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

FORM 10-Q/A
(Amendment No. 1)

(Mark One)

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

For the quarterly period ended September 30, 2019

OR

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

For the transition period from _____ to _____

Commission file number: 001-36571

T2 Biosystems, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

As of November 14, 2019, the registrant had 46,679,163 shares of common stock outstanding.

Explanatory Note

This Amendment No. 1 to T2 Biosystems, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 is being filed as an exhibit-only filing solely to add Exhibit 10.2 to Item 6 of the Form 10-Q. No other changes have been made to the Form 10-Q. This Amendment No. 1 speaks as of the original filing date of the Form 10-Q, does not reflect events that may have occurred subsequent to the original filing date, and does not modify or update in any way the disclosures made in the original Form 10-Q.

T2 BIOSYSTEMS, INC.

TABLE OF CONTENTS

		Page
	PART I FINANCIAL INFORMATION	
Item 1.	Financial Statements (unaudited)	1
	Condensed Consolidated Balance Sheets as of September 30, 2019 and December 31, 2018	1
	Condensed Consolidated Statements of Operations and Comprehensive Loss for three and nine months ended September 30, 2019 and 2018	2
	Condensed Consolidated Statements of Stockholders' Equity (Deficit) for the nine months ended September 30, 2019 and 2018	3
	Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2019 and 2018	4
	Notes to Condensed Consolidated Financial Statements	5
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	24
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	42
Item 4.	Controls and Procedures	42
	PART II OTHER INFORMATION	
Item 1.	Legal Proceedings	43
Item 1A.	Risk Factors	43
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	43
Item 3.	Defaults Upon Senior Securities	43
Item 4.	Mine Safety Disclosures	43
Item 5.	Other Information	43
Item 6.	Exhibits, Financial Statement Schedules	44
SIGNATURES		45

PART I.
FINANCIAL INFORMATION

Item 1. Financial Statements

T2 BIOSYSTEMS, INC.

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

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 16,213	$ 50,805
Accounts receivable	1,573	1,786
Inventories	4,110	2,677
Prepaid expenses and other current assets	1,917	1,340
Total current assets	23,813	56,608
Property and equipment, net	6,314	7,315
Operating lease right-of-use assets	3,740	—
Restricted cash	180	180
Other assets	206	206
Total assets	$ 34,253	$ 64,309
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Notes payable	$ 42,258	$ 42,373
Accounts payable	3,427	744
Accrued expenses and other current liabilities	8,800	6,073
Derivative liability	2,603	2,142
Deferred revenue	610	697
Current portion of lease incentives	—	268
Total current liabilities	57,698	52,297
Lease incentives, net of current portion	—	492
Operating lease liabilities, net of current portion	2,390	—
Deferred revenue, net of current portion	77	133
Commitments and contingencies (see Note 13)		
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized; 46,678,746 and 44,175,441 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	45	44
Additional paid-in capital	336,179	328,514
Accumulated deficit	(362,136)	(317,171)
Total stockholders' (deficit) equity	(25,912)	11,387
Total liabilities and stockholders' (deficit) equity	$ 34,253	$ 64,309

See accompanying notes to condensed consolidated financial statements.

T2 BIOSYSTEMS, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
Product revenue	$ 1,177	$ 1,218	$ 3,765	$ 3,486
Research revenue	56	1,248	269	5,222
Contribution revenue	444	—	1,232	—
Total revenue	1,677	2,466	5,266	8,708
Costs and expenses:				
Cost of product revenue	3,944	3,042	13,153	9,773
Research and development	4,098	2,725	12,047	11,193
Selling, general and administrative	5,981	5,873	19,756	19,238
Total costs and expenses	14,023	11,640	44,956	40,204
Loss from operations	(12,346)	(9,174)	(39,690)	(31,496)
Interest expense, net	(1,876)	(1,836)	(5,658)	(4,910)
Other income, net	51	243	383	402
Net loss and comprehensive loss	$ (14,171)	$ (10,767)	$ (44,965)	$ (36,004)
Net loss per share — basic and diluted	$ (0.31)	$ (0.25)	$ (1.01)	$ (0.91)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	45,413,215	43,762,551	44,711,463	39,363,294

See accompanying notes to condensed consolidated financial statements.

T2 BIOSYSTEMS, INC.

