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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2023

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 August 4, 2023, the registrant had 333,580,010 shares of common stock outstanding.

T2 BIOSYSTEMS, INC.

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PART I.
FINANCIAL INFORMATION

Item 1. Financial Statements

T2 BIOSYSTEMS, INC.

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

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 16,084	$ 10,329
Accounts receivable	1,349	2,163
Inventories	4,337	4,285
Prepaid expenses and other current assets	2,100	2,582
Total current assets	23,870	19,359
Property and equipment, net	4,572	4,533
Operating lease right-of-use assets	8,088	8,741
Restricted cash	551	1,551
Other assets	49	143
Total assets	$ 37,130	$ 34,327
Liabilities and stockholders' deficit		
Current liabilities:		
Notes payable	$ 50,571	$ —
Accounts payable	2,234	1,296
Accrued expenses and other current liabilities	10,400	7,269
Operating lease liability	1,480	1,352
Derivative liability related to Term Loan	836	—
Warrant liabilities	270	39
Deferred revenue	265	172
Total current liabilities	66,056	10,128
Notes payable, net of current portion	—	49,651
Operating lease liabilities, net of current portion	7,433	8,214
Deferred revenue, net of current portion	64	52
Derivative liability related to Term Loan, net of current portion	—	1,088
Accrued interest on term loan	—	4,849
Total liabilities	73,553	73,982
Commitments and contingencies (see Note 13)		
Stockholders' deficit		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; 241,849,922 and 7,716,519 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	242	8
Additional paid-in capital	521,866	494,556
Accumulated deficit	(558,531)	(534,219)
Total stockholders' deficit	(36,423)	(39,655)
Total liabilities and stockholders' deficit	$ 37,130	$ 34,327

See accompanying notes to condensed consolidated financial statements.

T2 BIOSYSTEMS, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue:				
Product revenue	$ 1,964	$ 2,559	$ 3,619	$ 6,403
Contribution revenue	—	3,352	423	6,742
Total revenue	1,964	5,911	4,042	13,145
Costs and expenses:				
Cost of product revenue	4,869	5,081	8,864	11,286
Research and development	3,850	8,025	8,321	14,681
Selling, general and administrative	6,296	7,824	13,595	17,054
Total costs and expenses	15,015	20,930	30,780	43,021
Loss from operations	(13,051)	(15,019)	(26,738)	(29,876)
Other income (expense):				
Interest income	2	2	4	5
Interest expense	(1,541)	(1,346)	(3,063)	(2,996)
Change in fair value of derivative related to Term Loan	1,022	(1,675)	252	(1,675)
Change in fair value of warrant liabilities	7,192	—	5,888	—
Other income	37	4	37	13
Other expense	—	—	(682)	—
Other losses	(8)	—	(10)	—
Total other income (expense)	6,704	(3,015)	2,426	(4,653)
Net loss	$ (6,347)	$ (18,034)	$ (24,312)	$ (34,529)
Net loss per share — basic and diluted	$ (0.08)	$ (5.10)	$ (0.51)	$ (9.96)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	80,916,888	3,535,763	47,460,986	3,466,816
Other comprehensive loss:				
Net loss	$ (6,347)	$ (18,034)	$ (24,312)	$ (34,529)
Net unrealized gain on marketable securities arising during the period	—	9	—	2
Net realized loss on marketable securities included in net loss	—	2	—	2
Total other comprehensive income, net of taxes	—	11	—	4
Comprehensive loss	$ (6,347)	$ (18,023)	$ (24,312)	$ (34,525)

See accompanying notes to condensed consolidated financial statements.

T2 BIOSYSTEMS, INC.

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

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	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)	—	(230)	—	—	(230)
Issuance of common stock from secondary offering, net	70,981	—	1,432	—	—	1,432
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)

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Loss	Deficit
Balance at December 31, 2022	7,716,519	$ 8	$ 494,556	$ (534,219)	$ —	$ (39,655)
Stock-based compensation expense	—	—	1,833	—	—	1,833
Issuance of common stock from vesting of restricted stock	67,526	—	—	—	—	—
Issuance of common stock from secondary offering, net	653,122	1	929	—	—	930
Issuance of common stock and Pre-Funded Warrant from public offering, net	9,018,519	9	4,022	—	—	4,031
Issuance of common stock upon Common Stock Warrant cashless exercises	1,172,037	1	937	—	—	938
Issuance of common stock upon Pre-Funded Warrant exercises	1,740,740	2	—	—	—	2
Net loss	—	—	—	(17,965)	—	(17,965)
Balance at March 31, 2023	20,368,463	$ 21	$ 502,277	$ (552,184)	$ —	$ (49,886)
Stock-based compensation expense	—	—	913	—	—	913
Issuance of common stock from vesting of restricted stock	10,000	—	2	—	—	2
Issuance of common stock from secondary offering, net	214,606,459	215	18,170	—	—	18,385
Issuance of common stock upon Common Stock Warrant cashless exercises	6,513,148	6	504	—	—	510
Issuance of common stock upon Pre-Funded Warrant exercises	351,852	—	—	—	—	—
Net loss	—	—	—	(6,347)	—	(6,347)
Balance at June 30, 2023	241,849,922	$ 242	$ 521,866	$ (558,531)	$ —	$ (36,423)

See accompanying notes to condensed consolidated financial statements.

T2 BIOSYSTEMS, INC.

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

	Six Months Ended June 30,	
	2023	2022
Cash flows from operating activities		
Net loss	$ (24,312)	$ (34,529)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	523	532
Non-cash lease expense	653	597
Stock-based compensation expense	2,746	4,086
Change in fair value of derivative related to Term Loan	(252)	1,675
Loss on sales of marketable securities	—	2
Change in fair value of warrant liabilities	(5,888)	—
Issuance costs related to Common Stock Warrants	682	—
Loss on disposal of property and equipment	3	—
Non-cash interest expense	1,050	1,054
Changes in operating assets and liabilities:		
Accounts receivable	814	2,413
Prepaid expenses and other assets	574	711
Inventories	(374)	(1,882)
Accounts payable	938	2,392
Accrued expenses and other liabilities	(1,936)	(563)
Deferred revenue	105	(316)
Operating lease liabilities	(653)	(569)
Net cash used in operating activities	(25,327)	(24,397)
Cash flows from investing activities		
Proceeds from sales of marketable securities	—	9,998
Purchases and manufacture of property and equipment	(153)	(177)
Net cash (used in) provided by investing activities	(153)	9,821
Cash flows from financing activities		
Payment of employee restricted stock tax withholdings	—	(242)
Proceeds from issuance of shares from employee stock purchase plan and stock option exercises	2	139
Proceeds from public offering, net of issuance costs	10,918	5,226
Proceeds from secondary offering, net of issuance costs	19,315	—
Net cash provided by financing activities	30,235	5,123
Net change in cash, cash equivalents and restricted cash	4,755	(9,453)
Cash, cash equivalents and restricted cash at beginning of period	11,880	23,796
Cash, cash equivalents and restricted cash at end of period	$ 16,635	$ 14,343
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 2,005	$ 1,936
Supplemental disclosures of noncash activities		
Transfer of T2 owned instruments and components from inventory	$ (322)	$ (118)
Cashless exercise of Common Stock Warrants	$ (1,448)	$ —
Purchases of property and equipment included in accounts payable and accrued expenses	$ 131	$ 60

	June 30, 2023	June 30, 2022
Reconciliation of cash, cash equivalents and restricted cash at end of period		
Cash and cash equivalents	$ 16,084	$ 13,212
Restricted cash	551	1,131
Total cash, cash equivalents and restricted cash	$ 16,635	$ 14,343

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. The Company's 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"). 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. The Company's current development efforts primarily target sepsis, bioterrorism, and Lyme disease, which represent areas of significant unmet medical need in which rapid detection and targeted treatment could lead to improved patient outcomes.

Liquidity and Going Concern

At June 30, 2023, the Company had cash and cash equivalents of $16.1 million, an accumulated deficit of $558.5 million, stockholders' deficit of $36.4 million and has experienced cash outflows from operating activities since its inception. 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. The Company has primarily funded its operations through public equity and private debt financings.

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 Company's T2Dx® Instrument, the T2Candida® Panel, and the T2Bacteria® Panel are authorized for use in the United States by the Food and Drug Administration, or FDA. In June 2020 the FDA extended Emergency Use Authorization, or EUA, to the Company's T2SARS-CoV-2™ Panel. In 2023, customers have significantly reduced their purchases of the Company's COVID-19 test and the Company has not forecasted any COVID-19 test sales in 2023.

The Company has a milestone-based product development contract with the Biomedical Advanced Research and Development Authority ("BARDA") (see Note 11 below) and should BARDA reduce, cancel or not exercise additional options, the Company's ability to continue to fund the development of its next-generation products may be hindered.

The Company believes that its cash and cash equivalents of $16.1 million at June 30, 2023 will not be sufficient to fund its current operating plan through the fourth quarter of 2023. Certain elements of the Company's operating plan cannot be considered probable, and in order to support the business, the Company initiated a process to explore a range of strategic alternatives focused on maximizing values. 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.

In May 2023, as part of a strategic restructuring program, the Company initiated a workforce reduction of nearly 30%. Additionally, the Company is continuing to explore alternative strategic options, including an acquisition, merger, reverse merger, other business combination, sale of assets or licensing. In May 2023, CRG reduced the minimum liquidity covenant under its Term Loan Agreement with CRG from $5.0 million to $500,000 until December 31, 2023. In July 2023, the Company also converted $10 million of the outstanding debt under its Term Loan Agreement with CRG to equity (see Note 6 below).

The Nasdaq Stock Market LLC ("Nasdaq") has rules that require all companies listed on the Nasdaq Capital Market to maintain a $1.00 minimum bid price (the "Minimum Bid Price Rule") and to maintain a minimum value of listed securities (the "MVLS Rule") of at least $35 million.

On November 22, 2022, the Company received notice from the Nasdaq indicating that the Company was in violation of the MVLS Rule. The Company was provided 180 days, or until May 22, 2023, to regain compliance, which includes maintaining a closing market value of its listed securities of at least $35 million for a minimum of ten consecutive trading days. On March 30, 2023, the Company received notice from the Nasdaq indicating that the Company was in violation of the Minimum Bid Price Rule. On May 23, 2023, the Nasdaq notified the Company that its securities were subject to delisting due to non-compliance with Nasdaq's MVLS Rule. The Company requested a hearing with the Nasdaq and on July 6, 2023 appealed to the Nasdaq Hearings Panel for an extension to the time period in which to regain compliance with the MVLS Rule and the Minimum Bid Price Rule. On July 26, 2023, we filed a definitive proxy statement to effect a reverse stock split of our common stock in connection with our annual meeting that will occur in September 2023 to help regain compliance with the Nasdaq rules. However, there is no assurance that the shareholder vote required for the reverse stock split or that any other actions that we take to restore our compliance with the Nasdaq rules will be successful. On July 27, 2023, the Nasdaq granted the Company's request for an extension to comply with applicable rules until November 20, 2023.

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 and maintaining reduced operating expenses in order to continue as a going concern for a period of 12 months from the date these 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 maintain reduced 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. See Part II, Item 1A—"Risk Factors" in this Quarterly Report on Form 10-Q.

