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 September 30, 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 Capital 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 November 8, 2022, the registrant had 7,319,105 shares of common stock outstanding.

T2 BIOSYSTEMS, INC.

TABLE OF CONTENTS

PART I.
FINANCIAL INFORMATION

Item 1. Financial Statements

T2 BIOSYSTEMS, INC.

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 20,366	$ 22,245
Marketable securities	—	9,996
Accounts receivable	1,578	5,134
Inventories	4,242	3,909
Prepaid expenses and other current assets	2,690	3,110
Total current assets	28,876	44,394
Property and equipment, net	4,734	4,675
Operating lease right-of-use assets	9,058	9,766
Restricted cash	1,131	1,551
Other assets	153	153
Total assets	$ 43,952	$ 60,539
Liabilities, Series A redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 2,063	$ 2,832
Accrued expenses and other current liabilities	8,531	8,338
Derivative warrant liability	186	—
Deferred revenue	163	518
Total current liabilities	10,943	11,688
Notes payable	49,188	47,790
Operating lease liabilities, net of current portion	8,569	9,359
Deferred revenue, net of current portion	8	28
Derivative liability	1,792	—
Other liabilities	4,791	4,577
Commitments and contingencies (see Note 14)		
Series A redeemable convertible preferred stock; $0.001 par value; 3,000 shares authorized at September 30, 2022; 3,000 shares issued and outstanding at September 30, 2022; liquidation value of $330,000; 0 shares issued and outstanding at December 31, 2021 (see Note 7)	330	—
Stockholders' deficit		
Preferred stock, $0.001 par value; 9,997,000 and 10,000,000 shares authorized at September 30, 2022 and December 31, 2021, respectively; no shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; 7,050,849 and 3,328,017 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	7	3
Additional paid-in capital	492,444	459,314
Accumulated other comprehensive loss	—	(4)
Accumulated deficit	(524,120)	(472,216)
Total stockholders' deficit	(31,669)	(12,903)
Total liabilities, Series A convertible redeemable preferred stock and stockholders' deficit	$ 43,952	$ 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue:				
Product revenue	$ 2,641	$ 4,306	$ 9,044	$ 12,634
Contribution revenue	1,036	3,122	7,778	8,444
Total revenue	3,677	7,428	16,822	21,078
Costs and expenses:				
Cost of product revenue	6,085	4,720	17,371	15,341
Research and development	6,375	6,384	21,056	16,448
Selling, general and administrative	7,017	8,536	24,071	21,983
Total costs and expenses	19,477	19,640	62,498	53,772
Loss from operations	(15,800)	(12,212)	(45,676)	(32,694)
Other income (expense):				
Interest income	1	6	6	18
Interest expense	(1,560)	(1,919)	(4,556)	(5,642)
Change in fair value of derivative instrument	(117)	—	(1,792)	1,010
Change in fair value of derivative warrant liability	179	—	179	—
Other income (expense), net	(78)	163	(65)	211
Total other expense	(1,575)	(1,750)	(6,228)	(4,403)
Net loss	$ (17,375)	$ (13,962)	$ (51,904)	$ (37,097)
Deemed dividend on Series A redeemable convertible preferred stock	$ (330)	$ —	$ (330)	$ —
Net loss attributable to common stockholders	$ (17,705)	$ (13,962)	$ (52,234)	$ (37,097)
Net loss per share — basic and diluted	$ (2.95)	$ (4.21)	$ (12.08)	$ (11.86)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	6,008,819	3,317,646	4,323,452	3,127,951
Other comprehensive loss:				
Net loss	$ (17,375)	$ (13,962)	$ (51,904)	$ (37,097)
Net unrealized gain on marketable securities arising during the period	—	—	2	9
Net realized (gain) loss on marketable securities included in net loss	—	—	2	(14)
Total other comprehensive (loss) income, net of taxes	—	—	4	(5)
Comprehensive loss	$ (17,375)	$ (13,962)	$ (51,900)	$ (37,102)

See accompanying notes to condensed consolidated financial statements.

T2 BIOSYSTEMS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF SERIES A CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share data)
(Unaudited)

	Temporary Equity		Permanent Equity					
	Series A Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	(Deficit)
Balance at December 31, 2020	—	$ —	2,961,579	$ 3	$ 431,689	$ (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	—	—	8,253	—	53	—	—	53
Unrealized gain on marketable securities	—	—	—	—	—	—	7	7
Net loss	—	—	—	—	—	(10,660)	—	(10,660)
Balance at March 31, 2021	—	$ —	2,969,832	$ 3	$ 433,050	$ (433,635)	$ 16	$ (566)
Stock-based compensation expense	—	—	—	—	1,843	—	—	1,843
Issuance of common stock from vesting of restricted stock, exercise of stock options and employee stock purchase plan	—	—	9,253	—	251	—	—	251
Issuance of common stock from secondary public offering, net	—	—	336,188	—	19,968	—	—	19,968
Unrealized loss on marketable securities	—	—		—	—	—	(12)	(12)
Net loss	—	—	—	—	—	(12,475)	—	(12,475)
Balance at June 30, 2021	—	$ —	3,315,273	$ 3	$ 455,112	$ (446,110)	$ 4	$ 9,009
Stock-based compensation expense	—	—	—	—	2,466	—	—	2,466
Issuance of common stock from vesting of restricted stock and exercise of stock options	—	—	4,082	—	24	—	—	24
Net loss	—	—	—	—	—	(13,962)	—	(13,962)
Balance at September 30, 2021	—	$ —	3,319,355	$ 3	$ 457,602	$ (460,072)	$ 4	$ (2,463)

	Temporary Equity		Permanent Equity					
	Series A Redeemable Convertible Preferred Stock Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	(Deficit)
Balance at December 31, 2021	—	$ —	3,328,017	$ 3	$ 459,314	$ (472,216)	$ (4)	$ (12,903)
Stock-based compensation expense	—	—	—	—	2,552	—	—	2,552
Issuance of common stock from vesting of restricted stock	—	—	40,028	—	—	—	—	—
Surrender of shares due to tax withholding	—	—	(10,781)	—	(231)	—	—	(231)
Issuance of common stock from secondary offering, net	—	—	70,981	—	1,433	—	—	1,433
Unrealized loss on marketable securities	—	—	—	—	—	—	(7)	(7)
Net loss	—	—	—	—	—	(16,495)	—	(16,495)
Balance at March 31, 2022	—	$ —	3,428,245	$ 3	$ 463,068	$ (488,711)	$ (11)	$ (25,651)
Stock-based compensation expense	—	—	—	—	1,534	—	—	1,534
Issuance of common stock from vesting of restricted stock, exercise of stock options and employee stock purchase plan	—	—	23,386	—	139	—	—	139
Surrender of shares due to tax withholding	—	—	—	—	(12)	—	—	(12)
Issuance of common stock from secondary offering, net	—	—	517,352	1	4,493	—	—	4,494
Unrealized gain on marketable securities	—	—	—	—	—	—	11	11
Net loss	—	—	—	—	—	(18,034)	—	(18,034)
Balance at June 30, 2022	—	$ —	3,968,983	$ 4	$ 469,222	$ (506,745)	$ —	$ (37,519)
Stock-based compensation expense	—	—	—	—	1,372	—	—	1,372
Issuance of common stock from vesting of restricted stock and exercise of stock options	—	—	1,365	—	—	—	—	—
Issuance of common stock from secondary offering, net	—	—	3,080,451	3	22,180	—	—	22,183
Issuance of Series A redeemable convertible preferred stock	3,000	—	—	—	—	—	—	—
Deemed dividend on Series A redeemable convertible preferred stock	—	330	—	—	(330)	—	—	(330)
Misc adjustment to reflect rounding on reverse stock split	—	—	50	—	—	—	—	—
Net loss	—	—	—	—	—	(17,375)	—	(17,375)
Balance at September 30, 2022	3,000	$ 330	7,050,849	$ 7	$ 492,444	$ (524,120)	$ —	$ (31,669)

See accompanying notes to condensed consolidated financial statements.

T2 BIOSYSTEMS, INC.

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

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (51,904)	$ (37,097)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	792	1,000
Amortization of bond premium	—	114
Amortization of operating lease right-of-use assets	907	982
Stock-based compensation expense	5,458	5,617
Change in fair value of derivative instrument	1,792	(1,010)
Change in fair value of derivative warrant liability	(179)	—
(Gain) loss on sales of marketable securities	2	(14)
(Gain) loss on issuance of Series A redeemable convertible preferred stock and derivative warrant liability	65	—
Impairment of property and equipment	30	—
Non-cash interest expense	1,613	2,803
Changes in operating assets and liabilities:		
Accounts receivable	3,556	877
Prepaid expenses and other assets	356	(692)
Inventories	(815)	(1,915)
Accounts payable	(791)	523
Accrued expenses and other liabilities	61	619
Deferred revenue	(375)	9
Operating lease liabilities	(868)	(848)
Net cash used in operating activities	(40,300)	(29,032)
Cash flows from investing activities		
Proceeds from maturities of marketable securities	—	15,251
Proceeds from sales of marketable securities	9,998	—
Purchases and manufacture of property and equipment	(303)	(261)
Net cash provided by investing activities	9,695	14,990
Cash flows from financing activities		
Payment of employee restricted stock tax withholdings	(243)	—
Proceeds from issuance of shares from employee stock purchase plan and stock option exercises	139	328
Proceeds from issuance of common stock in public offerings, net of offering costs	28,110	19,968
Proceeds from issuance of Series A redeemable convertible preferred stock and derivative warrant liability	300	—
Net cash provided by financing activities	28,306	20,296
Net change in cash, cash equivalents and restricted cash	(2,299)	6,254
Cash, cash equivalents and restricted cash at beginning of period	23,796	17,344
Cash, cash equivalents and restricted cash at end of period	$ 21,497	$ 23,598
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 2,916	$ 2,815
Supplemental disclosures of noncash activities		
Transfer of T2 owned instruments and components (from) to inventory	$ (482)	$ (729)
Deemed dividend on Series A redeemable convertible preferred stock	$ 330	$ —
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 199	$ —
Purchases of property and equipment included in accounts payable and accrued expenses	$ 72	$ 80

	September 30, 2022	September 30, 2021
Reconciliation of cash, cash equivalents and restricted cash at end of period		
Cash and cash equivalents	$ 20,366	$ 22,047
Restricted cash	1,131	1,551
Total cash, cash equivalents and restricted cash	$ 21,497	$ 23,598

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 September 30, 2022, the Company had cash, cash equivalents, and restricted cash of $21.5 million, an accumulated deficit of $524.1 million and stockholders' deficit of $31.7 million. The Company 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 proceeds from 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 8), its March 2021 establishment of an Equity Distribution Agreement (Note 8), private placements of redeemable convertible preferred stock as well as borrowings from 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 the Company's operations. Although the Company did not see any material impact to accounts receivable during the three and nine month period ended September 30, 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 the Biomedical Advanced Research and Development Authority ("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 continue to be 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.

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, and restricted cash of $21.5 million at September 30, 2022 will not be sufficient to fund its current operating plan for 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 first quarter of 2023. 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 a minimum liquidity covenant which requires the Company to maintain a minimum cash balance of $5.0 million. There can be no assurances that the Company 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. In November 2022, CRG amended the Term Loan Agreement, extending the interest only period and maturity to December 30, 2024.

