of Individual Project/Contract, 2 pages**

6. **Inclusion Enrollment Report**

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Inclusion Enrollment Report, 5/01 (Modified OAMP: 10/01), 1 page.

7. Research Patient Care Costs

Research Patient Care Costs, 1 page.

8. Report of Government Owned, Contractor Held Property

Report of Government Owned, Contractor Held Property, 1 page. Located at : http://rcb.coancer.gov/rcb-internet/forms/Govt-Owned-Prop.pdf

9. Go No-Go Success Criteria, 2 pages.

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AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 1

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00007	See Block 16C		

6. ISSUED BY CODE ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

7. ADMINISTERED BY (If other than Item 6) CODE ASPR-BARDA

ASPR-BARDA
US DEPT OF HEALTH & HUMAN SERVICES
BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT
200 INDEPENDENCE AVE, S.W.
Washington DC 20201

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)

T2 BIOSYSTEMS, INC. 1512719
Attn: ALEC BARCLAY
T2 BIOSYSTEMS, INC.
101 HARTWELL AVE
LEXINGTON MA 02421

CODE 1512719 FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (SEE ITEM 11)

X 10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50119C00053

10B. DATED (SEE ITEM 13) 09/30/2019

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)
See Schedule

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	FAR Part 43.103(a) - Bilateral Modification
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Tax ID Number: 20-4827488
DUNS Number: 803126320
The purpose of this modification is to remove Stephen Hagan as T2 Biosystems, Inc. point of contact. Add Alec Barclay as the T2 Biosystems, Inc. point of contact.
Period of Performance: 04/01/2022 to 07/31/2022

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
Alec Barclay Chief Operations Officer	RICHARD A. HALL
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED
(Signature of person authorized to sign)	04/22/2022
	16B. UNITED STATES OF AMERICA
	(Signature of Contracting Officer)
	16C. DATE SIGNED

Richard A. Hall -S Digitally signed by Richard A. Hall -S Date: 2022.04.22 15:10:21 -04'00'

Previous edition unusable

STANDARD FORM 30 (REV. 11/2016)
Prescribed by GSA FAR (48 CFR) 53.243

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 Chairman of the
Board of Directors
(principal executive officer)

Date: May 12, 2022

Exhibit 31.2

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

I, John M. Sprague, certify that:

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

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

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

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

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

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

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

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

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

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

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

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

Date: May 12, 2022

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of T2 Biosystems, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John Sperzel, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

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

Date: May 12, 2022

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

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

Exhibit 32.2

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of T2 Biosystems, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John M. Sprague, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

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

Date: May 12, 2022

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.