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 generally accepted accounting principles as found 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, the Company effected a 50 for 1 reverse stock split. One share of common stock was issued for every 50 shares of issued and outstanding common stock, and fractional shares were settled in cash. All references to share and per share amounts (excluding authorized shares) in the condensed consolidated financial statements and accompanying notes have been retroactively restated to for the reverse split.

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, 2022.

The accompanying interim condensed consolidated balance sheet as of June 30, 2023, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2023 and 2022, the condensed consolidated statements of stockholders' deficit for the three and six months ended June 30, 2023 and 2022, the condensed consolidated statements of cash flows for the six months ended June 30, 2023 and 2022 and the related financial data and other information disclosed in these notes are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements, and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2023, and the results of its operations for the three and six months ended June 30, 2023 and 2022 and its cash flows for the six months ended June 30, 2023 and 2022. The results for the three and six months ended

June 30, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023, 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, launching commercially 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.

Going Concern

Pursuant to the requirements of Accounting Standards Codification 205-40, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASC 205-40"), 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.

Geographic Information

The Company sells its products domestically and internationally. Total international sales were approximately $1.0 million, or 50% of total revenue, and $1.0 million, or 17% of total revenue, for the three months ended June 30, 2023 and 2022, respectively. Total international sales were approximately $1.7 million, or 43% of total revenue, and $2.0 million, or 15% of total revenue, for the six months ended June 30, 2023 and 2022, respectively.

International sales to Italy were approximately $0.7 million, or 33% of total revenue, and $1.0 million, or 26% of total revenue, for the three and six months ended June 30, 2023, respectively. International sales to any customer in a single country did not exceed 10% of total revenue for the three and six months ended June 30, 2022.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Customer A	—%	57%	10%	51%
Customer B	33%	5%	26%	5%
Customer C	11%	4%	9%	3%

Customer A is a U.S. government customer (BARDA). Customer B is an international distributor. Customer C is a U.S. hospital.

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

	June 30, 2023	December 31, 2022
Customer A	—%	32%
Customer B	36%	2%

Customer A is a U.S. government customer (BARDA). Customer B is an international diagnostics solutions provider.

As of June 30, 2023 and December 31, 2022, the Company had outstanding receivables of $0.7 million and $0.4 million, respectively, from customers located outside of the U.S.

Net Loss Per Share

The Company has issued certain securities that are participating securities; therefore, the Company must apply the two-class method to determine basic and diluted earnings per share. To the extent that a dividend or distribution is declared or paid during the period, the Company applies the two-class method to determine the allocation of the dividends or distributions between the common shareholders and the holders of the participating securities. The Company's participating securities do not have an obligation to share in the losses of the Company. To the extent that the Company remains in a net loss position, the two-class method will not apply since the entire net loss would be allocated to the common shareholders.

Basic net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period and potential common shares exercisable for little to no consideration, without consideration for other common stock equivalents.

Diluted net loss per share is calculated by adjusting the weighted-average number of shares outstanding and potential common shares exercisable for little to no consideration used to compute basic earnings per share for the dilutive effect of other common stock equivalents that were outstanding during the period, determined using either the if-converted method or the treasury-stock method.

Derivative Instruments

The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives requiring bifurcation in accordance with ASC Topic 815, *Derivatives and Hedging*. Derivative instruments are measured at fair value at issuance and at each reporting date in accordance with ASC 820 with changes in fair value recognized in the period of change in the condensed consolidated statements of operations and comprehensive loss.

The Company determined that both the warrant issued in conjunction with the Series A redeemable convertible preferred stock in August of 2022 and the Common Stock Warrants issued in February 2023 are derivative instruments. The warrant liabilities are classified on the condensed consolidated balance sheets as current because settlement of the warrant liability could be required by the holder within 12 months of the balance sheet date. Changes in fair value are recognized in change in fair value of warrant liabilities in the period of change in the condensed consolidated statements of operations and comprehensive loss. See Notes 3 and 7.

The Company has identified a single compound derivative liability related to its Term Loan Agreement with CRG that is classified as current on the condensed consolidated balance sheets to match the classification of the related Term Loan Agreement. Changes in fair value are recognized in change in fair value of derivative related to Term Loan in the period of change in the condensed consolidated statements of operations and comprehensive loss. See Note 6.

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. See Note 13 for a discussion about the Billerica, Massachusetts lease.

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

As of June 30, 2023 and December 31, 2022, 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

Lessee

Pursuant to ASC 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 the Company's discretion and the periods subject to renewal option are not included in the measurement of the Company's right-of-use assets and lease liabilities as the renewal options are not reasonably certain of exercise. The Company will continue to 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 associated non-lease components. Each lease component and the related non-lease components are accounted for together as a single component.

Lessor

The Company derives revenue from leasing its T2-owned instruments through reagent rental agreements (see the Revenue Recognition section below). Customers typically have the right to cancel every twelve months but subject to penalty. As a result of the penalty, the customers are deemed reasonably certain of not exercising their termination rights resulting in a lease term of generally three years. These lease agreements impose no requirement on the customer to purchase the instrument, and the instrument is not transferred to the customer at the end of the lease term. The short-term nature of the lease agreements does not result in lease payments accumulating to an amount that exceeds substantially all of the fair value of the instrument nor is the lease term for the majority of the remaining economic life of the instrument. Instrument leases are generally classified as operating leases as they do not meet any of the sales-type lease or direct financing lease criteria per ASC 842 and are recognized ratably over the duration of the lease. In accordance with these contracts, customers only make payments when consumables are ordered and delivered thus making these payments variable by nature. The Company estimates the expected volume of consumables to be purchased by each customer over the lease term to measure and recognize rental and consumables revenue.

Generally, lease arrangements include both lease and non-lease components. The lease component relates to the customer's right-to-use the T2-owned instrument over the lease term. The non-lease components relate to (1) consumables and (2) maintenance services. Because the timing and pattern of transfer for the operating lease component, the T2-owned instrument, and maintenance components of a reagent rental agreement are recognized over the same time period and in the same pattern, the Company elected the practical expedient to aggregate non-lease components with the associated lease component and account for the combined component as an operating lease for all instrument leases. In the evaluation of whether the lease component (T2-owned instrument) or the non-lease component associated with the lease component (maintenance) is the predominant component, the Company determined that the lease component is predominant as we believe the customer would ascribe more value to the use of the T2-owned instrument than that of the maintenance services. The T2-owned instrument lease and maintenance service performance obligations are classified as a single category of instrument rental revenue within product revenue in the condensed consolidated statements of operations and comprehensive loss (see disaggregated revenue table below in Revenue Recognition section). The consumables non-lease component does not meet the requirements to elect the practical expedient and thus must apply ASC Topic 606, *Revenue from Contracts with Customers*, as described below in the Revenue Recognition section.

The Company considers the economic life of its T2-owned instruments to be five years. The Company believes five years is representative of the period during which the instrument is expected to be economically usable by one or more users, with normal service, for the purpose for which it is intended. The residual value is estimated to be the value at the end of the lease term based on the anticipated fair market value of the units. The Company mitigates residual value risk of its leased instrument by performing regular management and maintenance, as necessary.

Revenue Recognition

The Company generates revenue from the sale of instruments, consumable diagnostic tests, related services, reagent rental agreements and government contributions. For arrangements in the scope of ASC Topic 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 either 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 generally does not offer product returns 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 and nonlease components 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 recognized when control has passed to the customer, typically at shipping point.

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

The government contract with BARDA is considered a government grant and not considered a contract with a customer and thus not subject to ASC 606. Revenue 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 condensed consolidated statements of operations and comprehensive loss; the related reimbursable expenses are expensed as incurred as research and development expense. The Company accounts for these contracts as a government grant by analogy to International Accounting Standards 20 ("IAS 20"), *Accounting for Government Grants and Disclosure of Government Assistance*.

The Company has a milestone-based product development contract with BARDA and should BARDA reduce, cancel or not exercise additional options, the Company's ability to continue to fund the development of its next-generation products may be hindered. Refer to Note 11 for further details regarding the development contract with BARDA.

Disaggregation of Revenue

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Product revenue				
Instruments	550	587	872	1,233
Consumables	1,238	1,670	2,415	4,620
Instrument rentals	49	51	104	69
Service	127	251	228	481
Total product revenue	1,964	2,559	3,619	6,403
Contribution revenue	—	3,352	423	6,742
Total revenue	$ 1,964	$ 5,911	$ 4,042	$ 13,145

Remaining Performance Obligations

Under ASC 606, the Company is required to disclose the aggregate amount of the transaction price that is allocated to unsatisfied or partially satisfied performance obligations as of June 30, 2023. 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 June 30, 2023. The Company expects to recognize 54% of this amount as revenue within one year and the remainder within three years.

Judgments

Certain contracts with customers include promises to transfer multiple products and services to a customer. Determining whether products and services are considered distinct performance obligations that should be accounted for separately versus together may require significant judgment. Once the performance obligations are determined, the Company determines the transaction price, which includes estimating the amount of variable consideration, based on the most likely amount, to be included in the transaction price, if any. The Company then allocates the transaction price to each performance obligation in the contract based on a relative standalone

selling price method. The corresponding revenue is recognized as the related performance obligations are satisfied as discussed in the revenue categories above.

Judgment is required to determine the standalone selling price for each distinct performance obligation. The Company determines standalone selling price based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as a range of selling prices, market conditions and the expected costs and margin related to the performance obligations.

Contract Assets and Liabilities

At June 30, 2023 and December 31, 2022, the Company recorded $0.2 million and $0.1 million, respectively, of contract assets within other assets on the balance sheet. The contract assets represent revenue recognized for performance obligations in advance of invoicing at the contract level based on the transaction price allocated to the respective performance obligations.

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 non-current based on the timing of when revenue is expected to be recognized. At June 30, 2023 and December 31, 2022, the Company had contract liabilities of $0.3 million and $0.2 million, respectively. Revenue recognized during the six months ended June 30, 2023 relating to contract liabilities at December 31, 2022 was $0.1 million and related to straight-line revenue recognition associated with maintenance agreements.

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 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 the Company's 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. The Company expenses 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

On September 29, 2022, the FASB issued ASU 2022-04, *Liabilities-Supplier Finance Programs (Subtopic 405-50) Disclosure of Supplier Finance Program Obligations* ("ASU 2022-04"). This ASU requires that a buyer in a supplier finance program disclose additional information about the program to allow financial statement users to better understand the effect of the programs on an entity's working capital, liquidity, and cash flows. This update is effective for the Company for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, except for the amendment on roll forward information, which is effective for fiscal

years beginning after December 15, 2023. Early adoption is permitted. The Company adopted ASU 2022-04 on January 1, 2023. 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 June 30, 2023 and December 31, 2022 (in thousands):

	Balance at June 30, 2023	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Liabilities:				
Warrant liabilities	$ 270	$ —	$ 270	$ —
Derivative liability related to Term Loan	836	—	—	836
	$ 1,106	$ —	$ 270	$ 836

	Balance at December 31, 2022	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Liabilities:				
Warrant liabilities	$ 39	$ —	$ 39	$ —
Derivative liability related to Term Loan	1,088	—	—	1,088
	$ 1,127	$ —	$ 39	$ 1,088

The Company maintains money market accounts classified as restricted cash, which are Level 1 assets, for $0.6 million at June 30, 2023 and $1.6 million at December 31, 2022 (Note 4).