The Company's stock had been trading under $1.00 since September 27, 2021. On November 5, 2021, the Company received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that the Company was not in compliance with the requirement of Nasdaq Listing Rule 5450(a)(1) for continued listing on the Nasdaq Global Market as a result of the closing bid price of the Company's common stock being below $1.00 per share for thirty consecutive business days (the "Bid Price Rule"). Under the Nasdaq rules, the Company had 180 days (or until May 4, 2022) to regain compliance by maintaining a minimum closing bid price of $1.00 per share of the Company's common stock for at least ten consecutive trading days during such compliance period. 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 Bid Price Rule for continued listing and, as a result, the Company's shares were 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 filed an appeal and hearing request to the Nasdaq Staff's determination to stay the delisting of the Company's shares of common stock from Nasdaq pending the Panel's decision. The Nasdaq Staff informed the Company that the delisting action had been stayed, pending a final written decision by the Panel, and the hearing date had been set for June 2, 2022.

On June 9, 2022, the Company received a letter from the Nasdaq notifying the Company that the Nasdaq had granted the Company's request to be transferred to The Nasdaq Capital Market, effective at the open of trading on June 13, 2022, and the Company's request for an exception to the Bid Price Rule until November 1, 2022.

On October 11, 2022, at the Company's annual meeting of stockholders, the Company's stockholders approved an amendment to the Company's restated certificate of incorporation to effect a reverse stock split of the Company's common stock. Following the receipt of the stockholders' approval, the Company's board of directors approved the reverse stock split at the ratio of 1 post-split share for every 50 pre-split shares, which was effective as of October 12, 2022. On October 31, 2022, the Company received a letter from Nasdaq informing the Company that it has regained compliance with the Bid Price Rule.

On July 22, 2022, the Company received a letter from the Nasdaq (the "Nasdaq Staff Deficiency Letter") indicating that, for the last thirty-five consecutive business days, the Market Value of Listed Securities, as defined by Nasdaq ("MVLS") had been below the $35 million minimum requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company has been provided an initial period of 180 calendar days, or until January 18, 2023, to regain compliance. The letter states that the Nasdaq staff will provide written notification that the Company has achieved compliance with Rule 5550(b)(2) if at any time before January 18, 2023, the Company maintains its MVLS at $35 million or more for a minimum of ten consecutive business days. The Nasdaq Staff Deficiency Letter has no immediate effect on the listing or trading of the Company's common stock. If compliance is not achieved by January 18, 2023, the Company expects that Nasdaq would provide written notification to the Company that its securities are subject to delisting. The Company will continue to monitor its MVLS and consider its available options to regain compliance with the Nasdaq minimum MVLS requirements, which may include applying for an extension of the compliance period or appealing to a Nasdaq Hearings Panel. On August 24, 2022, in a Compliance

Notice, the Nasdaq notified the Company that, from August 10, 2022 to August 23, 2022, the Company's MVLS had been $35 million or greater and, accordingly, the Company had regained compliance with Rule 5550(b)(2) and that the matter was now closed.

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 these unaudited condensed consolidated 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 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.

On October 12, 2022, we effected a reverse stock split at the ratio of 1 post-split share for every 50 pre-split shares. All common stock amounts and references have been retroactively adjusted for all figures presented to reflect this split unless specifically stated otherwise.

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 September 30, 2022, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2022 and 2021, the condensed consolidated statements of Series A convertible preferred stock and stockholders' deficit for the three and nine months ended September 30, 2022 and 2021, the condensed consolidated statements of cash flows for the nine months ended September 30, 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 September 30, 2022, and the results of its operations for the three and nine months ended September 30, 2022 and 2021 and its cash flows for the nine months ended September 30, 2022 and 2021. The results for the three and nine months ended September 30, 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 $1.2 million or 32% of total revenue and $0.6 million or 9% of total revenue for the three months ended September 30, 2022 and 2021, respectively. Total international sales were approximately $3.2 million or 19% of total revenue and $1.6 million or 8% of total revenue for the nine months ended September 30, 2022 and 2021, respectively.

For the three months ended September 30, 2022, one international customer represented 12% of total revenue. For the three months ended September 30, 2021, no international customer represented greater than 10% of total revenue. For the nine months ended September 30, 2022 and 2021, no international customer represented greater than 10% of total revenue.

The following table shows customers that represent greater than 10% of revenue for the period presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Customer A	28%	42%	46%	40%
Customer B	—%	14%	—%	15%
Customer C	12%	—%	—%	—%

As of September 30, 2022 and December 31, 2021, the Company had outstanding receivables of $0.9 million and $0.6 million, respectively, from customers located outside of the U.S.

Net Loss Per Share

The Company applies the two-class method for computing earnings per share because its Series A redeemable convertible preferred stock and the warrants issued with that preferred stock are participating securities. Under the two-class method, net income for the period is allocated between common stockholders and the participating securities according to dividends declared, if any, and participation rights in undistributed earnings. Because the Company incurred a net loss for the three and nine months ended September 30, 2022, and the holders of the participating securities do not have the contractual obligation to share in the losses of the Company on a basis that is objectively determinable, none of the net loss attributable to common stockholders was allocated to the participating securities when computing earnings per share.

Basic net loss per share is calculated by dividing net loss attributable to commons stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. Any accretion of the carrying amount of the Company's Series A redeemable convertible preferred stock to its redemption amount is treated as a deemed dividend to the preferred stockholders and will increase the amount of the net loss attributable to common stockholders.

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 either the if-converted method (for its Series A redeemable, convertible preferred stock) or the treasury-stock method. For purposes of the diluted net loss per share calculation, stock options and unvested restricted stock, restricted stock contingently issuable upon achievement of certain market conditions, and the warrants issued with Series A redeemable convertible preferred stock are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. In periods in which the Company recognizes gains due to changes in the fair value of its warrant liability, the Company will further assess whether the effect of adjusting its computation of diluted net loss per share to include the potential common shares and reverse the gain associated with the warrant would result in a more diluted net loss per share, and modify the computation if necessary. The Series A redeemable convertible preferred stock was not considered a common stock equivalent because exercise of the conversion option was contingent upon occurrence of the reverse stock split, which had not yet occurred as of September 30, 2022. 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 (expense) 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).

The Company had no marketable securities at September 30, 2022. The following table summarizes the Company's marketable securities at December 31, 2021 (in thousands):

	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 December 31, 2021 (in thousands):

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

Derivative Warrant Liability

The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives in accordance with ASC Topic 815, *"Derivatives and Hedging*."

The Company determined that the liability for the warrant issued in conjunction with the Series A redeemable convertible preferred stock is a derivative instrument. The derivative warrant liability is classified on the condensed consolidated balance sheets as current because cash settlement of the warrant could be required by the holder within 12 months of the balance sheet date. The Company has identified a single compound derivative liability related to its Term Loan Agreement with CRG, that is classified as non-current on the condensed consolidated balance sheets to match the classification of the related Term Loan Agreement.

As the derivative liabilities meet the definition of a derivative, they are measured at fair value at issuance and at each reporting date in accordance with ASC 820, "*Fair Value Measurement,"* with changes in fair value recognized in change in fair value of derivative warrant liability in the period of change in the condensed consolidated statements of operations and comprehensive loss. The Company does not designate its derivative instruments as hedging instruments.

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 September 30, 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.

Classification of Series A Redeemable Convertible Preferred Stock

The Company has applied the guidance in ASC 480-10-S99-3A, SEC Staff Announcement: Classification and Measurement of Redeemable Securities and classified the Series A redeemable convertible preferred stock as temporary equity in the mezzanine section of the balance sheet. The Series A redeemable convertible preferred stock was recorded outside of stockholders' deficit because under the terms thereof, in the event of stockholder approval of the reverse stock split or a delisting event, which are events considered not solely within the Company's control, the Series A redeemable convertible preferred stock becomes redeemable at the option of the holders.

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 12 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, September 30,		Nine Months Ended, September 30,	
	2022	2021	2022	2021
Product revenue				
Instruments	$ 814	$ 522	$ 2,528	$ 1,427
Consumables	1,822	3,765	6,442	11,150
Instrument rentals	5	19	74	57
Total product revenue	2,641	4,306	9,044	12,634
Contribution revenue	1,036	3,122	7,778	8,444
Total revenue	$ 3,677	$ 7,428	$ 16,822	$ 21,078

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 September 30, 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 $0.1 million as of September 30, 2022. The Company expects to recognize 86% of this amount as revenue within one year and the remainder within fifteen months.

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 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 recorded $0.1 million of contract assets within other assets on the balance sheet at September 30, 2022. The contract assets represent revenue recognized for performance obligations in advance of cash receipt at the contract level based on the transaction price allocated to the respective performance obligations. The Company did not record any contract assets at 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 $0.2 million and $0.5 million at September 30, 2022 and December 31, 2021, respectively. Revenue recognized during the nine months ended September 30, 2022 relating to contract liabilities at December 31, 2021 was $0.4 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 September 30, 2022, capitalized costs to fulfill contracts of less than $0.1 million was included in prepaid and other current assets. At 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, depreciation on T2Dx instruments used for research and development activities and contract services.

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 commercial support activity, 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.

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 September 30, 2022 and December 31, 2021 (in thousands):

	Balance at September 30, 2022	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Liabilities:				
Derivative warrant liability	$ 186	$ —	$ 186	$ —
Derivative liability	1,792	—	—	1,792
	$ 1,978	$ —	$ 186	$ 1,792

	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 were 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 September 30, 2022 and $1.6 million at December 31, 2021 (Note 4).

The Company estimated the fair value of the derivative warrant liability (Note 7) using the Black-Scholes Model, which uses multiple inputs including the Company's stock price, the exercise price of the warrant, volatility of the Company's stock price, the risk-free interest rate and the expected term of the warrant.

The Company has a single compound derivative related to its Term Loan Agreement with CRG (the "Term Loan Agreement") (Note 6), which is required to be re-measured at fair value on a quarterly basis. The fair value of the derivative at September 30, 2022 is $1.8 million and is classified as a non-current liability on the balance sheet at September 30, 2022 to match the classification of the related Term Loan Agreement (Note 6). As of December 31, 2021, the Company had no derivative liability.

The estimated fair value of the derivative at September 30, 2022 was determined using a probability-weighted discounted cash flow model that includes contingent interest payments under the following scenarios:

	Probability
4% contingent interest beginning in Q1 2023	50%

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

Balance at December 31, 2021	$ —
Change in fair value of derivative liability	1,675
Balance at June 30, 2022	1,675
Change in fair value of derivative liability	117
Balance at September 30, 2022	$ 1,792

4. Restricted Cash

The Company is required to maintain security deposits for its operating lease agreements for the duration of the lease agreements. At September 30, 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):

	September 30, 2022	December 31, 2021
Raw materials	$ 2,195	$ 1,591
Work-in-process	1,231	953
Finished goods	816	1,365
Total inventories, net	$ 4,242	$ 3,909

Property and Equipment

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

	September 30, 2022	December 31, 2021
Office and computer equipment	$ 749	$ 749
Software	783	783
Laboratory equipment	5,573	5,507
Furniture	197	197
Manufacturing equipment	1,445	1,445
Manufacturing tooling and molds	478	478
T2-owned instruments and components	7,150	6,668
Leasehold improvements	3,785	3,768
Construction in progress	774	512
	20,934	20,107
Less accumulated depreciation and amortization	(16,200)	(15,432)
Property and equipment, net	$ 4,734	$ 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 September 30, 2022, there was $1.0 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 September 30, 2022 and 2021. 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 $0.1 million for the nine months ended September 30, 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 $0.3 million was charged to operations for the three months ended September 30, 2022 and 2021, respectively. Depreciation and amortization expense of $0.8 million and $1.0 million was charged to operations for the nine months ended September 30, 2022 and 2021, respectively.