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

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders' (Deficit)
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2017	35,948,900	$ 36	$ 267,421	$ (266,117)	$ 1,340
Stock-based compensation expense	—	—	1,381	—	1,381
Issuance of common stock from vesting of restricted stock, exercise of stock options and employee stock purchase plan	70,983	—	5	—	5
Prior year accumulated deficit adjustment from ASC 606 implementation	—	—	—	99	99
Net loss	—	—	—	(12,913)	(12,913)
Balance at March 31, 2018	36,019,883	$ 36	$ 268,807	$ (278,931)	$ (10,088)
Stock-based compensation expense	—	—	3,898	—	3,898
Issuance of common stock from vesting of restricted stock, exercise of stock options and employee stock purchase plan	382,114	—	1,119	—	1,119
Share issuance	55,414	—	—	—	—
Issuance of common stock from secondary offering, net	7,015,000	7	49,371	—	49,378
Net loss	—	—	—	(12,324)	(12,324)
Balance at June 30, 2018	43,472,411	$ 43	$ 323,195	$ (291,255)	$ 31,983
Stock-based compensation expense	—	—	2,208	—	2,208
Issuance of common stock from vesting of restricted stock, exercise of stock options and employee stock purchase plan	566,343	1	483	—	484
Issuance of common stock from secondary offering, net	—	—	(141)	—	(141)
Net loss	—	—	—	(10,767)	(10,767)
Balance at September 30, 2018	44,038,754	$ 44	$ 325,745	$ (302,022)	$ 23,767

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders' (Deficit)
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2018	44,175,441	$ 44	$ 328,514	$ (317,171)	$ 11,387
Stock-based compensation expense	—	—	2,033	—	2,033
Issuance of common stock from vesting of restricted stock	163,802	—	—	—	—
Change in fair value of warrants upon modification	—	—	147	—	147
Net loss	—	—	—	(15,147)	(15,147)
Balance at March 31, 2019	44,339,243	$ 44	$ 330,694	$ (332,318)	$ (1,580)
Stock-based compensation expense	—	—	1,277	—	1,277
Issuance of common stock from vesting of restricted stock, exercise of stock options and employee stock purchase plan	196,329	—	330	—	330
Net loss	—	—	—	(15,647)	(15,647)
Balance at June 30, 2019	44,535,572	$ 44	$ 332,301	$ (347,965)	$ (15,620)
Stock-based compensation expense	—	—	1,165	—	1,165
Issuance of common stock from vesting of restricted stock, exercise of stock options and employee stock purchase plan	50,438	—	53	—	53
Issuance of common stock from secondary offering, net	1,679,387	1	1,883	—	1,884
Change in fair value of warrants upon modification	—	—	117	—	117
Issuance of warrants	—	—	660	—	660
Shares issued in connection with Purchase Agreement	413,349	—	—	—	—
Net loss	—	—	—	(14,171)	(14,171)
Balance at September 30, 2019	46,678,746	$ 45	$ 336,179	$ (362,136)	$ (25,912)

See accompanying notes to condensed consolidated financial statements.

T2 BIOSYSTEMS, INC.

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

	Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities		
Net loss	$ (44,965)	$ (36,004)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,694	1,862
Amortization of operating lease right-of-use assets	1,065	—
Stock-based compensation expense	4,475	7,487
Change in fair value of derivative instrument	461	(175)
Loss on disposal of property and equipment	(3)	18
Impairment of property and equipment	—	173
Non-cash interest expense	1,763	1,658
Deferred rent	—	(162)
Changes in operating assets and liabilities:		
Accounts receivable	213	(1,267)
Prepaid expenses and other assets	(577)	(1,254)
Inventories	(1,464)	(1,191)
Accounts payable	2,683	(40)
Accrued expenses and other liabilities	1,250	(771)
Deferred revenue	(143)	(784)
Operating lease liabilities	(1,694)	—
Net cash used in operating activities	(35,242)	(30,450)
Cash flows from investing activities		
Purchases and manufacture of property and equipment	(735)	(950)
Net cash used in investing activities	(735)	(950)
Cash flows from financing activities		
Proceeds from issuance of common stock and stock option exercises, net	383	1,604
Proceeds from issuance of common stock in public offering, net of offering costs	1,884	49,236
Principal repayments of finance leases	(882)	(1,094)
Net cash provided by financing activities	1,385	49,746
Net (decrease) increase in cash, cash equivalents and restricted cash	(34,592)	18,346
Cash, cash equivalents and restricted cash at beginning of period	50,985	42,059
Cash, cash equivalents and restricted cash at end of period	$ 16,393	$ 60,405
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 3,435	$ 2,859
Supplemental disclosures of noncash activities		
Transfer of T2 owned instruments and components to (from) inventory	$ 31	$ 802
Change in fair value of warrants issued and modified	$ 924	—
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 4,805	—
Purchases of property and equipment included in accounts payable and accrued expenses	$ 43	$ 109

See accompanying notes to condensed consolidated financial statements.