The Company estimated the fair value of the warrant issued in conjunction with the Series A redeemable convertible preferred stock in August of 2022 (the "Series A Warrant") (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 estimated fair value of the Series A Warrant at June 30, 2023 was determined using the following assumptions:

Risk-free interest rate	4.20 %
Expected dividend yield	0.00 %
Expected volatility	129.00 %
Expected term	4.63

The Company estimated the fair value of the Common Stock Warrant issued in February of 2023 (the "Common Stock Warrant") (Note 7) using both the Black-Scholes Model and Monte Carlo simulation methods to model different potential settlement outcomes. These models use 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. Such inputs may vary depending on the model applied and the underlying scenario assumptions. Key inputs included the warrant exercise price of $1.08 per share, a risk-free interest rate of 4.20%, expected volatility ranging from 129% to 192%, an expected dividend yield of 0.00%, a stock price of $0.08 (adjusted to reflect volume weighting) and an expected term ranging from zero years to 4.63 years, depending on the simulation.

The following table provides a roll-forward of the fair value of the Common Stock Warrants (in thousands):

Balance at December 31, 2022	$	—
Issuance of Common Stock Warrant		7,568
Settlement due to cashless exercise		(938)
Change in fair value		1,326
Balance at March 31, 2023	$	7,956
Issuance of Common Stock Warrant		—
Settlement due to cashless exercise		(510)
Change in fair value		(7,178)
Balance at June 30, 2023	$	268

The Company has a single compound derivative instrument related to its Term Loan Agreement (Note 6) that requires the Company to pay additional interest of 4% per annum upon an event of default or if any obligation other than the unpaid principal amount of the Term Loan is not paid when due. Fair value is determined quarterly. The fair value at June 30, 2023 and December 31, 2022 is $0.8 million and $1.1 million, respectively, and is classified as a current liability on the balance sheet at June 30, 2023 and a non-current liability at December 31, 2022 to match the classification of the related Term Loan Agreement (Note 6).

The estimated fair value of the derivative at June 30, 2023 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 Q4 2023	50%

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

Balance at December 31, 2022	$	1,088
Change in fair value of derivative related to Term Loan		770
Balance at March 31, 2023	$	1,858
Change in fair value of derivative related to Term Loan		(1,022)
Balance at June 30, 2023	$	836

The Company is required to disclose the fair value and the level within the fair value hierarchy for financial instruments that are not measured at fair value on a recurring basis. For certain financial instruments, including accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses, the carrying amounts approximate their fair values as of June 30, 2023 and December 31, 2022 because of their short-term nature. Cash and cash equivalents were classified as Level 1 and all other financial instruments were classified as Level 2 within the fair value hierarchy. The Company used Level 3 inputs to measure the fair value of its Term Loan Agreement. Based on these measurements, the Company concluded that the carrying value of the Term Loan Agreement approximates its fair value at June 30, 2023.

4. Restricted Cash

The Company is required to maintain security deposits for its office lease agreements. At December 31, 2022, the Company had lease security deposits, invested in money market accounts, aggregating $1.6 million. In January 2023 one of these deposits of $1.0 million was claimed by a landlord as compensation for a lease dispute (Note 13). The remaining collateral deposits aggregating $0.6 million at June 30, 2023 were held at Silicon Valley Bank, which was taken over by the FDIC in March 2023. The Company’s full exposure was ultimately covered by the FDIC and no loss was incurred.

5. Supplemental Balance Sheet Information

Inventories

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

	June 30, 2023	December 31, 2022
Raw materials	$ 2,704	$ 2,004
Work-in-process	1,090	1,176
Finished goods	543	1,105
Total inventories, net	$ 4,337	$ 4,285

Property and Equipment

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

	June 30, 2023	December 31, 2022
Office and computer equipment	$ 757	$ 757
Software	783	783
Laboratory equipment	5,593	5,570
Furniture	210	197
Manufacturing equipment	1,668	1,454
Manufacturing tooling and molds	494	494
T2-owned instruments and components	4,259	4,052
Leased T2-owned instruments	967	1,014
Leasehold improvements	3,785	3,784
Construction in progress	669	685
	19,185	18,790
Less accumulated depreciation and amortization	(14,613)	(14,257)
Property and equipment, net	$ 4,572	$ 4,533

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 and completed instruments that will be used for internal research and development, clinical studies and reagent rental agreement with customers. At June 30, 2023 and December 31, 2022, there were $0.9 million and $0.8 million of T2-owned instrument raw materials and work-in-process, respectively. Depreciation expense, a component of cost of product revenue, from instruments under the T2-owned reagent rental pool was immaterial for the three months ended June 30, 2023 and 2022. Depreciation expense, a component of cost of product revenue, from instruments under the T2-owned reagent rental pool was $0.1 million for the six months ended June 30, 2023 and 2022.

Total 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 $0.1 million and $0.2 million was charged to operations for the three months ended June 30, 2023 and 2022, respectively. Depreciation and amortization expense of $0.4 million and $0.5 million was charged to operations for the six months ended June 30, 2023 and 2022, respectively.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	June 30, 2023	December 31, 2022
Accrued payroll and compensation	$ 2,771	$ 2,930
Accrued clinical trial and development expenses	806	1,097
Accrued professional services	444	1,626
Accrued interest	1,016	1,009
Accrued final fee	4,979	—
Other accrued expenses	384	607
Total accrued expenses and other current liabilities	$ 10,400	$ 7,269

Accrued professional services at December 31, 2022 includes a $1.0 million estimated liability related to the Billerica, Massachusetts lease (Note 13).

6. Notes Payable

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

	June 30, 2023	December 31, 2022
Term Loan Agreement including PIK interest, before unamortized discount and issuance costs	$ 53,453	$ 53,453
Less: unaccrued paid-in-kind interest	(2,767)	(3,647)
Less: unamortized discount and deferred issuance costs	(115)	(155)
Total notes payable	$ 50,571	$ 49,651

The Term Loan Agreement with CRG is classified as a current liability at June 30, 2023. In May 2023, the Company received a modification and waiver reducing the term loan's minimum cash covenant from $5.0 million to $500,000 until December 31, 2023. After considering the probability the Company may not comply with the covenant unless additional funds are raised during the period June 30, 2023, through June 30, 2024, the Company concluded the term loan and related liabilities are current liabilities. The Term Loan Agreement with CRG is classified as a non-current liability at December 31, 2022, as the Company amended the agreement in November 2022, extending the interest only period and principal maturity to December 30, 2024. The warrants to purchase a total of 21,944 shares of the Company's common stock remain outstanding at June 30, 2023.

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. Also, at CRG's discretion, a default interest rate of an additional 4.0% per annum may apply during the occurrence and continuance of an event of default.

In January 2023, CRG waived certain specified events of default associated with the Company's issuance of shares of Series A convertible preferred stock in August 2022 and the subsequent redemption. On May 19, 2023, the Company, the lenders party thereto and CRG entered into a waiver and consent with respect to the Term Loan Agreement, reducing the minimum liquidity covenant to $500,000 until December 31, 2023. In July 2023, CRG converted $10 million of the loan to common and preferred stock. The preferred stock will convert to common stock upon shareholder approval. There were no other covenant violations during the three and six months ended June 30, 2023.

Term Loan Agreement

In December 2016, the Company entered into a Term Loan Agreement with CRG and borrowed $40.0 million. The Agreement initially had a six-year term, and provided for quarterly interest-only payments through December 30, 2020 and quarterly principal and interest payments thereafter through maturity. The Company issued warrants to CRG to purchase a total of 10,579 shares of the Company's common stock, exercisable any time prior to December 30, 2026 at a price of $77.50 per share. The Agreement has been subsequently amended as described below.

Interest on borrowings, as amended, accrue at 11.50% per year, 8% of which is payable in cash quarterly and 3.5% of which is deferred and added to principal until maturity. The Company paid CRG a financing fee based on the loan principal amount drawn and the fee is being amortized over the loan term as debt discount interest expense. A final fee payment of 10% (initially 8%, then amended)

is due at maturity based on the principal outstanding at maturity. The final fee is accrued as interest expense and recorded as a current liability consistent with the classification of the associated debt.

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") exercisable any time prior to September 9, 2029 at an exercise price of $77.50 per share.

The Company may prepay principal at any time partially or in full without prepayment penalty. Borrowings are collateralized by a lien on substantially all Company assets, including intellectual property. The Term Loan Agreement provides for affirmative and negative covenants including a requirement to maintain a minimum cash balance of $5.0 million. 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 at CRG's discretion in the acceleration of the obligations under the Term Loan Agreement. Also at CRG's discretion, a default interest rate of an additional 4.0% per annum may apply during the occurrence and continuance of an event of default. In January 2023, CRG waived certain specified events of default associated with the Company's issuance of shares of Series A convertible preferred stock in August 2022 and the subsequent redemption.

Amendments

In 2019, the Term Loan Agreement was amended to reduce minimum revenue targets, extend the interest-only period, extend the principal repayment period and to increase the final payment fee from 8% to 10%. The Company issued the New Warrants to CRG, with 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. 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 December 30, 2022, extend the initial principal repayment until December 30, 2022, and to reduce the minimum product revenue target for the 24-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 remaining revenue covenant.

In February 2022, the Term Loan Agreement was amended to extend the interest-only and the principal maturity dates 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 was deemed granted as per ASC Topic 470-60, *Debt: Troubled Debt Restructurings by Debtors* ("ASC 470-60"), and the amendment was accounted for as a troubled debt restructuring. The future undiscounted cash outflows required under the amended agreement exceed the carrying value of the debt immediately prior to the amendment and the amendment did not result in a gain on restructuring.

In November 2022, CRG amended the Term Loan Agreement, extending the interest only period and principal maturity to December 30, 2024. No consideration was given in exchange for the amendment. There were no costs paid to the lender or third parties in association with the amendment. Because a concession was granted, the agreement was accounted for as a troubled debt restructuring under ASC 470-60. The future undiscounted cash outflows required under the amended agreement exceed the carrying value of the debt immediately prior to the amendment and the amendment did not result in a gain on restructuring.

7. Warrants

Series A Warrant

On August 15, 2022, the Company issued an aggregate of 3,000 shares of Series A Redeemable Convertible Preferred Stock with a par value of $0.001 per share and the Series 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 are adjusted for the reverse stock split described in Note 2) for an aggregate subscription amount equal to $0.3 million, before deducting estimated offering expenses payable by the Company. In the fourth quarter of 2022, the Series A Redeemable Convertible Preferred Stock was redeemed. The Series A Warrant became exercisable on February 15, 2023 and expires on February 15, 2028. The Series A Warrant contains certain anti-dilution provisions to protect the holder.

On February 17, 2023, the Company issued and sold shares of common stock, pre-funded warrants to purchase common stock and warrants to purchase common stock to an underwriter pursuant to an underwriting agreement (see discussion below). The terms of that offering triggered an adjustment to the exercise price of the Series A Warrant to $0.54 effective as of February 17, 2023.

The Company is required to measure the Series A Warrant at fair value at inception and in subsequent reporting periods with changes in fair value recognized in change in fair value of warrant liabilities in the period of change in the condensed consolidated statements of operations and comprehensive loss. The fair value of the liability related to the Series A Warrant at inception was $0.4 million. The Series A Warrant was not exercised as of June 30, 2023 and remains outstanding. The change in fair value during the three and six months ended June 30, 2023 was immaterial.