.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Accrued payroll and compensation	$ 3,894	$ 3,687
Accrued research and development expenses	1,482	1,250
Accrued professional services	392	384
Accrued interest	1,000	974
Operating lease liabilities	1,295	1,174
Other accrued expenses	468	869
Total accrued expenses and other current liabilities	$ 8,531	$ 8,338

6. Notes Payable

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

	September 30, 2022	December 31, 2021
Term Loan Agreement including PIK interest, before unamortized discount and issuance costs	$ 51,597	$ 49,364
Less: unaccrued paid-in-kind interest	(2,233)	(1,287)
Less: unamortized discount and deferred issuance costs	(176)	(287)
Total notes payable	$ 49,188	$ 47,790

The Term Loan Agreement with CRG is classified as non-current September 30, 2022 and at December 31, 2021, as the Company has sufficient cash and cash equivalents 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, under the Term Loan Agreement are due and payable upon maturity, December 30, 2023. There were no covenant violations at September 30, 2022. In November 2022, CRG amended the Term Loan Agreement, extending the interest only period and maturity to December 30, 2024.

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 September 30, 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 11,365 shares of the Company's common stock ("New Warrants") (Note 10) at an exercise price of $77.50, 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 10,579 shares of the Company's common stock to $77.50. 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 June 2021, the Company satisfied the only remaining revenue covenant which was for the 24-month period beginning on January 1, 2020.

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.

In November 2022, CRG amended the Term Loan Agreement, extending the interest only period and maturity to December 30, 2024.

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. Series A Redeemable Convertible Preferred Stock and Related Warrant

On August 15, 2022, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement"), pursuant to which we entered into a private placement transaction an aggregate of 3,000 shares of Series A Redeemable Convertible Preferred Stock with a par value of $0.001 per share and a warrant to purchase up to an aggregate of 42,857 shares of common stock of the Company at an exercise price of $7.50 per share (such number of shares and exercise price adjusted for the reverse stock split described in Note 15) for an aggregate subscription amount equal to $0.3 million, before deducting estimated offering expenses payable by the Company. Pursuant to the Purchase Agreement, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock with the Secretary of State of the State of Delaware designating the rights, preferences and limitations of the Series A Redeemable Convertible Preferred Stock.

Series A Redeemable Convertible Preferred Stock

The Series A Redeemable Convertible Preferred Stock was issued at a price of $100 per share (the Stated Value).

Conversion -The Series A Redeemable Convertible Preferred Stock is convertible at the option of the holder, at any time after the date of the reverse stock split proposed by the board of directors, into that number of shares of common stock (subject to certain beneficial ownership limitations) determined by dividing the stated value of the Series A Redeemable Convertible Preferred Stock share by the conversion price then in effect, rounded down to the nearest whole share (with cash paid in lieu of any fractional shares). The initial conversion price was $7.00 per share, adjusted for the reverse stock split that was effected on October 12, 2022 (the "Conversion Price"). The Conversion Price will be (1) adjusted proportionately upon occurrence of any subsequent stock splits or stock dividends and (2) lowered to a price per share equal to that of any common stock, convertible securities or option that is subsequently issued or sold by the Company for a price per share less than the Conversion Price in effect immediately prior to such issue or sale; however, the Conversion Price cannot fall below the par value per share of the Common Stock nor exceed ten dollars ($10.00) per share, in each case, as adjusted for the reverse stock split that was effected on October 12, 2022.

Redemption - Series A Redeemable Convertible Preferred Stock do not contain any mandatory redemption provisions. Beginning on the date of the reverse stock split, as proposed by the board of directors (1) the Company may redeem in cash all or any portion of the Series A Redeemable Convertible Preferred Stock at a price per share equal to one hundred and five percent (105%) of the stated value and (2) each holder of Series A Preferred Stock may require the Company to redeem in cash all or any portion of the Series A Redeemable Convertible Preferred Stock held by such holder at a price per share equal to one hundred and ten percent (110%) of the stated value. In addition, if the Company's common shares become delisted, the Series A Redeemable Convertible Preferred Stock will automatically be redeemed by the Company at a price per share equal to one hundred and ten percent (110%) of the Stated Value. At September 30, 2022, the Company determined that the Series A Redeemable Convertible Preferred Stock was redeemable and is being carried at its redemption value on the balance sheet, which is equal to its liquidation value under the terms of the certification of designation.

Dividend Rights-Holders of the Series A Redeemable Convertible Preferred Stock are entitled to receive dividends on shares of Series A Redeemable Convertible Preferred Stock equal (on an as-converted to common stock basis) to and in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of the common stock.

Voting Rights -The Series A Redeemable Convertible Preferred Stock will have no voting rights other than the right to vote on certain matters. Each share of Series A Redeemable Convertible Preferred entitles the holder to 1,000,000 votes on a proposal to approve a reverse stock split of the Company's outstanding common stock (the "Proposal") and any proposal to adjourn any meeting of stockholders called for the purpose of voting on the Proposal; provided, however, that such shares of Series A Redeemable Convertible Preferred Stock shall be voted in the same proportion as the shares of common stock (excluding any shares of common stock that are not voted) *are voted on the Proposal.*

Warrant

In connection with the execution of the Securities Purchase Agreement, the Company issued a warrant to purchase 42,857 shares of the Company's common stock (the "Warrant") at an exercise price equal to $7.50 per share, subject to adjustments noted below. The Warrant will become exercisable on February 15, 2023 and has a term ending February 15, 2028. At issuance, the Company determined that the Warrant should be classified as a liability because such Warrant could require cash redemption in certain circumstances. Recognition of the warrant liability created a day one loss of $0.1 million. The Warrant is carried at fair value, with changes in fair value recognized in changes in fair value of the derivative warrant liability each reporting period.

The exercise price of the Warrant and the number of shares issuable upon exercise will be adjusted proportionately upon the occurrence of any subsequent stock dividend or stock split of the Company's common stock. In addition, if at any time the Company

grants, issues or sells any common stock equivalents or rights to purchase stock, warrants, securities or other property pro rata to holders of any class of shares of common stock (the "Purchase Rights"), then the Warrant holder will be entitled to acquire, upon the terms applicable to the Purchase Rights, the aggregate Purchase Rights which the holder could have acquired if the holder had held the number of shares of common stock acquirable upon complete exercise of the Warrant (subject to certain beneficial ownership limitations). Furthermore, after the issuance of the Warrant and while it is outstanding, if the Company declares or makes any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of common stock, by way of return of capital or otherwise (a "Distribution"), the Warrant holder will be entitled to participate in that Distribution to the same extent that the holder would have participated if the holder had held the number of shares of common stock acquirable upon complete exercise of this Warrant (subject to certain beneficial ownership limitations).

After the occurrence of a Fundamental Transaction, as defined, then, upon any subsequent exercise of the Warrant the holder will, at its option, have the right to receive for each Warrant that would have been issuable upon such exercise immediately prior to the occurrence of the Fundamental Transaction the number of shares of common stock (or its equivalent) of the successor or acquiring corporation or of the Company, if it is the surviving corporation, or such other consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of common stock for which the Warrant is exercisable immediately prior to the Fundamental Transaction. For purposes of any such exercise, the determination of the exercise price will be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of common stock in such Fundamental Transaction, and the Company will apportion the exercise price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of common stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Warrant holder will be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction.

While any Warrant is outstanding, if the Company issues or sells, any common stock, convertible securities or options, for a consideration per share (the "New Issuance Price") less than a price equal to the exercise price of the Warrant in effect immediately prior to such issue or sale (a "Dilutive Issuance"), then immediately after the Dilutive Issuance, the exercise price then in effect will be reduced to an amount equal to the New Issuance Price.

If at the time of a Warrant's exercise there is no effective registration statement registering, or no current prospectus available for, the resale of the Warrant Shares by the holder, then the Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise".

8. Stockholders' Deficit

Shares Authorized

In July 2021, the Company's shareholders approved 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 its 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.

Under the New Sales Agreement, the Company sold 3,668,784 shares for net proceeds of $28.1 million during the nine months ended September 30, 2022 and 336,188 shares for net proceeds of $20.0 million during the nine months ended September 30, 2021.

Under the New Sales Agreement, the Company sold 3,080,451 shares for net proceeds of $22.2 million during the three months ended September 30, 2022 and did not sell any shares during the three months ended September 30, 2021.

9. 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) 16,470 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 700,000 shares may be issued upon the exercise of incentive stock options. As of September 30, 2022, there were 52,676 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 192,500 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 September 30, 2022, there were 84,501 shares available for future grant under the Inducement Plan.

Stock Options

During the nine months ended September 30, 2022 and 2021, the Company granted stock options with an aggregate fair value of $0.6 million and $1.1 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	197,171	$ 143.96	7.09	$ 51
Granted	33,520	21.50		
Exercised	—	—	—	—
Forfeited	(25,608)	42.64		
Cancelled	(11,863)	119.60		
Outstanding at September 30, 2022	193,220	$ 137.64	6.78	$ —
Exercisable at September 30, 2022	127,461	$ 186.38	5.90	$ —
Vested or expected to vest at September 30, 2022	182,864	$ 143.27	6.66	$ —

There were no options exercised in the nine months ended September 30, 2022 and 1,566 options exercised in the nine months ended September 30, 2021. The weighted-average grant date fair values of stock options granted in the nine month periods ended September 30, 2022 and 2021 were $17.58 per share and $54.77 per share, respectively, and were calculated using the following estimated assumptions:

	Nine Months Ended September 30,	
	2022	2021
Weighted-average risk-free interest rate	2.27%	0.92%
Expected dividend yield	—%	—%
Expected volatility	106%	104%
Expected terms	6.0 years	6.0 years

The total fair values of options that vested during the nine months ended September 30, 2022 and 2021 were $1.4 million and $2.1 million, respectively.

As of September 30, 2022, there was $2.1 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 2.1 years as of September 30, 2022.

Restricted Stock Units

During the nine months ended September 30, 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 $3.7 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	142,434	$ 91.77
Granted	160,575	22.79
Vested	(50,352)	93.13
Forfeited	(28,355)	42.40
Nonvested at September 30, 2022	224,302	$ 48.32

As of September 30, 2022, there was $8.5 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 1.7 years, as of September 30, 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 September 30, 2022 and 2021 was approximately $0.1 million. Stock-based compensation expense from the 2014 ESPP for the nine months ended September 30, 2022 and 2021 was approximately $0.3 million and $0.3 million, respectively.

The 2014 ESPP, which was amended and restated effective August 6, 2020, provides for the issuance of up to 90,478 shares of the Company's common stock to eligible employees. At September 30, 2022, there were 29,181 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Cost of product revenue	$ 64	$ 40	$ 309	$ 211
Research and development	230	269	851	707
Selling, general and administrative	1,060	2,114	4,280	4,655
Total stock-based compensation expense	$ 1,354	$ 2,423	$ 5,440	$ 5,573

For the three and nine months ended September 30, 2022 and 2021, stock-based compensation expenses capitalized as part of inventory or T2Dx instruments and components were immaterial.