1. Nature of Business

T2 Biosystems, Inc. (the "Company") was incorporated on April 27, 2006 as a Delaware corporation with operations based in Lexington, Massachusetts. The Company is an *in vitro* diagnostics company that has developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. The Company is using its T2 Magnetic Resonance technology ("T2MR") to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. T2MR enables rapid detection of pathogens, biomarkers and other abnormalities in a variety of unpurified patient sample types, including whole blood, plasma, serum, saliva, sputum, cerebral spinal fluid and urine, and can detect cellular targets at limits of detection as low as one colony forming unit per milliliter ("CFU/mL"). The Company's initial development efforts target sepsis and Lyme disease, which are areas of significant unmet medical need in which existing therapies could be more effective with improved diagnostics. On September 22, 2014, the Company received market clearance from the U.S. Food and Drug Administration ("FDA") for its first two products, the T2Dx Instrument (the "T2Dx") and T2Candida Panel ("T2Candida"). On May 24, 2018, the Company received market clearance from the FDA for its T2Bacteria Panel ("T2Bacteria"). On February 6, 2019, the FDA granted the Company's T2Resistance Panel designation as a Breakthrough Device. On August 2, 2019, the Center for Medicare & Medicaid Services (CMS) granted approval for a New Technology Add-on Payment for the T2Bacteria Panel for fiscal year 2020.

The Company has devoted substantially all of its efforts to research and development, business planning, recruiting management and technical staff, acquiring operating assets, raising capital, and, most recently, the commercialization and improvement of its existing products.

Liquidity and Going Concern

At September 30, 2019, the Company had cash and cash equivalents of $16.2 million and an accumulated deficit of $362.1 million. The future success of the Company is dependent on its ability to successfully commercialize its products, obtain regulatory clearance for and successfully launch its future product candidates, obtain additional capital and ultimately attain profitable operations. Historically, the Company has funded its operations primarily through its August 2014 initial public offering, its December 2015 public offering, its September 2016 private investment in public equity ("PIPE") financing, its September 2017 public offering, its June 2018 public offering, its July 2019 establishment of an Equity Distribution Agreement and Equity Purchase Agreement, private placements of redeemable convertible preferred stock and debt financing arrangements.

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

Having obtained authorization from the FDA to market the T2Dx, T2Candida, and T2Bacteria, the Company has incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution. The Company may seek to fund its operations through public equity, private equity or debt financings, as well as other sources. However, the Company may be unable to raise additional funds or enter into such other arrangements when needed, on favorable terms, or at all. The Company's failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on the Company's business, results of operations, financial condition and the Company's ability to develop and commercialize T2Dx, T2Candida, T2Bacteria and other product candidates.

Pursuant to the requirements of Accounting Standards Codification ("ASC") 205-40, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are

issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued.

Management believes that its existing cash and cash equivalents at September 30, 2019, along with funding available through our Equity Distribution Agreement (the "Sales Agreement") with Canaccord Genuity LLC, as agent ("Canaccord") and our Purchase Agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") (Note 7), will be sufficient to allow us to fund our current operating plan at least a year from issuance of these financial statements. However, because certain elements of our operating plan are outside of our control, including our ability to sell shares under the Sales Agreement and the Purchase Agreement, they cannot be considered probable. Under ASC 205-40, the future receipt of potential funding from the Company's Co-Development partners and other resources cannot be considered probable at this time because none of the plans are entirely within the Company's control. In addition, the Company is required to maintain a minimum cash balance under its Term Loan Agreement with CRG Servicing LLC ("CRG") (Note 6).

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

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

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States GAAP as defined in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). The Company's condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, T2 Biosystems Securities Corporation. All intercompany balances and transactions have been eliminated.