Pre-Funded Warrants and Common Stock Warrants

On February 17, 2023, the Company sold 9,018,519 shares of $0.001 par value common stock, 2,092,592 Pre-Funded Warrants and 22,222,222 Common Stock Warrants through an offering underwritten by Craig-Hallum Capital Group LLC. Each of the shares and Pre-Funded Warrants were sold in combination with an accompanying Common Stock Warrant to purchase two shares of the Company's common stock. The combined purchase price for each share and accompanying Common Stock Warrant is $1.08, and for each Pre-Funded Warrant and accompanying Common Stock Warrant is $1.079, which was equal to the combined purchase price for each share and accompanying Common Stock Warrant sold in the offering, minus the Pre-Funded Warrant's exercise price per share of $0.001.

The total proceeds of $12.0 million from the February 17, 2023 offering were allocated between the common stock, Pre-Funded Warrants and Common Stock Warrants. Because the Common Stock Warrants are liability-classified, an amount of proceeds equal to the fair value of the liability were first allocated to the Common Stock Warrants. The remaining proceeds were allocated on a relative fair value basis to the common stock and the Pre-Funded Warrants and recognized in additional paid-in capital. Total issuance costs related to the offering of $1.1 million were allocated in a similar manner as the total proceeds. As a result, approximately $0.7 million of issuance costs were expensed at the issuance date and recognized as other expenses in the condensed consolidated statements of operations and comprehensive loss. The remaining issuance costs were recognized within additional paid-in-capital as a reduction to the proceeds received for the common stock and Pre-Funded Warrants.

The Pre-Funded Warrants have (i) an exercise price per share of Common Stock equal to $0.001 or (ii) a cashless exercise option, with the number of shares received determined according to the formula set forth in the Pre-Funded Warrant. The Pre-Funded Warrants are exercisable upon issuance and do not expire. The exercise price and the number of shares of common stock issuable upon exercise of the Pre-Funded Warrants is subject to adjustment in the event of certain stock dividends and distributions, splits, combinations, reclassifications or similar events affecting the common stock. Holders of Pre-Funded Warrants will participate in any distributions to common stockholders as if the holders had exercised the Pre-Funded Warrants.

The Company determined that the Pre-Funded Warrants are indexed to the Company's own stock and meet the requirements for equity classification. Proceeds allocated to such warrants totaled $0.8 million. During the second quarter of 2023, 351,852 Pre-Funded Warrants were exercised for an equivalent number of shares of common stock and zero Pre-Funded Warrants remain outstanding at June 30, 2023.

The Common Stock Warrants have (i) an exercise price per share of common stock equal to $1.08 per share, (ii) a cashless exercise option if, at the time of exercise, there is no effective registration statement registering or the prospectus is not available for the issuance of the warrant shares to the holder, with the number of shares received determined according to the formula set forth in the Common Stock Warrant or (iii) an alternate cashless exercise option, which became exercisable on March 15, 2023, equal to the product of (x) the aggregate number of shares of common stock that would be issuable upon a cash exercise and (y) 0.5. The Common Stock Warrants are exercisable upon issuance and expire on February 17, 2028. The exercise price and the number of shares of common stock issuable upon exercise of the Common Stock Warrants is subject to adjustment in the event of certain stock dividends and distributions, splits, combinations, reclassifications or similar events affecting the common stock. Holders of the Common Stock Warrants will participate in any distributions to common stockholders as if the holders had exercised the Common Stock Warrants. The Common Stock Warrants are redeemable upon the occurrence of a Fundamental Transaction (as defined in the Common Stock Purchase Warrant Agreement).

The Company determined that the Common Stock Warrants are not indexed to the Company's own stock and therefore are precluded from equity classification. In addition, the Common Stock Warrant liability meets the definition of a derivative instrument. The Common Stock Warrants will be measured at fair value at inception and in subsequent reporting periods with changes in fair value recognized in income as change in fair value of warrant liabilities in the period of change in the condensed consolidated statements of operations and comprehensive loss. The fair value of the Common Stock Warrant liability at inception was $7.6 million. During the second quarter of 2023, 13,026,296 Common Stock Warrants were exercised pursuant to the cashless exercise option resulting in the issuance of 6,513,148 shares of Common Stock. At June 30, 2023, 6,851,852 Common Stock Warrants remain outstanding. The change in fair value after issuance consisted of a reduction of expense of $7.2 million and $5.9 million during the three and six months ended June 30, 2023, respectively. The Company has also issued certain warrants in conjunction with its Term Loan Agreement. See Note 6.

8. Stockholders' Deficit

Preferred Stock

The Company has authorized the issuance of up to 10,000,000 shares of $0.001 par value preferred stock. The Board of Directors will determine the preferred stock's rights, preferences, privileges, restrictions, voting rights, dividend rights, conversion rights, redemption privileges, and liquidation preferences.

Common Stock

The Company has authorized the issuance of 400,000,000 shares of $0.001 par value common stock. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors, subject to the prior rights of holders of all classes of stock outstanding.

Equity Distribution Agreement

The Company entered into an Equity Distribution Agreement with Canaccord Genuity (the "Equity Distribution Agreement"), through which the Company may sell up to $75.0 million of gross proceeds of common stock. Canaccord, as agent, sells shares at the Company's request through "at the market" offerings, subject to shelf limitations, 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. Canaccord receives a fee of 3% of gross proceeds of common stock sold under the Equity Distribution Agreement for its services. Legal and accounting fees from sales under the Equity Distribution Agreement are charged to share capital. Under the Equity Distribution Agreement, the Company sold 214,606,459 shares of common stock during the three months ended June 30, 2023 for net proceeds of $18.4 million, and 25,868,356 shares of common stock during the three months ended June 30, 2022 for net proceeds of $4.5 million. Under the Equity Distribution Agreement, the Company sold 215,259,581 shares of common stock during the six months ended June 30, 2023 for net proceeds of $19.3 million, and 29,417,716 shares of common stock during the six months ended June 30, 2022 for net proceeds of $5.2 million. Prepaid expenses and other current assets at June 30, 2022 include $0.7 million of proceeds receivable from the sales of shares sold under the Equity Distribution Agreement during the six months ended June 30, 2022, which were received in early July 2022.

9. Stock-Based Compensation

Stock Incentive Plans

2006 Stock Incentive Plan

The Company's Amended and Restated 2006 Employee, Director and Consultant Stock 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"), which was amended and restated in June 2021, 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 June 30, 2023, there were 186,916 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 without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq listing rules ("Rule 5635(c)(4)") and most recently amended and restated in February 2023, 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. In accordance with Rule 5635(c)(4), awards under the Inducement Plan may only be made to a newly hired employee who has not previously been a member of the Company's Board of Directors, or an employee who is being rehired following a bona fide period of non-employment by us as a material inducement to the employee's entering into employment with us. The aggregate number of shares of common stock which may be issued or transferred pursuant to awards under the Inducement Plan is 692,500 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 June 30, 2023, there were 29,528 shares available for future grant under the Inducement Plan.

Stock Options

The aggregate fair value of stock options granted during the six months ended June 30, 2023 was immaterial. During the six months ended June 30, 2022, the Company granted stock options with an aggregate fair value of $0.6 million, 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, 2022	179,641	$ 145.09	5.93	$ —
Granted	39,370	0.31		
Exercised	—	—	—	$ —
Forfeited	(13,929)	24.03		
Cancelled	(16,289)	145.77		
Outstanding at June 30, 2023	188,793	$ 123.78	6.26	$ —
Exercisable at June 30, 2023	131,606	$ 169.77	5.04	$ —
Vested or expected to vest at June 30, 2023	176,801	$ 131.59	6.03	$ —

There were no options exercised in the six months ended June 30, 2023 and 2022. The weighted-average grant date fair values of stock options granted in the six months ended June 30, 2023 and 2022 were $0.26 per share and $19.43 per share, respectively, and were calculated using the following estimated assumptions:

	Six Months Ended June 30,	
	2023	2022
Weighted-average risk-free interest rate	3.87%	2.18%
Expected dividend yield	—%	—%
Expected volatility	118%	106%
Expected terms	6.0 years	6.0 years

The total fair values of options that vested during the six months ended June 30, 2023 and 2022 were $0.5 million and $1.0 million, respectively.

As of June 30, 2023, there was $0.8 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 1.3 years as of June 30, 2023.

Restricted Stock Units

During the six months ended June 30, 2023, 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 $0.2 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 and Inducement Plan:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Nonvested at December 31, 2022	201,998	$ 44.47
Granted	339,950	0.67
Vested	(67,526)	55.27
Forfeited	(96,184)	5.19
Nonvested at June 30, 2023	378,238	$ 13.16

As of June 30, 2023, there was $3.9 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 1.1 years, as of June 30, 2023.

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 was immaterial and $0.1 million for the three months ended June 30, 2023 and 2022, respectively. Stock-based compensation expense from the 2014 ESPP was immaterial and $0.2 million for the six months ended June 30, 2023 and 2022, 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 June 30, 2023, there were 12,849 shares available for issuance under the 2014 ESPP.

Stock-Based Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Cost of product revenue	$ 18	$ 91	$ 109	$ 232
Research and development	121	202	402	617
Selling, general and administrative	768	1,228	2,229	3,226
Total stock-based compensation expense	$ 907	$ 1,521	$ 2,740	$ 4,075

For the three and six months ended June 30, 2023 and 2022, stock-based compensation expense capitalized as part of inventory or T2Dx Instruments and components was immaterial.

10. Net Loss Per Share

The Company applies the two-class method for computing earnings per share because its Series A Warrants, Pre-Funded Warrants and Common Stock Warrants are participating securities. Under the two-class method, net income for the period is allocated between common stockholders and holders of 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 six months ended June 30, 2023, and the holders of the participating securities do not have the contractual obligation to share in the losses of the Company, none of the net loss attributable to common stockholders was allocated to the participating securities when computing earnings per share. The Company did not have any participating securities outstanding for the three and six months ended June 30, 2023.

The Pre-Funded Warrants allow the holders to acquire a specified number of common shares at a nominal exercise price of $0.001 per share and are classified as equity. Since the shares underlying the Pre-Funded Warrants are exercisable for little or no consideration, the underlying shares are considered outstanding at the issuance of the Pre-Funded Warrants for purposes of calculating the weighted-average number of shares of common stock outstanding in basic and diluted earnings per share.

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

	Three and Six Months Ended June 30,	
	2023	2022
Options to purchase common shares	188,793	198,579
Restricted stock units	378,238	227,966
Term Loan Warrants	21,944	21,944
Series A Warrant	42,857	—
Common Stock Warrants	6,851,852	—
Total	7,483,684	448,489

11. U.S. Government Contract

In September 2019, BARDA awarded the Company a milestone-based product development contract, with an initial value of $6.0 million, and a potential value of up to $62.0 million, if BARDA exercises 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 exercises 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 the T2Biothreat™ Panel, the T2Resistance Panel, the T2NxT Instrument, and the T2AMR Panel. 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 $0.0 million and $3.4 million for the three months ended June 30, 2023 and 2022, respectively, under the BARDA contract. The Company recorded contribution revenue of $0.4 million and $6.7 million for the six months ended June 30, 2023 and 2022, respectively, under the BARDA contract.