In July 2021, a previous director of the Company resigned. In conjunction with his resignation, all of the director's outstanding options vested in full and the exercise term was extended to the final expiration date for each respective outstanding option. Additionally, the non-vested restricted stock units granted to the director in June 2021 vested in full upon his resignation. These were accounted for as Type I equity modifications for the accelerated vesting and Type III equity modifications for the extended exercise period and resulted in an increase of $0.8 million to stock-based compensation expense for the three and nine months ended September 30, 2021. Included within selling, general and administrative above for the three and nine months ended September 30, 2021 is $0.6 million and $0.2 million related to the Type I modification and the Type III modification, respectively, from the director's resignation.

10. Warrants associated with Term Loan

In connection with the Term Loan Agreement entered into in December 2016, the Company issued to CRG warrants to purchase a total of 10,579 shares of the Company's common stock. The warrants are exercisable any time prior to December 30, 2026 at a price of $77.50 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 September 30, 2022 and December 31, 2021.

In connection with a 2019 amendment of the Term Loan Agreement, the Company issued to CRG warrants to purchase 11,365 shares of the Company's common stock ("New Warrants") at an exercise price of $77.50, 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 September 30, 2022.

11. Net Loss Per Share

The Company applies the two-class method for computing earnings per share because its Series A redeemable convertible preferred stock and the warrants issued with that preferred stock are participating securities. Under the two-class method, net income for the period is allocated between common stockholders and the participating securities according to dividends declared, if any, and participation rights in undistributed earnings. Because the Company incurred a net loss for the three and nine months ended September 30, 2022, and the holders of the participating securities do not have the contractual obligation to share in the losses of the Company on a basis that is objectively determinable, none of the net loss attributable to common stockholders was allocated to the participating securities when computing earnings per share.

The net loss attributable to common stockholders was increased by $0.3 million to reflect the deemed dividend paid to holders of the Series A redeemable convertible preferred stock to accrete the carrying amount of that preferred stock to its redemption value.

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 or if-converted methods, because their effect would have been anti-dilutive for the periods presented:

	Three and Nine Months Ended September 30,	
	2022	2021
Options to purchase common shares	193,220	186,352
Restricted stock units	224,302	134,599
Warrants to purchase common stock	64,801	21,944
Series A redeemable convertible preferred stock	3,000	—
Total	485,323	342,895

Note that the net loss per share computations for all periods presented reflect the changes in the number of shares resulting from the 50 to 1 reverse stock split that was approved by shareholders on October 11, 2022 and became effective as of October 12, 2022. The number of shares of common stock issued and outstanding immediately before the reverse stock split was 352,957,478; the number of shares outstanding immediately after the reverse split was 7,059,144, a decrease of 345,898,334 shares.

12. U.S. Government Contract

In September 2019, 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 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.

In September 2022, BARDA exercised Option 3 and agreed to provide an additional $3.7 million in funding for the multiple-year cost-share contract. The additional funding under Option 3 will be used to advance the U.S. clinical trials for the T2Biothreat® Panel and T2Resistance® Panel, and to file submissions to the FDA for U.S. regulatory clearance.

The Company recorded contribution revenue of $1.0 million and $3.1 million for the three months ended September 30, 2022 and 2021, respectively, under the BARDA contract. The Company recorded contribution revenue of $7.8 million and $8.4 million for the nine months ended September 30, 2022 and 2021, respectively, under the BARDA contract.

The Company had no outstanding accounts receivable at September 30, 2022 and accounts receivable of $1.9 million at December 31, 2021, respectively, under the BARDA contract.

13. 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 May 2013, the Company entered into an operating lease for additional office, laboratory and manufacturing space in Wilmington, Massachusetts. In August 2018, the Company entered into an amendment to extend the term to December 2020. In October 2020, the Company entered into an amendment to extend the term to December 31, 2022. In September 2022, the Company entered into an amendment to extend the term to December 31, 2024. This amendment resulted in an increase to the operating lease right-of-use assets and lease liability accounts on the balance sheet of $0.2 million at September 30, 2022.

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 September 30, 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. At September 30, 2022, there is no effect on the operating lease right-of-use assets and lease liability accounts. 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 September 30, 2022. Occupancy of the building has been delayed due to disagreement between the Company and the landlord as to the parties' obligations under the lease agreement. Negotiations are on-going. The Company believes that a liability is reasonably possible but not probable. An estimate of the possible loss or range of loss cannot be made at this time.

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.

14. 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 1,693 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 September 30, 2022 and 2021 were immaterial. Royalties that became due under this agreement for the nine months ended September 30, 2022 and 2021 were $0.1 million.

15. Subsequent Events

Equity Distribution Agreement

Subsequent to September 30, 2022, the Company sold 256,628 shares for net proceeds of $0.7 million under the New Sales Agreement.

Reverse Stock Split

On October 11, 2022, at the Company's annual meeting of stockholders, the Company's stockholders approved an amendment to the Company's restated certificate of incorporation to effect a reverse stock split of the Company's common stock. Following the receipt of the stockholders' approval, the Company's board of directions approved the reverse stock split at the ratio of 1 post-split share for every 50 pre-split shares, and the amendment to the Company's restated certificate of incorporation became effective as of October 12, 2022. As a result of the reverse stock split, every 50 shares of issued and outstanding common stock of the Company were automatically reclassified and combined into 1 share of common stock, with any fractional interest in shares being paid out in cash. Immediately after the reverse stock split became effective, the Company had approximately 7,059,144 shares of common stock issued and outstanding. As a result of the reverse split, there was an adjustment of 50 shares for rounding. All common stock amounts and references have been retroactively adjusted for all figures presented to reflect this split unless specifically stated otherwise.

Securities Purchase Agreement

On October 26, 2022, the private investor in the Company's Series A redeemable convertible preferred stock redeemed all 3,000 shares of the Series A redeemable convertible preferred stock for an aggregate amount of $0.3 million.

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 within the meaning of the Private Securities Litigation Reform Act of 1955, as amended. 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 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, without limitation, 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 are neither promises nor guarantees, but 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. 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 ability to regain and maintain compliance with Nasdaq listing requirements;*
- *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;*
- *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 September 30, 2022 was $524.1 million and we have experienced net 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. Although we did not see any material impact to accounts receivable during the three and nine month period ended September 30, 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, 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 continue to be 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.

On August 9, 2022, the Company announced it was exploring the potential to develop a rapid molecular diagnostic test for detection of the monkeypox virus, including technical and commercial feasibility. While the Company believes it is
technically feasible, it has concluded that the current market opportunity does not currently support the investment of time and resources in developing a rapid molecular diagnostic test for detection of the monkeypox virus.

In the third quarter of 2021, we signed a lease for the purpose of consolidating our existing operations into a single 70,000 square foot, state-of-the-art life sciences facility in Billerica, Massachusetts, to accommodate current and future growth. Occupancy of the building has been delayed due to disagreement between Management and the landlord as to the parties' obligations under the lease agreement. Negotiations are on-going. We believe that a liability is reasonably possible but not probable. An estimate of the possible loss or range of loss cannot be made at this time.

We believe that our cash, cash equivalents, and restricted cash of $21.5 million at September 30, 2022 will not be sufficient to fund our current operating plan for 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 first quarter of 2023. Certain elements of our operating plan cannot be considered probable.

The Term Loan Agreement with CRG Servicing LLC ("CRG") (Note 6) has a minimum liquidity covenant which requires us to maintain a minimum cash balance of $5.0 million. 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. In November 2022, CRG amended the Term Loan Agreement, extending the interest only period and maturity to December 30, 2024.

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 us. The total potential BARDA funding if all contract options are exercised is $69.0 million.

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.

In September 2022, BARDA exercised Option 3 under our existing multiple-year cost-share agreement and agreed to provide an additional $3.7 million in funding. The additional funding under Option 3 will be used to advance the U.S. clinical trials for the T2Biothreat® Panel and T2Resistance® Panel and to file submissions to the FDA for U.S. regulatory clearance.

On November 5, 2021, we received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that we were not in compliance with the requirement of Nasdaq Listing Rule 5450(a)(1) for continued listing on the Nasdaq Global Market as a result of the closing bid price of our common stock being below $1.00 per share for thirty consecutive business days (the "Bid Price Rule"). Under the Nasdaq rules, we had 180 days (or until May 4, 2022) to regain compliance by maintaining a minimum closing bid price of $1.00 per share of our common stock for at least ten consecutive trading days during such compliance period. On May 5, 2022, we received a letter from Nasdaq informing us that our shares of common stock have failed to comply with the Bid Price Rule for continued listing and, as a result, our shares were 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 filed an appeal and hearing request to the Nasdaq Staff's determination to stay the delisting of our shares of common stock from Nasdaq pending the Panel's decision. The Nasdaq Staff informed us that the delisting action had been stayed, pending a final written decision by the Panel, and the hearing date had been set for June 2, 2022.

On June 9, 2022, we received a letter from the Nasdaq notifying us that the Nasdaq had granted our request to be transferred to The Nasdaq Capital Market, effective at the open of trading on June 13, 2022, and our request for an exception to the Bid Price Rule until November 1, 2022.

On October 11, 2022, at the annual meeting of stockholders, our stockholders approved an amendment to our restated certificate of incorporation to effect a reverse stock split of our common stock. Following the receipt of the stockholders' approval, our board of directors approved the reverse stock split ratio at the ratio of 1 post-split share for every 50 pre-split shares, which was effective as of October 12, 2022. On October 31, 2022, we received a letter from Nasdaq informing us that we regained compliance with the Bid Price Rule. All common stock amounts and references in this Quarterly Report have been retroactively adjusted for all figures presented to reflect this split unless specifically stated otherwise.

On July 22, 2022, we received a letter from the Nasdaq indicating that, for the last thirty-five consecutive business days, the Market Value of Listed Securities, as defined by Nasdaq ("MVLS") had been below the $35 million minimum requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we have been provided an initial period of 180 calendar days, or until January 18, 2023, to regain compliance. The letter states that the Nasdaq staff will provide written notification that we have achieved compliance with Rule 5550(b)(2) if at any time before January 18, 2023, we maintain our MVLS at $35 million or more for a minimum of ten consecutive business days. The Nasdaq Staff Deficiency Letter has no immediate effect on the listing or trading of our common stock. If compliance is not achieved by January 18, 2023, we expect that Nasdaq would provide written notification to us that our securities are subject to delisting. We will continue to monitor our MVLS and consider our available options to regain compliance with the Nasdaq minimum MVLS requirements, which may include applying for an extension of the compliance period or appealing to a Nasdaq Hearings Panel. On August 24, 2022, in a Compliance Notice, the Nasdaq notified us that, from August 10, 2022 to August 23, 2022, our MVLS had been $35 million or greater and, accordingly, we had regained compliance with Rule 5550(b)(2) and that the matter was now closed.

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 these unaudited condensed consolidated financial statements are issued. Management has concluded the likelihood that its plan to successfully obtain sufficient funding from one or more of these sources or adequately reduce expenditures, while reasonably possible, is less than probable. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of issuance of these financial statements.

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. We expect cost of product revenue to decrease as a percentage of revenue as a result of the cost of product revenue improvement initiatives.

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, depreciation on T2Dx instruments used in research and development activities 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 to 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 commercial support activity, 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. We expect selling, general and administrative expenses to decrease as a percentage of revenue in future periods.

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, the amortization of deferred financing costs and debt discount.