Unaudited Interim Financial Information

Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

The accompanying interim condensed consolidated balance sheet as of September 30, 2019, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2019 and 2018, the condensed consolidated statements of stockholders' equity (deficit) for the nine months ended September 30, 2019 and 2018, the condensed consolidated statements of cash flows for the nine months ended September 30, 2019 and 2018 and the related financial data and other information disclosed in these notes are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements, and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of September 30, 2019, and the results of its operations for the three and nine months ended September 30, 2019 and 2018 and its cash flows for the nine months ended September 30, 2019 and 2018. The results for the three and nine months ended September 30, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019, any other interim periods, or any future year or period.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker is the Chief Executive Officer. The Company views its operations and manages its business in one operating segment, which is the business of developing and, upon regulatory clearance, commercializing its diagnostic products aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier.

Geographic Information

The Company sells its products domestically and internationally. For the three and nine months ended September 30, 2019, there were no international customers that represented greater than 10% of total revenue. For the three months ended September 30, 2018, there was one international customer that represented greater than 10% of total revenue. For the nine months ended September 30, 2018, there were no international customers that represented greater than 10% of total revenue. Total international sales were approximately $0.6 million or 36% of total revenue and $0.6 million or 25% of total revenue for the three months ended September 30, 2019 and 2018, respectively. Total international sales were approximately $1.8 million or 34% of total revenue and $1.4 million or 16% of total revenue for the nine months ended September 30, 2019 and 2018, respectively.

As of September 30, 2019 and December 31, 2018, the Company had outstanding receivables of $0.5 million and $0.9 million, respectively, from customers located outside of the U.S.

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting the weighted-average number of shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, stock options and unvested restricted stock and restricted stock contingently issuable upon achievement of certain market conditions are considered to be common stock equivalents, but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share applicable to common stockholders was the same for all periods presented.

Guarantees

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

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

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

As of September 30, 2019 and December 31, 2018, 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

The Company adopted Topic 842, *Leases* (“ASC 842”), using the modified retrospective approach through a cumulative-effect adjustment and utilizing the effective date of January 1, 2019 as its date of initial application, with prior periods unchanged and presented in accordance with the previous guidance in Topic 840**,** *Leases* (“ASC 840”).

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. Most 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. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. However, certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued lease payments. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rates, which are the rates incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

In accordance with the guidance in ASC 842, components of a lease should be split into three categories: lease components (e.g. land, building, etc.), non-lease components (e.g. common area maintenance, consumables, etc.), and non-components (e.g. property taxes, insurance, etc.) Then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components.

The Company made the policy election to not separate lease and non-lease components. Each lease component and the related non-lease components are accounted for together as a single component.

Revenue Recognition

The Company generates revenue from the sale of instruments, consumable diagnostic tests, related services, reagent rental agreements and research and development agreements with third parties. Pursuant to ASC 606, *Revenue from Contracts with Customers* (“ASC 606”), revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration the Company expects to be entitled to receive in exchange for these goods and services.

Once a contract is determined to be within the scope of ASC 606 at contract inception, the Company reviews the contract to determine which performance obligations the Company must deliver and which of these performance obligations are distinct. The Company recognizes as revenues the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied or as it is satisfied. Generally, the Company's performance obligations are transferred to customers at a point in time, typically upon shipment, or over time, as services are performed.

Most of the Company’s contracts with customers contain multiple performance obligations. For these contracts, the Company accounts for individual performance obligations separately if they are distinct. The transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. Excluded from the transaction price are sales tax and other similar taxes which are presented on a net basis.