The Company had no outstanding accounts receivable at June 30, 2023 and unbilled accounts receivable of $0.7 million at December 31, 2022, respectively, under the BARDA contract.

12. Leases

Operating Leases

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

In August 2010, the Company entered into an operating lease for office and laboratory space at its headquarters in Lexington, Massachusetts. The lease commenced in January 2011, with the Company providing a security deposit of $400,000. In accordance with the operating lease agreement, the Company reduced its security deposit to $160,000 in January 2018, which is recorded as restricted cash in the condensed consolidated balance sheets. In March 2017, the Company entered into an amendment to extend the term to December 2021. In October 2020, the Company entered into an amendment to extend the term to December 31, 2028. In accordance with the October 2020 amendment, the Company increased its security deposit to $420,438, which is classified as restricted cash at June 30, 2023 and December 31, 2022.

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.

In November 2014, the Company entered into a lease for additional laboratory space in Lexington, Massachusetts. The lease term commenced in April 2015 and extended for six years. The rent expense, inclusive of the escalating rent payments, is recognized on a straight-line basis over the lease term. As an incentive to enter into the lease, the landlord paid approximately $1.4 million of the $2.2 million space build-out costs. The unamortized balance of the lease incentive as of January 1, 2019 was reclassified as a reduction to the initial recognition of the right-of-use asset related to this lease. In connection with this lease agreement, the Company paid a security deposit of $281,000, which was recorded as a component of both prepaid expenses and other current assets and other assets in the condensed consolidated balance sheets at December 31, 2019. In October 2020, the Company entered into an amendment to extend the term of the lease to October 31, 2025. In accordance with this amendment, the Company paid a replacement security deposit of $130,977, which is classified as restricted cash at June 30, 2023 and December 31, 2022 and received the initial $281,000 security deposit in return.

In September 2021, the Company entered into a lease for office, research, laboratory and manufacturing space in Billerica, Massachusetts. The lease has a term of 126 months from the commencement date. The 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 December 31, 2022 and 2021. Occupancy of the building had been delayed due to disagreement between the Company and the landlord as to the parties' obligations under the lease agreement. Included within accrued expenses and other current liabilities on the balance sheet at December 31, 2022 is a $1.0 million estimated liability pertaining to this lease. Subsequent to December 31, 2022, the Company was notified that the landlord terminated the lease because of the Company's alleged failure to perform its obligations under the Lease in a timely manner and the Company's alleged breach of the covenant of good faith and fair dealing and exercised its right to draw upon the $1.0 million security deposit. In addition, the landlord is seeking damages for unpaid rent, brokerage fees, transaction costs, attorney's fees and court costs. The Company filed a response to the landlord's complaint and a counterclaim alleging that the landlord breached its obligations under the contract and unlawfully drew on the security deposit, in addition to breaching its covenants of good faith and fair dealing, making fraudulent misrepresentations, and engaging in deceptive and unfair trade practices. The matter is in dispute (Note 13).

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. Variable lease costs may include costs such as common area maintenance, utilities, real estate taxes or other costs. Expenses related to short-term leases were not material for periods presented.

13. Commitments and Contingencies

Contingencies

In September 2021, the Company entered into a lease for office, research, laboratory and manufacturing space in Billerica, Massachusetts. The lease has a term of 126 months from the commencement date. The 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 December 31, 2022 and 2021. Occupancy of the building had been delayed due to disagreement between the Company and the landlord as to the parties' obligations under the lease agreement. Included within accrued expenses and other current liabilities on the balance sheet at December 31, 2022 is a $1.0 million estimated liability pertaining to this lease. Subsequent to December 31, 2022, the Company was notified that the landlord terminated the lease because of the Company's alleged failure to perform its obligations under the Lease in a timely manner and the Company's alleged breach of the covenant of good faith and fair dealing and exercised its right to draw upon the $1.0 million security deposit. In addition, the landlord is seeking damages for unpaid rent, brokerage fees, transaction costs, attorney's fees and court costs. The Company filed a response to the landlord's complaint and a counterclaim alleging that the landlord breached its obligations under the contract and unlawfully drew on the security deposit, in addition to breaching its covenants of good faith and fair dealing, making fraudulent misrepresentations, and engaging in deceptive and unfair trade practices. The Company intends to vigorously defend itself and pursue all legal remedies available under applicable laws. The Company believes it will continue to meet its current manufacturing needs with its operations at its Lexington and Wilmington, Massachusetts facilities.

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, sublicensable 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 and six months ended June 30, 2023 and 2022 were immaterial.

Letter Agreements

On March 30, 2023, the Company entered into agreements with Mr. Sprague, Mr. Giffin, and Mr. Gibbs that provide for the payment of retention bonuses, subject to the respective executive's continued employment through such payment dates, of $80,000 each, to be paid in two installments of $40,000. The first installment, of $40,000 each, was paid in July 2023, and the second installment, of $40,000 each, will be paid in November 2023.

14. Subsequent Events

On July 3, 2023, the Company entered into a Securities Purchase Agreement (the "Series B Purchase Agreement") with CRG and affiliated entities pursuant to which the Company issued an aggregate of 48,345,798 shares of Common Stock and (ii) an aggregate of 93,297.26 shares of newly designated Series B Convertible Preferred Stock, par value $0.001 per share ("Series B Preferred"), in exchange for the surrender for cancellation of $10.0 million of outstanding borrowing under the Term Loan Agreement. Each share of Series B Preferred is convertible into 1,000 shares of our common stock at the holder's election following the adoption of a reverse split amendment, subject to beneficial ownership limitations.

The Company also sold 1,000 shares of preferred stock to CRG entities for $100. The shares provide for super-voting rights of 400,000 votes per share, to be voted in proportion to the percentage of common shareholder votes actually cast and voted in favor and voted against on the Company's reverse stock split proposal and no other preferred rights.

On July 27, 2023, the Nasdaq granted the Company an extension to the time period in which it is required to comply with the MVLS Rule and Minimum Bid Rule through November 20, 2023.

Equity Distribution Agreement

In July 2023, the Company filed a prospectus supplement to increase the maximum amount of shares that the Company may sell pursuant to its Equity Distribution Agreement with Canaccord Genuity by $65 million. Subsequent to June 30, 2023, the Company sold 88,538,763 shares for net proceeds of $17.1 million under the Equity Distribution Agreement.

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 and receipt if shareholder approval at our upcoming meeting of a reverse stock split;*
- *our status as an early-stage commercial company;*
- *our expectation to incur losses in the future and our ability to utilize limited net operating losses against future profitability, if any;*
- *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 ability to gain the support of hospitals and key thought leaders and publish the results of our clinical studies 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 or certifications for new product candidates in other jurisdictions, including IVDR in the European Union;*
- *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 the manufacturing of our products and backlogs in order fulfillment;*
- *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 litigation, including our ability to adequately resolve current legal claims; 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" in our Annual Report on Form 10-K for the year ended December 31, 2022, as updated by 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, 2022.

Business Overview

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, bioterrorism, and Lyme disease, which represent areas of significant unmet medical need in which rapid detection and targeted treatment could lead to improved patient outcomes.

Our primary commercial products include the T2Dx® Instrument, the T2Candida® Panel, the T2Bacteria® Panel, and the T2Resistance® Panel.

We have never been profitable and have incurred net losses in each year since inception. Our accumulated deficit at June 30, 2023 was $558.5 million and we have experienced cash outflows from operating activities over the past years. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations. We have incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution of our FDA-cleared products, the T2Dx Instrument, T2Candida Panel and T2Bacteria Panel. In addition, we will continue to incur significant costs and expenses as we continue to develop other product candidates, improve existing products and maintain, expand and protect our intellectual property portfolio. We may seek to fund our operations through public equity or private equity or debt financings, as well as other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on our business, results of operations and financial condition and our ability to develop, commercialize and drive adoption of the T2Dx Instrument, T2Candida, T2Bacteria, T2Resistance, 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 the Company's operations as the pandemic shifts to an endemic health threat. Customers have significantly reduced their purchases of the Company's COVID-19 tests and we forecast minimal COVID-19 test sales in the remainder of 2023.

We believe that our cash and cash equivalents of $16.1 million at June 30, 2023 will not be sufficient to fund our current operating plan through the fourth quarter of 2023. Certain elements of our operating plan cannot be considered probable, and in order to support our business we initiated a process to explore a range of strategic alternatives focused on maximizing value.

As part of our strategic restructuring program, we initiated a workforce reduction of nearly 30% in May 2023. Additionally, we are continuing to explore alternative strategic options, including an acquisition, merger, reverse merger, other business combination, sale of assets or licensing. We converted approximately 20% of our outstanding indebtedness into equity.

The Term Loan Agreement with CRG Servicing LLC ("CRG"), as administrative agent and collateral agent (Note 6) has a minimum liquidity covenant which requires us to maintain a minimum cash balance of $5.0 million. In February 2022, CRG, the lenders party thereto and we 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 May 15, 2023, we notified CRG that we were not in compliance with the minimum liquidity covenant as of May 12, 2023 and on May 19, 2023, we, the lenders party thereto and CRG entered into a waiver and consent with respect to the Term Loan Agreement, reducing the minimum liquidity covenant to $500,000 until December 31, 2023.

On November 22, 2022, the Company received notice from the Nasdaq indicating that the Company was in violation of the MVLS Rule. The Company was provided 180 days, or until May 22, 2023, to regain compliance, which includes maintaining a closing market value of its listed securities of at least $35 million for a minimum of ten consecutive trading days. On March 30, 2023, the Company received notice from the Nasdaq indicating that the Company was in violation of the Minimum Bid Price Rule. On May 23, 2023, the Nasdaq notified the Company that its securities were subject to delisting due to non-compliance with the MVLS Rule and the Minimum Bid Price Rule. The Company requested a hearing with the Nasdaq and on July 6, 2023 appealed to the Nasdaq Hearings Panel for an extension to the time period in which to regain compliance with the MVLS Rule and the Minimum Bid Price Rule. On July 26, 2023, we filed a definitive proxy statement to effect a reverse stock split of our common stock in connection with our annual meeting that will occur in September 2023 to help regain compliance with the Nasdaq rules. However, there is no assurance that the shareholder vote required for the reverse stock split or that any other actions that we take to restore our compliance with the Nasdaq rules will be successful. On July 27, 2023, the Nasdaq granted the Company's request for an extension to comply with the applicable Nasdaq rules until November 20, 2023.

These conditions raise substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that the financial statements are issued. Management's plans to alleviate the conditions that raise substantial doubt include raising additional funding, earning payments pursuant to our contract with BARDA, delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels for us to continue as a going concern for a period of 12 months from the date the financial statements are issued. Management has concluded the likelihood that its plan to successfully obtain sufficient funding from one or more of these sources or adequately reduce expenditures, while reasonably possible, is less than probable. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of issuance of these condensed consolidated financial statements. See Part II, Item 1A —"Risk Factors" in this Quarterly Report on Form 10-Q.