Change in fair value of derivative instrument

The change in fair value of the derivative consists of the change in fair value of the derivative associated with the CRG Term Loan Agreement.

Change in fair value of derivative warrant liability

The change in fair value of the derivative consists of the change in fair value of the derivative warrant liability associated with the Securities Purchase Agreement.

Other income (expense), 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 September 30, 2022 and 2021

	Three Months Ended September 30,		
	2022	2021	Change
	(in thousands)		
Revenue:			
Product revenue	$ 2,641	$ 4,306	$ (1,665)
Contribution revenue	1,036	3,122	(2,086)
Total revenue	3,677	7,428	(3,751)
Costs and expenses:			
Cost of product revenue	6,085	4,720	1,365
Research and development	6,375	6,384	(9)
Selling, general and administrative	7,017	8,536	(1,519)
Total costs and expenses	19,477	19,640	(163)
Loss from operations	(15,800)	(12,212)	(3,588)
Other income (expense):			
Interest income	1	6	(5)
Interest expense	(1,560)	(1,919)	359
Change in fair value of derivative instrument	(117)	—	(117)
Change in fair value of derivative warrant liability	179	—	179
Other income (expense), net	(78)	163	(241)
Total other expense	(1,575)	(1,750)	175
Net loss	$ (17,375)	$ (13,962)	$ (3,413)

Product revenue

Product revenue was $2.6 million for the three months ended September 30, 2022 compared to $4.3 million for the three months ended September 30, 2021, a decrease of $1.7 million, which was driven by lower consumables sales of $2.0 million mostly due to a decrease in sales of T2SARS-CoV-2, offset by higher T2Dx sales of $0.3 million.

Contribution revenue

Contribution revenue relates to our BARDA agreement and was $1.0 million for the three months ended September 30, 2022, compared to $3.1 million for the three months ended September 30, 2021. The decrease of $2.1 million was due to timing of the contract activity and the option amounts.

Cost of product revenue

Cost of product revenue was $6.1 million for the three months ended September 30, 2022, compared to $4.7 million for the three months ended September 30, 2021, an increase of $1.4 million. The increase was driven by $2.4 million of higher costs due to the effect of a change in build plan and manufacturing inefficiencies and $0.3 million of costs related to higher instrument sales, partially offset by $1.0 million of decreased costs related to lower consumable sales, $0.1 million of lower service and repair costs, $0.1 million of lower royalties, and $0.1 million of lower shipping and other costs.

Research and development expenses

Research and development expenses were $6.4 million for the three months ended September 30, 2022 and 2021. Clinical-related expenses increased by $0.9 million primarily for our T2Resistance Panel 510(k) Study and T2Biothreat Panel, and internal usage for our T2Resistance research and development projects increased by $0.8 million. These increases were offset by decreased lab and facility expenses of $0.9 million primarily due to BARDA and less IT support services, decreased materials costs of $0.4 million, decreased consulting expenses of $0.2 million for BARDA, and decreased stock based compensation expenses of $0.2 million.

Selling, general and administrative expenses

Selling, general and administrative expenses were $7.0 million for the three months ended September 30, 2022, compared to $8.5 million for the three months ended September 30, 2021, a decrease of $1.5 million. The decrease was driven by lower stock based compensation expenses of $1.1 million primarily due to the $0.8 million equity modification recorded in the third quarter of 2021 upon a previous director's resignation, lower consulting expenses of $0.3 million due to the timing of the annual meeting and the 2021 payments associated with a previous director's resignation, and lower payroll related expenses of $0.2 million due to lower 2022 quarter-to-date average headcount, partially offset by $0.1 million of increased travel expenses due to increased tradeshows and conferences.

Interest income

Interest income was immaterial for the three months ended September 30, 2022 and 2021.

Interest expense

Interest expense was $1.6 million for the three months ended September 30, 2022, compared to $1.9 million for the three months ended September 30, 2021, a decrease of $0.3 million, primarily due to amortization of the debt discount and the final fee interest associated with the CRG Term Loan Agreement (Note 6).

Change in fair value of derivative instrument

The change in fair value of the derivative instrument associated with the CRG Term Loan Agreement (Note 6) was $0.1 million of expense for the three months ended September 30, 2022. There was no derivative liability recorded at September 30, 2021 as we had achieved the only remaining revenue covenant in June 2021 and had sufficient cash and cash equivalents that the minimum liquidity covenant would not be triggered, relieving the derivative liability.

Change in fair value of derivative warrant liability

The change in fair value of the derivative warrant liability associated with the Securities Purchase Agreement (Note 7) was a $0.2 million reduction of expense for the three months ended September 30, 2022. There was no derivative warrant liability recorded at September 30, 2021.

Other income (expense), net

Other income (expense), net, was expense of $0.1 million for the three months ended September 30, 2022 primarily due to the loss recorded upon issuance of the Series A redeemable convertible preferred stock and warrant compared to income of $0.2 million for the three months ended September 30, 2021 primarily from a one-time payment.

Results of Operations for the Nine Months Ended September 30, 2022 and 2021

	Nine Months Ended September 30,		
	2022	2021	Change
	(in thousands)		
Revenue:			
Product revenue	$ 9,044	$ 12,634	$ (3,590)
Contribution revenue	7,778	8,444	(666)
Total revenue	16,822	21,078	(4,256)
Costs and expenses:			
Cost of product revenue	17,371	15,341	2,030
Research and development	21,056	16,448	4,608
Selling, general and administrative	24,071	21,983	2,088
Total costs and expenses	62,498	53,772	8,726
Loss from operations	(45,676)	(32,694)	(12,982)
Other income (expense):			
Interest income	6	18	(12)
Interest expense	(4,556)	(5,642)	1,086
Change in fair value of derivative instrument	(1,792)	1,010	(2,802)
Change in fair value of derivative warrant liability	179	—	179
Other income (expense), net	(65)	211	(276)
Total other expense	(6,228)	(4,403)	(1,825)
Net loss	$ (51,904)	$ (37,097)	$ (14,807)

Product revenue

Product revenue was $9.0 million for the nine months ended September 30, 2022 compared to $12.6 million for the nine months ended September 30, 2021, a decrease of $3.6 million, which was driven by lower consumables sales of $4.7 million mostly due to a decrease in sales of T2SARS-CoV-2, offset by higher T2Dx sales of $1.1 million.

Contribution revenue

Contribution revenue relates to our BARDA agreement and was $7.8 million for the nine months ended September 30, 2022 compared to $8.4 million for the nine months ended September 30, 2021. The decrease of $0.6 million was primarily due to decreased contract activity and the amount of the options.

Cost of product revenue

Cost of product revenue was $17.3 million for the nine months ended September 30, 2022, compared to $15.3 million for the nine months ended September 30, 2021, an increase of $2.0 million. The increase in cost was driven by $4.2 million of higher costs due to the effect of a change in build plan and manufacturing inefficiencies, $1.7 million of costs due to higher instrument sales, $0.6 million of higher service and repair costs, $0.2 million of higher shipping and other related expenses, partially offset by $4.5 million of decreased costs related to lower consumable sales, and $0.2 million of lower royalties.

Research and development expenses

Research and development expenses were $21.0 million for the nine months ended September 30, 2022, compared to $16.4 million for the nine months ended September 30, 2021, an increase of $4.6 million. The increase was driven by clinical related expenses of $1.8 million for our T2Resistance Panel 510(k) Study and T2Biothreat Panel, internal usage of $1.3 million primarily for T2Resistance research and development projects, higher payroll related expenses of $0.8 million and stock based compensation expenses of $0.2 million due to a higher 2022 year-to-date average headcount, higher materials costs of $0.6 million and consulting expenses of $0.3 million primarily for BARDA, partially offset by a decrease of $0.1 million in lab and facility expenses related to less IT support services.

Selling, general and administrative expenses

Selling, general and administrative expenses were $24.1 million for the nine months ended September 30, 2022, compared to $22.0 million for the nine months ended September 30, 2021, an increase of $2.1 million. The increase was driven by a $1.5 million increase in payroll related expenses due to higher year-to-date average headcount, $0.5 million of increased travel primarily from higher average sales headcount, tradeshows and conferences, $0.4 million of increased marketing expenses primarily for tradeshows and conferences, and other expenses of $0.1 million for software, professional dues and equipment to support the higher 2022 year-to-date average headcount, partially offset by lower stock based compensation expenses of $0.4 million primarily due to the $0.8 million equity modification recorded in the third quarter of 2021 upon a previous director's resignation, partially offset by the higher 2022 year-to-date average headcount.

Interest income

Interest income was immaterial for the nine months ended September 30, 2022 and 2021.

Interest expense

Interest expense was $4.5 million for the nine months ended September 30, 2022, compared to $5.6 million for the nine months ended September 30, 2021. Interest expense decreased by $1.1 million primarily due to amortization of the debt discount and the final fee interest associated with the CRG Term Loan Agreement.

Change in fair value of derivative instrument

The change in fair value of the derivative instrument was $1.8 million of expense for the nine months ended September 30, 2022 due to the probability of triggering a violation of the minimum liquidity covenant associated with the CRG Term Loan Agreement (Note 6). The change in fair value of the derivative instrument was a $1.0 million reduction of expense for the nine months ended September 30, 2021 as we achieved the only remaining revenue covenant in June 2021 and had sufficient cash and cash equivalents that the minimum liquidity covenant would not be triggered, relieving the derivative liability.

Change in fair value of derivative warrant liability

The change in fair value of the derivative warrant liability associated with the Securities Purchase Agreement (Note 7) was a $0.2 million reduction of expense for the nine months ended September 30, 2022. There was no derivative warrant liability recorded at September 30, 2021.

Other income (expense), net

Other income (expense), net, was expense of $0.1 million for the nine months ended September 30, 2022 primarily due to the loss recorded upon issuance of the Series A redeemable convertible preferred stock and warrant compared to income of $0.2 million for the nine months ended September 30, 2021 primarily from a one-time payment.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception, and as of September 30, 2022 and December 31, 2021, we had an accumulated deficit of $524.1 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

8), our March 2021 establishment of an Equity Distribution Agreement (Note 8), private placements of redeemable convertible preferred stock and debt financing arrangements.

In July 2021, our shareholders approved 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. Under the New Sales Agreement, we sold 3,668,784 shares for net proceeds of $28.1 million during the nine months ended September 30, 2022 and 336,188 shares for net proceeds of $20.0 million during the nine months ended September 30, 2021. Under the New Sales Agreement, we sold 3,080,451 shares for net proceeds of $22.2 million during the three months ended September 30, 2022 and did not sell any shares during the three months ended September 30, 2021.

Subsequent to September 30, 2022, we sold 256,628 shares for net proceeds of $0.7 million under the New Sales Agreement.

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 September 30, 2022 and December 31, 2021, we had unrestricted cash and cash equivalents of approximately $21.5 million and $22.2 million, respectively. 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. Although we did not see any material impact to accounts receivable during the nine months ended September 30, 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 continue to be 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, and restricted cash of $21.5 million at September 30, 2022 will not be sufficient to fund our current operating plan for at least a year from issuance of these financial statements. Absent any reductions in current operating expenses, we believe we will require additional financing during the first quarter of 2023. Certain elements of our operating plan cannot be considered probable.

The Term Loan Agreement with CRG Servicing LLC ("CRG") (Note 6) has a minimum liquidity covenant which requires us to maintain a minimum cash balance of $5.0 million. 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. In November 2022, CRG amended the Term Loan Agreement, extending the interest only period and maturity to December 30, 2024.