Product revenue is generated by the sale of instruments and consumable diagnostic tests predominantly through the Company’s direct sales force in the United States and distributors in geographic regions outside the United States. The Company does not offer product return or exchange rights (other than those relating to defective goods under warranty) or price protection allowances to its customers, including its distributors. Payment terms granted to distributors are the same as those granted to end-user customers and payments are not dependent upon the distributors’ receipt of payment from their end-user customers. The Company either sells instruments to customers and international distributors, or retains title and places the instrument at the customer site pursuant to a reagent rental agreement. When an instrument is purchased by a customer, the Company recognizes revenue when the related performance obligation is satisfied (i.e. when the control of an instrument has passed to the customer; typically, at shipping point). When the instrument is placed under a reagent rental agreement, the Company’s customers generally agree to fixed term agreements, which can be extended, and incremental charges on each consumable diagnostic test purchased. Revenue from the sale of consumable diagnostic tests (under a reagent rental agreement) is recognized upon shipment. The transaction price from consumables purchases is allocated between the lease of the instrument (under a contingent rent methodology as provided for in ASC 842, *Leases*), and the consumables when related performance obligations are satisfied, as a component of lease and product revenue, and is included as Instrument Rentals in the below table. Revenue associated with reagent rental consumables purchases is currently classified as variable consideration and constrained until a purchase order is received and related performance obligations have been satisfied. Shipping and handling costs billed to customers in connection with a product sale are recorded as a component of the transaction price

and allocated to product revenue in the condensed consolidated statements of operations and comprehensive loss as they are incurred by the Company in fulfilling its performance obligations.

Direct sales of instruments include warranty, maintenance and technical support services typically for one year following the installation of the purchased instrument ("Maintenance Services"). Maintenance Services are separate performance obligations as they are service based warranties and are recognized on a straight-line basis over the service delivery period. After the completion of the initial Maintenance Services period, customers have the option to renew or extend the Maintenance Services typically for additional one-year periods in exchange for additional consideration. The extended Maintenance Services are also service based warranties that represent separate purchasing decisions. The Company recognizes revenue allocated to the extended Maintenance Services performance obligation on a straight-line basis over the service delivery period.

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

The Company warrants that consumable diagnostic tests will be free from defects, when handled according to product specifications, for the stated life of the product. To fulfill valid warranty claims, the Company provides replacement product free of charge. Accordingly, the Company accrues warranty expense associated with the estimated defect rates of the consumable diagnostic tests.

Revenue earned from activities performed pursuant to research and development agreements is reported as research revenue in the condensed consolidated statements of operations and comprehensive loss, and is recognized over time using an input method as the work is completed. The related costs are expensed as incurred as research and development expense. The timing of receipt of cash from the Company's research and development agreements generally differs from when revenue is recognized. Milestones are contingent on the occurrence of future events and are considered variable consideration being constrained until the Company believes a significant revenue reversal will not occur. Refer to Note 11 for further details regarding the Company's research and development arrangements.

Grants received, including cost reimbursement agreements, are assessed to determine if the agreement should be accounted for as an exchange transaction or a contribution. An agreement is accounted for as a contribution if the resource provider does not receive commensurate value in return for the assets transferred. Contribution revenue is recognized when all donor-imposed conditions have been met.

Disaggregation of Revenue

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

	Three months ended, September 30,		Nine months ended, September 30,	
	2019	2018	2019	2018
Product Revenue				
Instruments	$ 543	$ 504	$ 1,540	$ 1,213
Consumables	604	608	2,054	1,929
Instrument rentals	30	106	171	344
Total Product Revenue	1,177	1,218	3,765	3,486
Research Revenue	56	1,248	269	5,222
Contribution Revenue	444	—	1,232	—
Total Revenue	$ 1,677	$ 2,466	$ 5,266	$ 8,708

Remaining Performance Obligations

Remaining performance obligations represent the transaction price of firm orders for which work has not been performed or goods and services have not been delivered. As of September 30, 2019, the aggregate amount of transaction price allocated to remaining performance obligations for contracts with an original duration greater than one year was $3.5 million, of which $3.0 million is constrained revenue. We do not disclose the value of unsatisfied performance obligations for (i) contracts with an original expected length of one year or less and (ii) contracts for which we recognize revenue at the amount to which we have the right to invoice for services performed. The Company expects to recognize revenue on the remaining performance obligations over the next two years.

Significant Judgments

Our contracts with customers often include promises to transfer multiple products and services to a customer. Determining whether products and services are considered distinct performance obligations that should be accounted for separately versus together may require significant judgment. Once we determine the performance obligations, the Company determines the transaction price, which includes estimating the amount of variable consideration, based on the most likely amount, to be included in the transaction price, if any. We then allocate the transaction price to each performance obligation in the contract based on a relative stand-alone selling price method. The corresponding revenue is recognized as the related performance obligations are satisfied as discussed in the revenue categories above.

Judgment is required to determine the standalone selling price for each distinct performance obligation. We determine standalone selling price based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, we estimate the standalone selling price taking into account available information such as market conditions and the expected costs and margin related to the performance obligations.