Product History

In September 2014, we received marketing authorization from the United States Food and Drug Administration, or FDA, for our first two products, the T2Dx Instrument and the T2Candida Panel, or T2Candida, which have the ability to rapidly identify the five most clinically relevant species of Candida, a fungal pathogen known to cause sepsis, directly from whole blood specimens. The T2Dx Instrument and T2Candida Panel were CE marked in the European Union, or EU, in July 2014.

In May 2018, we received market clearance from the FDA for the T2Bacteria® Panel, or T2Bacteria, which runs on the T2Dx Instrument and has the ability to rapidly identify five of the most common and deadly sepsis-causing bacteria directly from whole blood specimens. The T2Bacteria Panel was CE marked in the EU in June 2017.

In February 2019, our T2Resistance® Panel, or T2Resistance, was granted FDA Breakthrough Device designation and in November 2019, it was CE marked in the EU. In December 2021, we initiated a U.S. clinical trial for the T2Resistance Panel.

In September 2019, the Biomedical Advanced Research and Development Authority, or BARDA, awarded us a milestone-based contract, with an initial value of $6 million, and a potential value of up to $62 million, for the development of a next-generation diagnostic instrument, a comprehensive sepsis panel, and a multi-target biothreat panel. In September 2020, BARDA exercised the first contract option valued at $10.5 million. In April 2021, BARDA agreed to modify the contract to accelerate product development by advancing future deliverables, and adding a U.S. T2Resistance Panel into Option 1 of the BARDA contract. In September 2021, BARDA exercised Option 2A valued at approximately $6.4 million to further advance the new product development initiatives. In March 2022, BARDA

exercised Option 2B valued at approximately $4.4 million. In December 2021, we initiated the U.S. clinical trials for the T2Resistance and T2Biothreat Panels. In May 2022, BARDA exercised Option 3 valued at approximately $3.7 million to complete the U.S. clinical trials for the T2Resistance® Panel and T2Biothreat Panel and subsequently submit applications to the FDA for U.S. regulatory clearance for those product candidates. In December 2022, the T2Biothreat clinical evaluation was completed.

In June 2020, we launched the T2SARS-CoV-2 Panel, our COVID-19 molecular diagnostic test, after validation of the test pursuant to the FDA's policy permitting COVID-19 tests to be marketed prior to receipt of an Emergency Use Authorization, or EUA, subject to certain prerequisites. In August 2020, the FDA granted an EUA to the T2SARS-CoV-2 Panel for the qualitative direct detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (such as nasal, mid-turbinate, nasopharyngeal, and oropharyngeal swab specimens) and bronchoalveolar lavage specimens from individuals suspected of COVID-19 by their healthcare provider. We expect to continue to experience a decline in COVID-19 product sales tied to our T2SARS-CoV-2 Panel, and the focus of our go-to-market strategy continues to be increasing sales of our sepsis test panels, expanding the installed base of our T2Dx Instruments, and solidifying commercial plans for the T2Lyme™ Panel.

On July 8, 2022, the T2Lyme Panel was granted FDA Breakthrough Device Designation.

On May 8, 2023, we filed an FDA 510(k) submission for the T2Biothreat™ Panel, a product that we developed in collaboration with the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA). The T2Biothreat Panel is a fully-automated, direct-from-blood test designed to run on the FDA-cleared T2Dx® Instrument and simultaneously detects six biothreat pathogens identified as threats by the U.S. Centers for Disease Control and Prevention, or CDC, including the organisms that cause anthrax, tularemia glanders, plague and typhus.

On July 27, 2023, the FDA informed the Company that its application for Breakthrough Device Designation for the Company's *Candida auris* direct-from-blood molecular diagnostic test had been granted. The *Candida auris* test is a fully-automated, direct-from-blood test designed to rapidly detect the *Candida auris* pathogen and to run on the FDA-cleared T2Dx Instrument. *Candida auris (C. auris)* is a multidrug-resistant fungal pathogen with a mortality rate of up to 60% that has been labeled as a serious global health threat by the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO). The CDC has deemed C. auris as an urgent antimicrobial resistant threat, as it can be difficult to identify with standard laboratory methods, some strains are resistant to all three available classes of antifungals, it spreads easily in healthcare facilities, and can cause severe infections with high death rates. The CDC estimates the costs associated with U.S. fungal diseases, in general, are as high as $48 billion annually, and has called on public health professionals to help lower the burden of fungal disease by continuing to raise awareness of the life-saving benefits of early detection and proper treatment.

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 generally do not offer product returns or exchange rights (other than those relating to defective goods under warranty) or price protection allowances to our customers, including our distributors. Payment terms granted to distributors are the same as those granted to end-user customers and payments are not dependent upon the distributors' receipt of payment from their end-user customers. We either sell instruments to customers and international distributors or retain title and place the instrument at the customer site pursuant to a reagent rental agreement. When the instrument is 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 convert 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.

The Company has a milestone-based product development contract with the BARDA and should BARDA reduce, cancel or not exercise additional options, the Company's ability to continue to fund the development of its next-generation products may be hindered.

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. We expect to continue developing additional product candidates, improving existing products, and conducting ongoing and new clinical trials. We have a milestone-based product development contract with the BARDA and should BARDA reduce, cancel or not exercise additional options, the Company's ability to continue to fund the development of its next-generation products may be hindered.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of costs for our sales, marketing, service, medical affairs, finance, legal, human resources, information technology, 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 related to Term Loan

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

Change in fair value of warrant liabilities

The change in fair value of warrant liabilities consists of the changes in fair value of the Common Stock Warrants, Pre-Funded Warrants and Series A Warrant.

Other income

Other income consists of dividend and other investment income.

Other expense

Other expense consists of non-recurring expenses, including issuance costs allocated to the Common Stock Warrants.

Other losses

Other losses consists of non-recurring losses, including the loss on disposal of property and equipment.

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, 2022 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, 2022.

Results of Operations for the Three Months Ended June 30, 2023 and 2022

	Three Months Ended June 30,		
	2023	2022	Change
		(in thousands)	
Revenue:			
Product revenue	$ 1,964	$ 2,559	$ (595)
Contribution revenue	—	3,352	(3,352)
Total revenue	1,964	5,911	(3,947)
Costs and expenses:			
Cost of product revenue	4,869	5,081	(212)
Research and development	3,850	8,025	(4,175)
Selling, general and administrative	6,296	7,824	(1,528)
Total costs and expenses	15,015	20,930	(5,915)
Loss from operations	(13,051)	(15,019)	1,968
Other income (expense):			
Interest income	2	2	—
Interest expense	(1,541)	(1,346)	(195)
Change in fair value of derivative related to Term Loan	1,022	(1,675)	2,697
Change in fair value of warrant liabilities	7,192	—	7,192
Other income	37	4	33
Other expense	—	—	—
Other gains (losses)	(8)	—	(8)
Total other expense	6,704	(3,015)	9,719
Net loss	$ (6,347)	$ (18,034)	$ 11,687

Product revenue

Product revenue was $2.0 million for the three months ended June 30, 2023 compared to $2.6 million for the three months ended June 30, 2022, a decrease of $0.6 million, which was driven by lower consumables sales of $0.4 million primarily due to a decrease in sales of T2SARS-CoV-2 tests.

Contribution revenue

Contribution revenue relates to our BARDA agreement and was $0.0 for the three months ended June 30, 2023, compared to $3.3 million for the three months ended June 30, 2022. The decrease of $3.3 million was due to timing of the contract activity and less option amount available under Option 3, which was available for the first quarter of 2023, compared to Option 2A, which was available for the first quarter of 2022.

Cost of product revenue

Cost of product revenue was $4.9 million for the three months ended June 30, 2023, compared to $5.1 million for the three months ended June 30, 2022, a decrease of $0.2 million. The decrease was driven by $0.4 million of lower shipping and other costs, $0.2 million of lower service and repair costs, $0.1 million of decreased costs primarily related to lower consumable sales of T2SARS-CoV-2, offset by $0.4 million of costs due to the effect of a change in build plan and manufacturing inefficiencies, and $0.1 million of costs related to lower instrument sales.

Research and development expenses

Research and development expenses were $3.9 million for the three months ended June 30, 2023, compared to $8.0 million for the three months ended June 30, 2022, a decrease of $4.1 million. Lab and facility expenses decreased by $1.8 million primarily due to the timing of BARDA Option 3 compared to Option 2A due to lower employee headcount and material purchases, payroll related and stock-based compensation expenses decreased by $1.0 million due to lower employee headcount, clinical expenses decreased by $0.5 million due to the conclusion of several clinical trials, consulting expenses decreased by $0.5 million for BARDA, and R&D project related expenses decreased by $0.4 million.

Selling, general and administrative expenses

Selling, general and administrative expenses were $6.3 million for the three months ended June 30, 2023, compared to $7.8 million for the three months ended June 30, 2022, a decrease of $1.5 million. The decrease was driven by lower payroll related and stock-based compensation expenses of $1.3 million primarily due to lower employee headcount, lower marketing expenses of $0.3 million, and lower travel expenses of $0.1 million, partially offset by a $0.2 million increase in consulting expenses and legal expenses.

Interest income

Interest income was immaterial for the three months ended June 30, 2023 and 2022.

Interest expense

Interest expense was $1.5 million for the three months ended June 30, 2023, compared to $1.3 million for the three months ended June 30, 2022. Interest expense increased by $0.2 million primarily due to the February 2022 and November 2022 amendments to the CRG Term Loan Agreement which extended the interest only period and maturity date.

Change in fair value of derivative related to Term Loan

The change in fair value of the derivative instrument associated with the CRG Term Loan Agreement (see Note 6 of the notes to our condensed consolidated financial statements) was $1.0 million reduction of expense for the three months ended June 30, 2023, compared to $1.7 million of expense for the three months ended June 30, 2022.

Change in fair value of warrant liabilities

The change in fair value of the warrant liabilities consists of a $7.2 million reduction of expense primarily associated with the Common Stock Warrants (See Note 7 of the notes to our condensed consolidated financial statements) for the three months ended June 30, 2023. There was no change in fair value of warrant liabilities recorded during the three months ended June 30, 2022.

Other income

Other income was immaterial for the three months ended June 30, 2023 and 2022.

Other expense

Other expense was not recorded for the three months ended June 30, 2023 and 2022.

Other losses

Other losses were immaterial for the three months ended June 30, 2023 and were not recorded for the three months ended June 30, 2022.

Results of Operations for the Six Months Ended June 30, 2023 and 2022

	Six Months Ended June 30,		
	2023	2022	Change
		(in thousands)	
Revenue:			
Product revenue	$ 3,619	$ 6,403	$ (2,784)
Contribution revenue	423	6,742	(6,319)
Total revenue	4,042	13,145	(9,103)
Costs and expenses:			
Cost of product revenue	8,864	11,286	(2,422)
Research and development	8,321	14,681	(6,360)
Selling, general and administrative	13,595	17,054	(3,459)
Total costs and expenses	30,780	43,021	(12,241)
Loss from operations	(26,738)	(29,876)	3,138
Other income (expense):			
Interest income	4	5	(1)
Interest expense	(3,063)	(2,996)	(67)
Change in fair value of derivative related to Term Loan	252	(1,675)	1,927
Change in fair value of warrant liabilities	5,888	—	5,888
Other income	37	13	24
Other expense	(682)	—	(682)
Other gains (losses)	(10)	—	(10)
Total other expense	2,426	(4,653)	7,079
Net loss	$ (24,312)	$ (34,529)	$ 10,217

Product revenue

Product revenue was $3.6 million for the six months ended June 30, 2023 compared to $6.4 million for the six months ended June 30, 2022, a decrease of $2.8 million, which was driven by lower consumables sales of $2.1 million primarily due to a decrease in sales of T2SARS-CoV-2 tests, lower T2Dx Instrument and related sales of $0.4 million and lower revenue under our service agreements of $0.3 million.