On November 5, 2021, we received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that we were not in compliance with the requirement of Nasdaq Listing Rule 5450(a)(1) for continued listing on the Nasdaq Global Market as a result of the closing bid price of our common stock being below $1.00 per share for thirty consecutive business days (the "Bid Price Rule").

On October 11, 2022, at the annual meeting of stockholders, our stockholders approved an amendment to our restated certificate of incorporation to effect a reverse stock split of our common stock. Following the receipt of the stockholders' approval, our board of directors approved the reverse stock split ratio at the ratio of 1 post-split share for every 50 pre-split shares, which was effective as of October 12, 2022. On October 31, 2022, we received a letter from Nasdaq informing us that we regained compliance with the Bid Price Rule. See the discussion under "Liquidity and Going Concern" in Note 1 in the notes to the condensed consolidated financial statements for further information.

On July 22, 2022, we received a letter from the Nasdaq indicating that, for the last thirty-five consecutive business days, the Market Value of Listed Securities, as defined by Nasdaq ("MVLS") had been below the $35 million minimum requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we have been provided an initial period of 180 calendar days, or until January 18, 2023, to regain compliance. The letter states that the Nasdaq staff will provide written notification that we have achieved compliance with Rule 5550(b)(2) if at any time before January 18, 2023, we maintain our MVLS at $35 million or more for a minimum of ten consecutive business days. The Nasdaq Staff Deficiency Letter has no immediate effect on the listing or trading of our common stock. If compliance is not achieved by January 18, 2023, we expect that Nasdaq would provide written notification to us that our securities are subject to delisting. We will continue to monitor our MVLS and consider our available options to regain compliance with the Nasdaq minimum MVLS requirements, which may include applying for an extension of the compliance period or appealing to a Nasdaq Hearings Panel. On August 24, 2022, in a Compliance Notice, the Nasdaq notified us that, from August 10, 2022 to August 23, 2022, our MVLS had been $35 million or greater and, accordingly, we had regained compliance with Rule 5550(b)(2) and that the matter was now closed.

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 unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q are issued. Management has concluded the likelihood that its plan to successfully obtain sufficient funding from one or more of these sources or adequately reduce expenditures, while reasonably possible, is less than probable. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of issuance of these financial statements.

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

Cash flows

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

	Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (40,300)	$ (29,032)
Investing activities	9,695	14,990
Financing activities	28,306	20,296
Net change in cash, cash equivalents and restricted cash	$ (2,299)	$ 6,254

Net cash used in operating activities

Net cash used in operating activities was approximately $40.3 million for the nine months ended September 30, 2022, and consisted of a net loss of $51.9 million adjusted for non-cash items including stock-based compensation expense of $5.5 million, a change in fair value of the derivative of $1.8 million, non-cash interest expense of $1.6 million, non-cash lease expense of $0.9 million, depreciation and amortization expense of $0.8 million, a change in fair value of the derivative warrant liability of $0.2

million, loss on issuance of Series A redeemable convertible preferred stock and warrant of $0.1 million and a net change in operating assets and liabilities of $1.1 million. The net change in operating assets and liabilities was primarily driven by a decrease in accounts receivable of $3.6 million due to BARDA payments and the timing and volume of instrument and consumable sales, a decrease in prepaid expenses and other assets of $0.4 million due to timing of deposits for goods and services, an increase in accrued expenses of $0.1 million primarily from accrued clinical for our T2Resistance 510(k) Study, partially offset by a decrease in operating lease liabilities of $0.9 million, a decrease in accounts payable of $0.8 million primarily due to timing of invoices and payments, an increase in inventory of $0.8 million due to securing raw materials and bulk materials purchases for favorable pricing and a decrease in deferred revenue of $0.4 million due to timing of our ratably recognized service agreements.

Net cash used in operating activities was approximately $29.0 million for the nine months ended September 30, 2021, and consisted of a net loss of $37.1 million adjusted for non-cash items including stock-based compensation expense of $5.6 million, non-cash interest expense of $2.8 million, non-cash lease expense of $1.0 million, depreciation and amortization expense of $1.0 million, a change in fair value of the derivative of $1.0 million, amortization of bond premium of $0.1 million and a net change in operating assets and liabilities of $1.4 million. The net change in operating assets and liabilities was primarily driven by an increase of $1.9 million in inventory to support the 2021 build plan, a decrease in operating lease liabilities of $0.8 million, an increase in prepaid expenses and other assets of $0.7 million primarily related to an increase in insurance, increased software subscriptions and the security deposit receivable for one of our operating leases, partially offset by a decrease in accounts receivable of $0.9 million primarily due to the timing and volume of consumable and instrument sales partially offset by an increase in accounts receivable for our BARDA agreement, an increase in accrued expenses of $0.6 million primarily due to the timing and volume of increased research activities, consulting and the employee stock purchase plan, and an increase in accounts payable of $0.5 million due to timing of payments.

Net cash provided by investing activities

Net cash provided by investing activities was $9.7 million for the nine months ended September 30, 2022, and primarily consisted of proceeds from sales of marketable securities of $10.0 million, partially offset by equipment purchases of $0.3 million.

Net cash provided by investing activities was approximately $15.0 million for the nine months ended September 30, 2021, and primarily consisted of proceeds from maturities of marketable securities of $15.3 million, partially offset by equipment purchases of $0.3 million.

Net cash provided by financing activities

Net cash provided by financing activities was approximately $28.3 million for the nine months ended September 30, 2022, and consisted primarily of proceeds from sales of our common stock under the New Sales Agreement, net of issuance costs, of $28.1 million, proceeds from issuance of Series A redeemable convertible preferred stock and warrant of $0.3 million, proceeds from issuance of shares under our 2014 Employee Stock Purchase Plan of $0.1 million, offset by payment of employee restricted stock tax withholdings of $0.2 million.

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

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 (as defined therein), 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 September 30, 2022 and December 31, 2021 on the balance sheet.

The Term Loan Agreement with CRG is classified as non-current at September 30, 2022 and December 31, 2021 as we have sufficient cash and cash equivalents 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 the

probability of triggering the minimum liquidity covenant. 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 11,365 shares of the Company's common stock ("New Warrants") (Note 10) at an exercise price of $77.50, 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 10,579 shares of our common stock to $77.50. 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 June 2021, the Company satisfied the only remaining revenue covenant which was for the 24-month period beginning on January 1, 2020.

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.

In November 2022, CRG amended the Term Loan Agreement, extending the interest only period and maturity to December 30, 2024.

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.

Securities Purchase Agreement

On August 15, 2022, we entered into a securities purchase agreement (the "Securities Purchase Agreement"), pursuant to which we issued in a private placement transaction an aggregate of 3,000 shares of Series A Redeemable Convertible Preferred Stock with a par value of $0.001 per share and a warrant to purchase up to an aggregate of 42,857 shares of our common stock at an exercise price of $7.50 per share for an aggregate subscription amount equal to $0.3 million, before deducting estimated offering expenses payable. The Series A Redeemable Convertible Preferred Stock was issued at a price of $100 per share (the Stated Value). Pursuant to the

Purchase Agreement, we filed a Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock with the Secretary of State of the State of Delaware designating the rights, preferences and limitations of the Series A Redeemable Convertible Preferred Stock. On October 26, 2022, the private investor in our Series A Redeemable Convertible Preferred Stock redeemed all 3,000 shares of the Series A Redeemable Convertible Preferred Stock for an aggregate amount of $330,000.

In connection with the execution of the Securities Purchase Agreement, we also issued a warrant to purchase 42,857 shares of our common stock (the "Warrant Shares") at an exercise price equal to $7.50 per share, subject to adjustments noted below. The Warrant will become exercisable on February 15, 2023 and has a term ending February 15, 2028. At issuance, we determined that the Warrant should be classified as a liability because such Warrant could require cash redemption in certain circumstances. Recognition of the warrant liability created a day one loss of $0.1 million. Accordingly, the Warrant is carried at fair value, with changes in fair value recognized in other income (expense), net. See Note 7 in the notes to the condensed consolidated financial statements in this Quarterly Report for additional information.

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.

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 September 30, 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 September 30, 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.

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, and restricted cash at September 30, 2022 was $21.5 million, which will not be sufficient to fund our current operating plan for 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 first quarter of 2023. 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 a minimum liquidity covenant which requires 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, 2024. 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.

These conditions, as well as those described below under "*Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our common stock,*" 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 these unaudited condensed consolidated financial statements are issued. Management has concluded the likelihood that its plan to successfully obtain sufficient funding from one or more of these sources or adequately reduce expenditures, while reasonably possible, is less than probable. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of issuance of these financial statements.

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

If we fail to satisfy or maintain compliance with the continued listing requirements of The Nasdaq Capital Market, Nasdaq may take steps to delist our common stock.

Prior to the reverse stock split discussed below, our stock had been trading under $1.00 since September 27, 2021. On November 5, 2021, we received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that we were not in compliance with the requirement of Nasdaq Listing Rule 5450(a)(1) for continued listing on the Nasdaq Global Market as a result of the closing bid price of our common stock being below $1.00 per share for thirty consecutive business days (the "Bid Price Rule"). Under the Nasdaq rules, we had 180 days (or until May 4, 2022) to regain compliance by maintaining a minimum closing bid price of $1.00 per share of our common stock for at least ten consecutive trading days during such compliance period. On May 5, 2022, we received a letter from Nasdaq informing us that our shares of common stock had failed to comply with the Bid Price Rule for continued listing and, as a result, our shares were 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 filed an appeal and hearing request to the Nasdaq Staff's determination to stay the delisting of our shares of common stock from Nasdaq pending the Panel's decision. The Nasdaq Staff informed us that the delisting action had been stayed, pending a final written decision by the Panel, and the hearing date had been set for June 2, 2022.

On June 9, 2022, we received a letter from the Nasdaq notifying us that the Nasdaq had granted our request to be transferred to The Nasdaq Capital Market, effective at the open of trading on June 13, 2022, and our request for an exception to the Bid Price Rule was granted until November 1, 2022.

On October 11, 2022, at the annual meeting of stockholders, our stockholders approved an amendment to our restated certificate of incorporation to effect a reverse stock split of our common stock. Following the receipt of the stockholders' approval, our board of directors approved the reverse stock split at the ratio of 1 post-split share for every 50 pre-split shares, which was effective as of October 12, 2022. On October 31, 2022, we received a letter from Nasdaq informing us that we regained compliance with the Bid Price Rule. However, there is no assurance that the market price per share of our common stock will continue to remain in excess of the $1.00 minimum bid price as required by Nasdaq, or that we will otherwise meet the requirements of Nasdaq for continued inclusion for trading on The Nasdaq Capital Market.

On July 22, 2022, we received a letter from the Nasdaq indicating that, for the last thirty-five consecutive business days, the Market Value of Listed Securities, as defined by Nasdaq ("MVLS") had been below the $35 million minimum requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we have been provided an initial period of 180 calendar days, or until January 18, 2023, to regain compliance. The letter states that the Nasdaq staff will provide written notification that we have achieved compliance with Rule 5550(b)(2) if at any time before January 18, 2023, we maintain our MVLS at $35 million or more for a minimum of ten consecutive business days. The Nasdaq Staff Deficiency Letter has no immediate effect on the listing or trading of our common stock. If compliance is not achieved by January 18, 2023, we expect that Nasdaq would provide written notification to us that our securities are subject to delisting. We will continue to monitor our MVLS and consider our available options to regain compliance with the Nasdaq minimum MVLS requirements, which may include applying for an extension of the compliance period or appealing to a Nasdaq Hearings Panel. On August 24, 2022, in a Compliance Notice, the Nasdaq notified us that, from August 10, 2022 to August 23, 2022, our MVLS had been $35 million or greater and, accordingly, we had regained compliance with Rule 5550(b)(2) and that the matter was now closed.