Contract Assets and Liabilities

The Company did not record any contract assets at September 30, 2019 and December 31, 2018.

The Company's contract liabilities consist of upfront payments for research and development contracts and Maintenance Services on instrument sales. We classify these contract liabilities in deferred revenue as current or noncurrent based on the timing of when we expect to recognize revenue. Contract liabilities were $0.6 million at September 30, 2019 and $0.6 million at December 31, 2018. Revenue recognized in the three and nine months ended September 30, 2019 relating to contract liabilities at December 31, 2018 was $0.1 million and $0.4 million, respectively, and related to performance of research and development services and straight-line revenue recognition associated with maintenance agreements.

Cost to Obtain and Fulfill a Contract

The Company does not meet the recoverability criteria to capitalize costs to obtain or fulfill instrument purchases. Reagent rental agreements do not meet the recoverability criteria to capitalize costs to obtain the contracts and the costs to fulfill the contracts are under the scope of ASC 842. At the end of each reporting period, the Company assesses whether any circumstances have changed to meet the criteria for capitalization. The Company did not incur any expenses to obtain research and development agreements and costs to fulfill those contracts do not generate or enhance resources of the entity. As such, no costs to obtain or fulfill contracts have been capitalized at period end.

Cost of Product Revenue

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

Research and Development Costs

Costs incurred in the research and development of the Company's product candidates are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including activities associated with performing services under research revenue arrangements and contribution agreements, costs associated with the manufacture of developed products and include salaries and benefits, stock compensation, research-related facility and overhead costs, laboratory supplies, equipment and contract services.

Recent Accounting Standards

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

Accounting Standards Adopted

In February 2016, the FASB issued ASU 2016-02, Leases ("ASU 2016-02") in order to increase transparency and comparability among organizations by recognizing right-of-use assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous generally accepted accounting principles. ASU 2016-02 requires a lessee to recognize a lease liability for its future lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term on the balance sheet for most lease arrangements. The new standard also changes many key definitions, including the definition of a lease. The new standard includes a short-term lease exception for leases with a term of 12 months or less, as part of which a lessee can make an accounting policy election not to recognize right-of-use assets and lease liabilities. Lessees will continue to differentiate between finance leases (previously referred to as capital leases) and operating leases using classification criteria that are substantially similar to the previous guidance in ASC 840.

ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 (including interim periods within those periods) and early adoption is permitted. In August 2018, the FASB issued ASU 2018-11, *Leases, Targeted Improvements*, which provides a new transition option in which an entity initially applies ASU 2016-02 at the adoption date and recognizes a cumulative-effect adjustment in the period of adoption. Prior period comparative balances will not be adjusted. The Company used the new transition option and was also utilizing the package of practical expedients that allows it to not reassess: (1) whether any expired or existing contracts are or contain leases, (2) lease classification for any expired or existing leases, and (3) initial direct costs for any existing leases. We also used the short-term lease exception for leases with a term of twelve months or less. Additionally, the Company used the practical expedient that allowed each separate lease component of a contract and its associated non-lease components to be treated as a single lease component. As of the January 1, 2019 effective date the Company identified eight operating lease arrangements and two finance lease arrangements in which it is a lessee. The adoption of this standard resulted in the recognition of operating lease liabilities and right-of-use assets of $5.6 million and $4.8 million, respectively, on the Company's balance sheet, with the difference relating to a reclassification of the current accrued rent liability of $0.8 million as a reduction to the right-of-use-assets for its operating leases.

In calculating the present value of the lease payments, the Company applied an individual discount rate for each of its leases, and determined the appropriate discount rate based on the remaining lease terms at the date of adoption. As the lessee to several lease agreements, the Company did not have insight into the relevant information that would be required to arrive at the rate implicit in the lease. Therefore, the Company utilized its outstanding borrowings as a benchmark to determine its incremental borrowing rate for its leases. The benchmark rate was adjusted to arrive at an appropriate discount rate for each lease.