Contribution revenue

Contribution revenue relates to our BARDA agreement and was $0.4 million for the six months ended June 30, 2023, compared to $6.7 million for the six months ended June 30, 2022. The decrease of $6.3 million was due to timing of the contract activity and less option amount available under Option 3, which was available for the first quarter of 2023, compared to Option 2A, which was available for the first quarter of 2022.

Cost of product revenue

Cost of product revenue was $8.9 million for the six months ended June 30, 2023, compared to $11.3 million for the six months ended June 30, 2022, a decrease of $2.4 million. The decrease was driven by $0.8 million of lower shipping and other costs, $0.8 million of decreased costs primarily related to lower consumable sales of T2SARS-CoV-2, $0.7 million of lower service and repair costs, and $0.4 million of costs related to lower instrument sales, offset by $0.3 million of costs due to the effect of a change in build plan and manufacturing inefficiencies.

Research and development expenses

Research and development expenses were $8.3 million for the six months ended June 30, 2023, compared to $14.7 million for the six months ended June 30, 2022, a decrease of $6.4 million. Lab and facility expenses decreased by $3.0 million primarily due to the timing of BARDA Option 3 compared to Option 2A due to lower employee headcount, material purchases, payroll related and stock-based compensation expenses decreased by $1.4 million due to lower employee headcount, consulting expenses decreased by $1.1 million for BARDA, R&D project related expenses decreased by $0.5 million , and clinical-related expenses decreased by $0.4 million due to the conclusion of several clinical trials.

Selling, general and administrative expenses

Selling, general and administrative expenses were $13.6 million for the six months ended June 30, 2023, compared to $17.1 million for the six months ended June 30, 2022, a decrease of $3.5 million. The decrease was driven by lower payroll related and stock-based compensation expenses of $3.1 million primarily due to lower employee headcount, a $0.3 million decrease in other expense primarily due to less IT support services and less facilities costs, lower marketing expenses of $0.3 million, a decrease in travel expenses of $ 0.1 million, and a decrease in consulting expenses of $0.1 million, partially offset by a $0.4 million increase in legal expenses.

Interest income

Interest income was immaterial for six months ended June 30, 2023 and 2022.

Interest expense

Interest expense was $3.1 million and $3.0 million for six months ended June 30, 2023 and 2022, respectively.

Change in fair value of derivative related to Term Loan

The change in fair value of the derivative instrument associated with the CRG Term Loan Agreement (see Note 6 of the notes to our condensed consolidated financial statements) was $0.2 million reduction of expense for the six months ended June 30, 2023, compared to $1.7 million of expense for the six months ended June 30, 2022.

Change in fair value of warrant liabilities

The change in fair value of the warrant liabilities consists of a $5.9 million reduction of expense primarily associated with the Common Stock Warrants and Pre-Funded Warrants (See Note 7 of the notes to our condensed consolidated financial statements) for the six months ended June 30, 2023. There was no change in fair value of warrant liabilities recorded during the six months ended June 30, 2022.

Other income

Other income was immaterial for six months ended June 30, 2023 and 2022.

Other expense

Other expense relates to the issuance costs allocated to the Common Stock Warrants and was $0.6 million for the six months ended June 30, 2023. Other expense was not recorded for the six months ended June 30, 2022.

Other losses

Other losses were immaterial for the six months ended June 30, 2023 and were not recorded for the six months ended June 30, 2022.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception, and as of June 30, 2023 and December 31, 2022, we had an accumulated deficit of $558.5 million and $534.2 million, respectively. 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.

Historically, the Company has primarily funded its operations through public equity and private debt financings. The Company believes its cash position is insufficient to fund future operations through the second quarter of 2023 and in order to support our business, we initiated a process to explore a range of alternatives focusing on maximizing value.

Equity Distribution Agreement

On March 31, 2021, the Company entered into an Equity Distribution Agreement ("Equity Distribution Agreement") with Canaccord Genuity LLC, as agent ("Canaccord"), pursuant to which the Company may offer and sell shares of common stock, for aggregate gross sale proceeds of up to $75.0 million from time to time from the effective date of the respective registration statement through Canaccord. Under the Equity Distribution Agreement, the Company sold 214,606,459 shares of common stock during the three months ended June 30, 2023 for net proceeds of $18.4 million, and 25,868,356 shares of common stock during the three months ended June 30, 2022 for net proceeds of $4.5 million. Under the Equity Distribution Agreement, the Company sold 215,259,581 shares of common stock during the six months ended June 30, 2023 for net proceeds of $19.3 million, and 29,417,716 shares of common stock during the six months ended June 30, 2022 for net proceeds of $5.2 million. Prepaid expenses and other current assets at June 30, 2022 include $0.7 million of proceeds receivable from the sales of shares sold under the Equity Distribution Agreement during the six months ended June 30, 2022, which were received in early July 2022.

We pay Canaccord for its services of acting as agent 3% of the gross proceeds from the sale of the shares pursuant to the Equity Distribution Agreement. Legal and accounting fees are reclassified to share capital upon issuance of shares under the Equity Distribution Agreement.

In July 2023, the Company filed a prospectus supplement to increase the maximum amount of shares that the Company may sell pursuant to its Equity Distribution Agreement with Canaccord Genuity by $65 million.

Plan of operations and future funding requirements

As of June 30, 2023, we had unrestricted cash and cash equivalents of approximately $16.1 million. 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 the Company's operations as the pandemic shifts to an endemic health threat. Customers have significantly reduced their purchases of the Company's COVID-19 tests and the Company believes this trend will continue.

Going Concern

We believe that our cash and cash equivalents of $16.1 million at June 30, 2023 will not be sufficient to fund our current operating plan through the fourth quarter of 2023. Certain elements of our operating plan cannot be considered probable, and in order to support our business we initiated a process to explore a range of strategic alternatives focused on maximizing value.

In May 2023, as part of our strategic restructuring program, we initiated a workforce reduction of nearly 30%. Additionally, we are continuing to explore alternative strategic options, including an acquisition, merger, reverse merger, other business combination, sale of assets or licensing. In May 2023, CRG reduced the minimum liquidity covenant under the Term Loan Agreement from $5.0 million to $500,000. In July 2023, the Company also converted $10 million of the outstanding debt with CRG to equity (see Note 6).

The Term Loan Agreement with CRG Servicing LLC, as administrative agent and collateral agent ("CRG") (Note 6) has a minimum liquidity covenant which requires us to maintain a minimum cash balance of $5.0 million. In February 2022, CRG, the lenders party thereto and we 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 May 15, 2023, we notified CRG that we were not in compliance with the minimum liquidity covenant as of May 12, 2023 and on May 19, 2023, we, the lenders party thereto and CRG entered into a waiver and consent with respect to the Term Loan Agreement, reducing the minimum liquidity covenant to $500,000 until December 31, 2023.

On November 22, 2022, we received notice from the Nasdaq indicating that we were in violation of the MVLS Rule. We had 180 days, or until May 22, 2023, to regain compliance, which includes maintaining a closing market value of listed securities of at least $35 million for a minimum of ten consecutive trading days. On March 30, 2023, the Company received notice from the Nasdaq indicating that the Company was in violation of the Minimum Bid Price Rule. On May 23, 2023, the Nasdaq notified the Company that its securities were subject to delisting due to non-compliance with Nasdaq's MVLS Rule and Minimum Bid Price Rule. The Company requested a hearing with the Nasdaq and on July 6, 2023 appealed to the Nasdaq Hearings Panel for an extension to the time period in which to

regain compliance with the MVLS Rule and the Minimum Bid Price Rule. On July 26, 2023, we filed a definitive proxy statement to effect a reverse stock split of our common stock in connection with our annual meeting that will occur in September 2023 to help regain compliance with the Nasdaq rules. However, there is no assurance that the shareholder vote required for the reverse stock split or that any other actions that we take to restore our compliance with the Nasdaq rules will be successful. On July 27, 2023, the Nasdaq granted the Company's request for an extension to comply with the applicable rules until November 20, 2023.

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 and reducing operating expenses to continue as a going concern for a period of 12 months from the date the financial statements are issued. Management has concluded the likelihood that its plan to successfully obtain sufficient funding from one or more of these sources or adequately reduce expenditures, while reasonably possible, is less than probable. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of issuance of these condensed consolidated financial statements. See Part II, Item 1A—"Risk Factors" in this Quarterly Report on Form 10-Q.

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

Cash flows

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

	Six Months Ended June 30,	
	2023	2022
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (25,327)	$ (24,397)
Investing activities	(153)	9,821
Financing activities	30,235	5,123
Net change in cash, cash equivalents and restricted cash	$ 4,755	$ (9,453)

Net cash used in operating activities

Net cash used in operating activities was approximately $25.3 million for the six months ended June 30, 2023 and consisted of a net loss of $24.3 million adjusted for non-cash items including stock-based compensation expense of $2.7 million, a change in fair value of the derivative related to Term Loan of $0.3 million, non-cash interest expense of $1.1 million, non-cash lease expense of $0.7 million, depreciation and amortization expense of $0.5 million, a change in fair value of warrant liabilities of $5.9 million, issuance costs related to Common Stock Warrants of $0.7 million, and a net change in operating assets and liabilities of $0.5 million. The net change in operating assets and liabilities was primarily driven by a decrease in accrued expenses of $1.9 million primarily due to the payout of 2022 bonuses and $0.1 million reduction to legal fees due to expensing of the $0.1 million rent deposit for the Billerica lease, a decrease in operating lease liabilities of $0.6 million, an increase in inventory of $0.4 million due to market increases for securing raw materials and bulk materials purchases, partially offset by an increase in accounts payable of $0.9 million due to timing of invoices and payments, a decrease in accounts receivable of $0.8 million due to payment from BARDA and the timing and volume of instrument and consumable sales, a decrease in prepaid expenses and other assets of $0.6 million due to timing of deposits for goods and services, and an increase in deferred revenue of $0.1 million.

Net cash used in operating activities was approximately $24.4 million for the six months ended June 30, 2022, and consisted of a net loss of $34.5 million adjusted for non-cash items including stock-based compensation expense of $4.1 million, a change in fair value of the derivative of $1.7 million, non-cash interest expense of $1.1 million, non-cash lease expense of $0.6 million, depreciation and amortization expense of $0.5 million and a net change in operating assets and liabilities of $2.2 million. The net change in operating assets and liabilities was primarily driven by a decrease in accounts receivable of $2.4 million due to BARDA payments and the timing and volume of instrument and consumable sales, an increase in accounts payable of $2.4 million primarily due to timing of invoices and payments and increased spend on inventory, a decrease in prepaid expenses and other assets of $0.7 million due to timing of proceeds receivable under the Equity Distribution Agreement, partially offset by an increase in inventory of $1.9 million due to securing raw materials and bulk materials purchases for favorable pricing, a decrease in accrued expenses of $0.6 million primarily from bonus payouts, a decrease in operating lease liabilities of $0.5 million, and a decrease in deferred revenue of $0.3 million due to ratably recognized service agreements.