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.

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.

The EU regulatory landscape concerning in vitro diagnostic medical devices recently evolved. On May 26, 2022, the EU In Vitro Diagnostic Medical Devices Regulation, or IVDR, entered into force, which repeals and replaces the EU In Vitro Diagnostic Medical Devices Directive (*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 European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Subject to the transitional provisions (i.e., 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) and in order to sell our products in the member states of the EU our products must comply with the general safety and performance requirements of the IVDR. 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 IVDR 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. To demonstrate compliance with the general safety and performance requirements we must undergo a conformity assessment procedure, which varies according to the type of in vitro diagnostic medical device and its (risk) classification. A conformity assessment procedure generally requires the intervention of a notified body. 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 general safety and performance 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 laws and regulations, 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 EEA. 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 or 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. A public consultation by the MHRA was opened until end of November 2021 on the post-Brexit regulatory framework for medical devices and diagnostics. The consultation proposes amendments to the UK Medical Devices Regulations 2002 (which are based on EU legislation), in particular to create a new access pathways to support innovation, create an innovative framework for regulating software and artificial intelligence as medical devices, reform in vitro diagnostic regulation, and foster sustainability through the reuse and remanufacture of medical devices. On June 26, 2022, the MHRA published its long-awaited response to its consultation on the UK's post-Brexit regulatory regime for medical devices and in vitro diagnostic medical devices. The MHRA confirmed that the new regulatory landscape will mirror many of the provisions of the EU regulatory regime. However, the response also highlighted that in certain areas, medical devices regulation in Great Britain is likely to deviate from the EU framework. The UK government now needs to translate its proposals into legislation, via amendments to the UK Medical Devices Regulations (SI 2002 No 618, as amended). The regime is expected to come into force in July 2023 subject to appropriate transitional arrangements.

Even if granted, a 510(k) clearance, *de novo* classification, PMA approval, or similar authorization or certification from other regulators or notified bodies 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, 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.

We currently develop, manufacture and test our products and product candidates and some of their components in two facilities. If these or any future facility or our equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed.

We currently develop our diagnostic products exclusively in a facility in Lexington, Massachusetts and manufacture and test some components of our products and product candidates in, both, Wilmington and Lexington, Massachusetts. If these or any future facility were to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages, or otherwise, or if our business is disrupted for any other reason, we may not be able to develop or test our products and product candidates as promptly as our potential customers expect, or possibly not at all.

The manufacture of components of our products and product candidates at our Wilmington facility involves complex processes, sophisticated equipment and strict adherence to specifications and quality systems procedures. Any unforeseen manufacturing problems, such as contamination of our facility, equipment malfunction, or failure to strictly follow procedures or meet specifications, could result in delays or shortfalls in production of our products. Identifying and resolving the cause of any manufacturing issues could require substantial time and resources. If we are unable to keep up with future demand for our products by successfully manufacturing and shipping our products in a timely manner, our revenue growth could be impaired and market acceptance of our product candidates could be adversely affected.

In September 2021, we entered into a lease for office, research, laboratory and manufacturing space that will consolidate our existing operations into a single 70,000 square foot, state-of-the-art life sciences facility in Billerica, Massachusetts. Occupancy of the building has been delayed due to disagreement between Management and the landlord as to the parties' obligations under the lease agreement. Negotiations are on-going. We believe that a liability is reasonably possible but not probable. An estimate of the possible loss or range of loss cannot be made at this time.

We maintain insurance coverage against damage to our property and equipment, subject to deductibles and other limitations that we believe is adequate. If we have underestimated our insurance needs with respect to an interruption, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses.

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

We did not have any unregistered sales of equity securities during the quarter ended September 30, 2022 other than the issuance of Series A redeemable convertible preferred stock and related warrants to purchase shares of our common stock that had been previously reported in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 16, 2022.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits, Financial Statement Schedules

Exhibit Number	Exhibit Description
3.1	Restated Certificate of Incorporation of the Company, as amended (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36571) filed on August 12, 2014)
3.2	Certificate of Amendment of Restated Certificate of Incorporation of the Company dated July 23, 2021 (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36751) filed on July 23, 2021)
3.3	Certificate of Amendment of Restated Certificate of Incorporation of the Company dated October 12, 2022 (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36571) filed on October 12, 2022)
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.3 of the Company's Form 10-Q (File No. 001-36571) filed on August 16, 2022)
3.5	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.4 of the Company's Form 10-Q (File No. 001-36571) filed on August 16, 2022)
4.1	Form of Warrant (incorporated by reference to Exhibit 4.1 of the Company's Form 10-Q (File No. 001-36571) filed on August 16, 2022)
10.1	Securities Purchase Agreement, dated as of August 15, 2022 (incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q (File No. 001-36571) filed on August 16, 2022)
10.2	Amendment of Solicitation/Modification of Contract, dated as of July 26, 2022 by and between the Company and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services (incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q (File No. 001-36571) filed on August 16, 2022)
10.3	Registration Rights Agreement, dated as of August 15, 2022 (incorporated by reference to Exhibit 10.3 of the Company's Form 10-Q (File No. 001-36571) filed on August 16, 2022)
10.4*	Amendment of Solicitation/Modification of Contract, dated as of September 29, 2022 by and between the Company and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services
10.5*	Amendment No. 8 to Term Loan Agreement, dated November 10, 2022, between T2 Biosystems, Inc. and CRG Servicing LLC
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: November 14, 2022

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

Date: November 14, 2022

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

[****] = 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.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT | 1. CONTRACT ID CODE | PAGE OF PAGES: 1 of 53

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	15" PROJECT NO. (If applicable)
P00010	See Block 16C	OS301992	

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 HARTWE
101 HARTWELL AVE
LEXINGTON MA 02421

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

0 The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers 0 is extended. 0 is not extended.

Offers must acknowledge receipt of this amendmentprior 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_____ **cc** 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. tf by virtue of this amendment you desire to change an offe r already submitte d , suc h change may be made by letter or electronic communication, provided each letter or electronic communicationmakes reference to the solicitation and this amendment, and is received prior to the op ning hour and date specified.**

12 ACCOUNTING AND APPROPRIATION DATA/If *required)* Net Increase: $3,690,810.00 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 Part 43.103(a) - Bilate ral Modification
	D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor D is not **00** 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 UEI: QVYNQM9WLJG3

The purpose of this modification is to: 1) Exercise Option Period 3 - CLIN 0005, 2) Revise sections B.3, B.4, F.2, J, and Attachment 1. See Block 14 Continuation Sheet.

BARDA Share Price for Option Period 3 decreased by $6,926,391 from $10,617,201 to $3,690,810.

T2 Biosystems Share Price for Option Period 3 decreased by $5,234,359 from $8,566,423 to $3,332,064.

Total contract value including BARDA plus T2 Biosystems Shares decreased by $12,160,750

Continued ...

Except as provided herein, a ll 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 *(Signature of person authorized to sign)*	15C. DATE SIGNED: 09/28/2022	16B. UNITED STATES OF AMERICA: Richard A. Hall -S Date: 2022. *(Signature of Contrading Officer)*
		16 DA E SIGNE: 09.28 16:35:45 -04'00'

Digitally signed by Richard A. Hall -S

Previous edition unusable

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

NAME OF OFFEROR OR CONTRACTOR
T2 BIOSYSTEMS, INC. 1512719

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	from $106,922,207 to $94,761,457. Appr. Yr.: 2022 CAN: 1992022 Object Class: 25106 Period of Performance: 04/01/2022 to03/31/2025 Add Item 11 as follows:				
11	ASPR-22-02198- Option 3 funds to T2 Biosystems under Contract Number 75A50119C00053 Obligated Amount:$3,690,810.00				3,690,810.00

****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:

B.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	CLIN	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: Optimize the T2 Biothreat Panel to meetrequirements on the T2Dx device. Design, build, and optimizeT2Nxt subsystems, and integrate those subsystems into a working device. Optimize the T2AMR Panel	$10,495,783	$3,925,669	$14,421,452
2A	0003	09/30/2021-03/31/2022	Option 2A Continue T2Biothreat verification testing and initiate validation testing. Produce a functioning Beta instrument. Complete initial optimization studies and demonstrate required sensitivity with a manual process. Initiate T2Resistance Panel verification and clinical validation studies	$6,357,371	$2,087,418	$8,444,789
2B	0004	04/01/2022-09/30/2022	Option 2B Continue T2Biothreat verification testing and initiate validation testing. Produce a functioning Beta instrument. Complete initial optimization studies and demonstrate required sensitivity with a manual process.	$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.

3	0005	09/30/2022 - 03/31/2023	**Option 3 Period:** Complete validation testing of the T2Biothreat panel on the T2Dx instrument under BSL-3 and prepare and submit a 510(k) application to the FDA for the T2Biothreat panel for use on the T2Dx instrument. The contractor will also complete verification and validation testing and prepare and submit a 510(k) application to the FDA for the T2Resistance Panel for use on the T2Dx instrument. In AIM 1, the contractor will complete contrived sample verification studies of the T2Biothreat panel, prepare a 510(k) application and submit to FDA for clearance. In AIM 6, the contractor will complete verification and validation testing of the T2Resistance panel and prepare a 510(k) application and submit to FDA for clearance.	$3,690,810	$3,332,064	$7,022,874
4	0006	[****]- [****]	Option 4 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.

5	0007	[****]- [****]	Option 5 Period: [****]	$[****]	$[****]	$[****]
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	0009	TBD-TBD as Exercised	Option 7 Period: [****]	$[****]	$[****]	$[****]
		TOTALS	Only option years	$[****]	$[****]	$[****]
		TOTALS	Base+ options	**$62,024,574**	$[****]	$[****]

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 $2,875,256, Option 1 $3,925,669, Option 2A $2,087,418, Option 2B $2,960,502, Option 3 $3,332,064, 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, double sided, 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.

[****] = 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.

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. • Materials: 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. Face-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.

[****] = 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
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 number, description of submission, date of submission, status of submission and next steps. 5.Estimated and Actual Expenses. 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	• Due: Monthly Reports shall be submitted on **the 15th 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.
		subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.	

[****] = 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
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.

[****] = 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
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 Studies. 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 scheduling. • 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.

[****] = 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
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.

[****] = 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
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 required.	• 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.

[****] = 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
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.

[****] = 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
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 non-proprietary 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 and COR with a final and approved Study Protocol.

[****] = 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
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 J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. **Statement of Work**
Statement of Work, dated 9/30/2022, 34 pages

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**
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**.

[****] = 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.