Net cash provided by investing activities

Net cash used in investing activities was $0.2 million for the six months ended June 30, 2023, and consisted of equipment purchases.

Net cash provided by investing activities was $9.8 million for the six months ended June 30, 2022, and primarily consisted of proceeds from sales of marketable securities of $10.0 million, partially offset by equipment purchases of $0.2 million.

Net cash provided by financing activities

Net cash provided by financing activities was approximately $30.2 million for the six months ended June 30, 2023, and consisted primarily of proceeds from sales of our common stock under the Equity Distribution Agreement, net of issuance costs, of $19.3 million and proceeds from our February public offering, net of issuance costs, of $10.9 million.

Net cash provided by financing activities was approximately $5.1 million for the six months ended June 30, 2022, and consisted primarily of proceeds from sales of our common stock under the Equity Distribution Agreement, net of issuance costs, of $5.2 million and 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.

Borrowing Arrangements

Term Loan Agreement

In December 2016, we entered into a Term Loan Agreement with CRG. We borrowed $40.0 million pursuant to the Term Loan Agreement, which has a six-year term with three years (through December 30, 2019) of interest-only payments, which period was extended to four years (through December 30, 2020) upon achieving the Approval Milestone, after which quarterly principal and interest payments would be due through the December 30, 2022 maturity date. In February 2022, we amended our agreement with CRG to extend the maturity date from December 30, 2022 to December 30, 2023. In November 2022, CRG amended the Term Loan Agreement, extending the interest only period and maturity to December 30, 2024. Interest on the amounts borrowed under the Term Loan Agreement accrues at an annual fixed rate of (a) prior to the Approval Milestone, 12.50%, 4.0% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount and (b) following the Approval Milestone, 11.50%, 3.5% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount. In addition, if we achieve certain financial performance metrics, the loan will convert to interest-only until the December 30, 2024 maturity, at which time all unpaid principal and accrued unpaid interest will be due and payable. We are required to pay CRG a financing fee based on the loan principal amount drawn. We are also required to pay a final payment fee of 8%, subsequently amended to 10%, of the principal outstanding upon repayment. We are accruing the final payment fee as interest expense and it is included as a current liability at June 30, 2023 and December 31, 2022 on the balance sheet to conform to the classification of the associated debt in those periods.

The Term Loan Agreement with CRG is classified as a current liability at June 30, 2023. In May 2023, the Company received a modification and waiver reducing the term loan's minimum cash covenant from $5.0 million to $500,000 through December 31, 2023. After considering the probability the Company may not comply with the covenant unless additional funds are raised during the period June 30, 2023, through June 30, 2024, the Company concluded the term loan and related liabilities are current liabilities. The Term Loan Agreement with CRG is classified as a non-current liability at December 31, 2022, as the Company amended the agreement in November 2022, extending the interest only period and principal maturity to December 30, 2024. We have assessed the classification of the note payable as current based on facts and circumstances as of the date of this filing. 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.

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") (See Note 6 of the notes to our condensed consolidated financial statements) 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 our assets. 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. In November 2022, CRG amended the Term Loan, extending the interest only period and maturity to December 30, 2024. On May 19, 2023, we, the lenders party thereto and CRG entered into a waiver and consent with respect to the Term Loan Agreement, reducing the minimum liquidity covenant to $500,000 until December 31, 2023.

We did not pay or provide any consideration in exchange for these amendments. As the effective borrowing rate under the amended agreements was less than the effective borrowing rate under the previous agreement, a concession was deemed to have been granted under ASC 470-60. As a concession was granted, the agreements were accounted for as troubled debt restructurings under ASC 470-60. The amendments did not result in a gain on restructuring as the future undiscounted cash outflows required under the amended agreements exceed the carrying value of the debt immediately prior to the amendment.

The Term Loan Agreement includes a subjective acceleration clause whereby an event of default, including a material adverse change in the business, operations, or conditions (financial or otherwise), could result in the acceleration of the obligations under the Term Loan Agreement. Under certain circumstances, a default interest rate of an additional 4.0% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default. CRG has not exercised its right under this clause.

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

The fair value of the derivative at June 30, 2023 is $0.8 million and is classified as a current liability on the balance sheet at June 30, 2023 to match the classification of the related Term Loan Agreement. The fair value of the derivative at December 31, 2022 is $1.1 million and is classified as a non-current liability on the balance sheet at December 31, 2022 to match the classification of the related Term Loan Agreement.

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, 2022.

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, with the participation of the Chief Executive Officer and the Chief Financial Officer, evaluated the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of June 30, 2023. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized, and reported on a timely basis and that such information is accumulated and communicated to management, including the Chief Executive Officer and the Chief Financial Officer, as appropriate, to allow timely decisions regarding disclosure.

Based on the evaluation of our disclosure controls and procedures as of June 30, 2023, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, the Company's disclosure controls and procedures were not effective due to a material weakness in our internal control over and accounting conclusions reached in classifying the Company's term loan and related liabilities as of June 30, 2023. In May 2023, the Company received a modification and waiver reducing the term loan's minimum cash covenant from $5.0 million to $500,000 through December 31, 2023. The probability of the Company not complying with the covenant for a period of 12-months from June 30, 2023, through June 30, 2024, was not initially assessed and the term loan and related liabilities were initially classified as long-term liabilities. After considering the probability the Company may not comply with the covenant unless additional funds are raised during the period June 30, 2023, through June 30, 2024, the Company concluded the term loan and related liabilities are current liabilities as of June 30, 2023. The Company will establish enhanced evaluation considerations including the timely use of third-party experts to prevent future occurrences.

Previously our Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were not effective due to a material weakness in our internal control over the timeliness of assumptions and accounting conclusions reached in valuing the common stock warrants sold in the Company's February 17, 2023, public offering. Management determined that assumptions and valuation methodologies used to initially value and classify the warrants sold in the Company's February 17, 2023, public offering were inconsistent with the recent generally accepted accounting principles and the time required to refine the assumptions and methodologies and reach appropriate accounting and disclosure conclusions prevented the Company from filing its Form 10-Q timely and required an extension. The Company established enhanced evaluation considerations including the timely use of third-party experts to prevent future occurrences.

(b) Changes in Internal Control over Financial Reporting

Except as noted above, there have been no changes to the Company's internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II.
OTHER INFORMATION

Item 1. Legal Proceedings

On September 8, 2021, the Company entered into a 10-year lease agreement (the "Lease") with Farley White Concord Road, LLC (the "Landlord"), pursuant to which the Company leased approximately 70,125 square feet for its occupancy and use as office, laboratory and commercial manufacturing space at 290 Concord Road, Billerica, Massachusetts (the "Premises").

On January 17, 2023, the Landlord sent a Notice of Termination (the "Notice") of the Lease to the Company. The Notice provides that the Landlord terminated the Lease because of the Company's alleged failure to perform its obligations under the Lease in a timely manner and the Company's alleged breach of the covenant of good faith and fair dealing. In connection with the Notice, on January 18, 2023, the Landlord filed a complaint in the Massachusetts Superior Court and has unilaterally deducted the Company's $1,000,000 security deposit for its alleged damages. In addition, the Landlord is seeking damages for unpaid rent, brokerage fees, transaction costs, attorney's fees and court costs.

On March 1, 2023, the Company filed a response to the Landlord's complaint and a counterclaim alleging that the Landlord breached its obligations under the contract and unlawfully drew on the security deposit, in addition to breaching its covenants of good faith and fair dealing, making fraudulent misrepresentations, and engaging in deceptive and unfair trade practices.

We believe the Landlord's claims are without merit and we intend to vigorously contest the claim.

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, 2022. Other than as set forth 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, 2022.

Our management has performed an analysis of our ability to continue as a going concern and has identified substantial doubt about our ability to continue as a going concern.

As of June 30, 2023, we had $16.1 million in unrestricted cash and cash equivalents which, without additional funding, will not be sufficient to meet our obligations within the next twelve months from the date of issuance of this Quarterly Report. Based on their assessment, our management has raised concerns about our ability to continue as a going concern. As substantial doubt about our ability to continue as a going concern exists, our ability to finance our operations through equity financings or otherwise could be impaired. Our ability to fund working capital, make capital expenditures, and service our debt depends on our ability to generate cash from operating activities, which is subject to its future operating success, and obtain financing on reasonable terms, which is subject to factors beyond our control, including general economic, political, and financial market conditions. The capital markets have in the past experienced, are currently experiencing, and may in the future experience, periods of upheaval that could impact the availability and cost of financing and there can be no assurances that such financing will be available to the Company on satisfactory terms, or at all. Management continues to explore raising additional capital through equity financing to supplement the Company's capitalization and liquidity, but there can be no assurance that such financing will be available on terms commercially acceptable to the Company, or at all.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

(a) None.

(b) None.

(c) Not applicable.

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. 001-36571) 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 Preferred Stock (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36571) filed on July 6, 2023)
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 of the Company's Form 8-K (File No. 001-36571) filed on July 6, 2023)
3.6	Third 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 Common Stock Certificate of the Company (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A (File No. 333-197193) filed on July 28, 2014)
4.2	Fourth Amended and Restated Investors' Rights Agreement, dated as of March 22, 2013, as amended (incorporated by reference to Exhibit 4.2 of the Company's Registration Statement on Form S-1/A (File No. 333-197193) filed on July 28, 2014)
4.3	Registration Rights Agreement dated as of July 29, 2019 by and between T2 Biosystems Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 4.1 of the Company's Form 8-K (File No. 001-36571) filed on July 30, 2019)
4.4	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)
4.5	Pre-Funded Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of the Company's Form 8-K (File No. 001-36571) filed on February 16, 2023)
4.6	Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 of the Company's Form 8-K (File No. 001-36571) filed on February 16, 2023)
10.1†	Amendment of Solicitation/Modification of Contract, dated as of May 1, 2023 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 10.1 of the Company's Form 10-Q (File No. 001-36571) filed on May 22, 2023)
10.2	Waiver and Consent to Term Loan Agreement with CRG Servicing LLC, dated May 19, 2023 (incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q (File No. 001-36571) filed on May 22, 2023)
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

Exhibit Number	Exhibit Description
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: August 8, 2023

By: /s/ JOHN SPERZEL

John Sperzel
President, Chief Executive Officer and Chairman of the Board
(Principal Executive Officer)

Date: August 8, 2023

By: /s/ JOHN M. SPRAGUE

John M. Sprague
Chief Financial Officer
(Principal Accounting Officer and Principal Financial Officer)

Exhibit 31.1

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

I, John Sperzel, certify that:

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

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

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

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

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

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

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

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

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

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

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

/s/ John Sperzel
John Sperzel
President, Chief Executive Officer and Chairman of the Board of Directors
(Principal Executive Officer)

Date: August 8, 2023

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 Officer and Principal Financial Officer)

Date: August 8, 2023

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of T2 Biosystems, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2023 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, Chief Executive Officer and Chairman of the Board of Directors
(Principal Executive Officer)

Date: August 8, 2023

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

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

Exhibit 32.2

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of T2 Biosystems, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2023 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 Principal Financial Officer)

Date: August 8, 2023

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.