ATTACHMENT 1

Biomedical Advanced Research and Development Authority (BARDA) Broad Agency Announcement (BAA)
(Solicitation #BAA-18-100-SOL-00003)

Advanced Research and Development of Chemical, Biological, Radiological, and Nuclear Medical Countermeasures

RAPID, HIGH-THROUGHPUT, MULTIPLEXED DETECTION OF BIOTHREAT SPECIES ID AND RESISTANCE GENESUSING T2MR

Topic Area of Interest No. [7.2.4 & 7.3.3] Statement of Work DATED September 30, 2021 (Diagnostics/DevicesProduct Development)

STATEMENT OF WORK

[****]

Exhibit 10.5

AMENDMENT NO. 8 TO TERM LOAN AGREEMENT

THIS AMENDMENT NO. 8 TO TERM LOAN AGREEMENT, dated as of November 10, 2022 (this "***Amendment***") is made among T2 BIOSYSTEMS, INC., a Delaware corporation ("***Borrower***"), the other Obligors party hereto, CRG SERVICING LLC, as administrative agent and collateral agent (in such capacities, "***Administrative Agent***") and the lenders listed on the signature pages hereof under the heading "LENDERS" (each, a "***Lender***" and, collectively, the "***Lenders***"), with respect to the Loan Agreement described below.

RECITALS

WHEREAS, Borrower, Administrative Agent and the Lenders are parties to the Term Loan Agreement, dated as of December 30, 2016, with the Subsidiary Guarantors from time to time party thereto (as amended by Amendment No. 1 to Term Loan Agreement, dated as of March 1, 2017, as further amended by Amendment No. 2 to Term Loan Agreement, dated as of December 18, 2017, as further amended by Amendment No. 3 to Term Loan Agreement, dated as of March 16, 2018, as further amended by Amendment No. 4 to Term Loan Agreement, dated as of March 13, 2019, as further amended by Amendment No. 5 to Term Loan Agreement, dated as of September 10, 2019, as further amended by Amendment No. 6, dated as of January 25, 2021, and as further amended by Amendment No. 7, dated as of February 15, 2022, in each case, by and among Borrower, Administrative Agent and the lenders party thereto, and as further amended, supplemented or modified to date, the "***Loan Agreement***"); and

WHEREAS, Borrower has requested that Administrative Agent and the Lenders, and Administrative Agent and the Lenders have agreed to, amend the Minimum Required Revenue covenant in **Section 10.02(e)** of the Loan Agreement and make certain other changes as more fully set forth herein.

NOW, THEREFORE, in consideration of the mutual agreements, provisions and covenants contained herein, the parties agree as follows:

SECTION 1. Definitions; Interpretation.

(a) **Terms Defined in Loan Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement.

(b) **Interpretation**. The rules of interpretation set forth in **Section 1.03** of the Loan Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2. Amendments to Loan Agreement. Subject to **Section 3** of this Amendment, the following definitions in **Section 1.01** of the Loan Agreement are hereby amended and restated in their entirety:

> "***Interest-Only Period***" means the period from and including the first Borrowing Date and through but excluding the thirty-second (32nd) Payment Date following the first Borrowing Date.

"***Stated Maturity Date***" means the thirty-second (32nd) Payment Date following the first Borrowing Date.

SECTION 3. Conditions of Effectiveness. The effectiveness of **Section 2** of this Amendment shall be subject to the following conditions precedent:

(a) Borrower, Administrative Agent and each of the Lenders shall have duly executed and delivered this Amendment pursuant to **Section 13.04(a)(i)** of the Loan Agreement; *provided*, *however*, that this Amendment shall have no binding force or effect unless all conditions set forth in this **Section 3** have been satisfied;

(b) no Default or Event of Default (in each case subject to any cure period provided under the Loan Agreement) under the Loan Agreement shall have occurred and be continuing; and

(c) Borrower shall have paid or reimbursed Administrative Agent and the Lenders for their reasonable out of pocket costs and expenses (including the reasonable fees and expenses of Administrative Agent's and the Lenders' legal counsel) incurred in connection with this Amendment pursuant to **Section 13.03(a)(i)(z)** of the Loan Agreement.

SECTION 4. Representations and Warranties; Reaffirmation.

(a) Borrower hereby represents and warrants to each Lender as follows:

(i) Borrower has full power, authority and legal right to make and perform this Amendment. This Amendment is within Borrower's corporate powers and has been duly authorized by all necessary corporate action and, if required, by all necessary shareholder action. This Amendment has been duly executed and delivered by Borrower and constitutes a legal, valid and binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by (a) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors' rights and (b) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law). This Amendment (x) does not require any consent or approval of, registration or filing with, or any other action by, any Governmental Authority or any third party, except for such as have been obtained or made and are in full force and effect, (y) will not violate (i) the charter, bylaws or other organizational documents of Borrower and its Subsidiaries or (ii) any applicable law or regulation or any order of any Governmental Authority, other than any such violations in the case of this clause (ii) that, individually or in the aggregate, could not reasonably be expected to have a Material Adverse Effect and (z) will not violate or result in a default under any Material Agreement or agreement creating or evidencing any Material Indebtedness, or give rise to a right thereunder to require any payment to be made by any such Person.

(ii) No Default has occurred or is continuing or will result after giving effect to this Amendment.

(iii) The representations and warranties in **Section 7** of the Loan Agreement are true and correct in all material respects (taking into account any changes made to schedules updated in accordance with **Section 7.20** of the Loan Agreement) (unless qualified by materiality or Material Adverse Effect, in which case they are true in all respects (taking into account any changes made to schedules updated in accordance with **Section 7.20** of the Loan Agreement)) on and as of the date hereof, with the same force as if made on and as of the date hereof (except that the representation regarding representations and warranties that refer to a specific earlier date is that they were true and correct in all material respects (taking into account any changes made to schedules updated in accordance with **Section 7.20** of the Loan Agreement) (unless qualified by materiality

or Material Adverse Effect, in which case they are true in and correct in all respects (taking into account any changes made to schedules updated in accordance with **Section 7.20** of the Loan Agreement)) on such earlier date).

(iv) There has been no Material Adverse Effect since the date of the Loan Agreement.

(b) Each Obligor hereby ratifies, confirms, reaffirms, and acknowledges its obligations under the Loan Documents to which it is a party and agrees that the Loan Documents remain in full force and effect, undiminished by this Amendment, except as expressly provided herein. By executing this Amendment, Borrower acknowledges that it has read, consulted with its attorneys regarding, and understands, this Amendment.

SECTION 5. Release. In consideration of the agreements of Administrative Agent and the Lenders contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Borrower, on behalf of itself and its successors, assigns and other legal representatives, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Administrative Agent and each Lender, and their respective successors and assigns, and their respective present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Administrative Agent, each Lender and all such other persons being hereinafter referred to collectively as the "***Releasees***" and individually as a "***Releasee***"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower or any of its successors, assigns or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment, including, without limitation, for or on account of, or in relation to, or in any way in connection with the Loan Agreement or any of the other Loan Documents or transactions thereunder or related thereto (collectively, the "***Released Claims***"). Borrower understands, acknowledges and agrees that the release set forth above (the "***Release***") may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of the Release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the Release. Borrower acknowledges that the Release constitutes a material inducement to Administrative Agent and the Lenders to enter into this Amendment and that Administrative Agent and the Lenders would not have done so but

for Administrative Agent's and each Lender's expectation that the Release is valid and enforceable in all events.

SECTION 6. Governing Law; Submission to Jurisdiction; WAIVER OF JURY TRIAL.

(a) **Governing Law**. This Amendment and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction; *provided that* Section 5-1401 of the New York General Obligations Law shall apply.

(b) **Submission to Jurisdiction**. Borrower agrees that any suit, action or proceeding with respect to this Amendment or any judgment entered by any court in respect thereof may be brought initially in the federal or state courts in Houston, Texas or in the courts of its own corporate domicile and irrevocably submits to the non-exclusive jurisdiction of each such court for the purpose of any such suit, action, proceeding or judgment. This **Section 6** is for the benefit of Administrative Agent and the Lenders only and, as a result, none of Administrative Agent or any Lender shall be prevented from taking proceedings in any other courts with jurisdiction. To the extent allowed by applicable Laws, Administrative Agent and the Lenders may take concurrent proceedings in any number of jurisdictions.

(c) **WAIVER OF JURY TRIAL**. BORROWER, ADMINISTRATIVE AGENT AND EACH LENDER HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AMENDMENT.

SECTION 7. Miscellaneous.

(a) **No Waiver**. Except as expressly stated herein, nothing contained herein shall be deemed to constitute a waiver of compliance with any term or condition contained in the Loan Agreement or any of the other Loan Documents or constitute a course of conduct or dealing among the parties. Except as expressly stated herein, Administrative Agent and the Lenders reserve all rights, privileges and remedies under the Loan Documents. Except as amended hereby, the Loan Agreement and other Loan Documents remain unmodified and in full force and effect. All references in the Loan Documents to the Loan Agreement shall be deemed to be references to the Loan Agreement as amended hereby.

(b) **Severability**. In case any provision of or obligation under this Amendment shall be invalid, illegal or unenforceable in any jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

(c) **Headings**. Headings and captions used in this Amendment (including the Exhibits, Schedules and Annexes hereto, if any) are included for convenience of reference only and shall not be given any substantive effect.

(d) **Integration**. This Amendment constitutes a Loan Document and, together with the other Loan Documents, incorporates all negotiations of the parties hereto with respect to the

subject matter hereof and is the final expression and agreement of the parties hereto with respect to the subject matter hereof.

(e) **Counterparts**. This Amendment may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Amendment by signing any such counterpart. Executed counterparts delivered by facsimile or other electronic transmission (e.g., "PDF" or "TIF") shall be effective as delivery of a manually executed counterpart.

(f) **Controlling Provisions**. In the event of any inconsistencies between the provisions of this Amendment and the provisions of any other Loan Document, the provisions of this Amendment shall govern and prevail. Except as expressly modified by this Amendment, the Loan Documents shall not be modified and shall remain in full force and effect.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment as of the date first above written.

BORROWER:

T2 BIOSYSTEMS, INC.

By _/s/ John Sperzel_____
Name: John Sperzel
Title: Chairman & CEO

ADMINISTRATIVE
AGENT:

CRG SERVICING LLC

By: /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

LENDERS:

CRG PARTNERS III L.P.
By CRG PARTNERS III GP L.P., its General Partner
By CRG PARTNERS III GP LLC, its General Partner

By /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

CRG PARTNERS III – PARALLEL FUND "A" L.P.
By CRG PARTNERS III – PARALLEL FUND "A" GP L.P., its General Partner
By CRG PARTNERS III – PARALLEL FUND "A" GP LLC, its General Partner

By /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

CRG PARTNERS III (CAYMAN) UNLEV AIV I L.P.
By CRG PARTNERS III (CAYMAN) GP L.P., its General Partner
By CRG PARTNERS III (CAYMAN) GP LLC, its General Partner

By /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

Witness: /s/ Sean Scanlan
Name: Sean Scanlan

CRG PARTNERS III (CAYMAN) LEV AIV I L.P.
By CRG PARTNERS III (CAYMAN) GP L.P., its General Partner
By CRG PARTNERS III (CAYMAN) GP LLC, its General Partner

By /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

Witness: /s/ Sean Scanlan
Name: Sean Scanlan

CRG PARTNERS III PARALLEL FUND "B" (CAYMAN) L.P.
By CRG PARTNERS III (CAYMAN) GP L.P., its General Partner
By CRG PARTNERS III (CAYMAN) GP LLC, its General Partner

By /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

Witness: /s/ Sean Scanlan
Name: Sean Scanlan

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: November 14, 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: November 14, 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 September 30, 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: November 14, 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 September 30, 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: November 14, 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.