Under the new guidance, lessor accounting is largely unchanged. As of September 30, 2019, the Company was the lessor of T2Dx instruments. The lease agreements typically do not include fixed rental payments, but rather rental revenue is earned through usage-based variable lease payments. In accordance with ASC 842 the Company recognized lease revenue related to variable lease payments in the period in which it was earned. For the three and nine months ended September 30, 2019, the Company recognized $0.1 million and $0.2 million, respectively, of lease revenue for instrument rentals.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation: Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"), which expands the scope of *Compensation – Stock Compensation* ("Topic 718") to include share-based payment transactions for acquiring goods and services from nonemployees. This amendment applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The Company adopted ASU 2018-07 on January 1, 2019. The impact was immaterial to the financial statements.

In June 2018, the FASB issued ASU No. 2018-08, *Not-For-Profit Entities – Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made* ("ASU 2018-08"). ASU 2018-18 clarifies how an entity determines whether a resource provider is participating in an exchange transaction by evaluating whether the resource provider is receiving commensurate value in return for the resources transferred. The guidance is effective for annual periods beginning after June 15, 2018, including interim periods within those annual periods, and has been adopted on a modified prospective basis. The modified prospective adoption is applied to agreements that are not completed as of the effective date, or entered into after the effective date. Under the modified prospective adoption approach, prior period results have not been restated and no cumulative-effect adjustment has been recorded. As a result of applying ASU 2018-18, the Company recorded revenue of $0.1 million and $0.9 million earned under its agreement with CARB-X (Note 11) as contribution revenue during the three and nine months ended September 30, 2019, respectively.

Accounting Standards Issued, Not Adopted

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement* ("ASU 2018-13"), which eliminates, adds and modifies certain disclosure requirements for fair value measurements. The amendment is effective for interim and annual reporting periods beginning after December 15, 2019. The Company is currently assessing the impact this will have on the financial statements.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements* ("ASU 2018-18"), which clarifies the interaction between ASC 808, Collaborative Arrangements and ASC 606, Revenue from Contracts with Customers. Certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, ASU 2018-18 precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue if the counterparty is not a customer for that transaction. ASU 2018-18 should be applied retrospectively to the date of initial application of ASC 606. This guidance is effective for interim and fiscal periods beginning after December 15, 2019. The Company is currently assessing the impact this will have on the financial statements.

Emerging Growth Company Status

In April 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was enacted in the United States. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, as amended, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. As of December 31, 2019, the Company will no longer qualify as an emerging growth company.

3. Fair Value Measurements

The Company measures the following financial assets at fair value on a recurring basis. There were no transfers between levels of the fair value hierarchy during any of the periods presented. The following tables set forth the Company's financial assets carried at fair value categorized using the lowest level of input applicable to each financial instrument as of September 30, 2019 and December 31, 2018 (in thousands):

	Balance at September 30, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash	$ 11,926	$ 11,926	$ —	$ —
Money market funds	4,287	4,287	—	—
Restricted cash	180	180	—	—
	$ 16,393	$ 16,393	$ —	$ —
Liabilities:				
Derivative liability	$ 2,603	$ —	$ —	$ 2,603
	$ 2,603	$ —	$ —	$ 2,603

	Balance at December 31, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash	$ 6,868	$ 6,868	$ —	$ —
Money market funds	43,937	43,937	—	—
Restricted cash	180	180	—	—
	$ 50,985	$ 50,985	$ —	$ —
Liabilities:				
Derivative liability	$ 2,142	$ —	$ —	$ 2,142
	$ 2,142	$ —	$ —	$ 2,142

The Company maintains certificates of deposit, classified as restricted cash, for $0.2 million (Note 4). The Company's Term Loan Agreement with CRG (Note 6) contains certain provisions that change the underlying cash flows of the instrument, including acceleration of the obligations under the Term Loan Agreement under an event of default. In addition, under certain circumstances, a default interest rate of an additional 4.0% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default. The Company concluded that these features are not clearly and closely related to the host instrument, and represent a single compound derivative that is required to be re-measured at fair value on a quarterly basis.

In March 2019, the Term Loan Agreement was amended to reduce the 2019 minimum revenue target to $9.0 million and eliminate the 2018 revenue target. In September 2019, the Term Loan Agreement was amended to extend the interest-only payment period through December 31, 2021, to extend the initial principal repayment to March 31, 2022, and to reduce the minimum revenue targets. The fair value of the derivative at September 30, 2019 and December 31, 2018 is $2.6 million and $2.1 million, respectively. The estimated fair value of the derivative, at both dates, was determined using a probability-weighted discounted cash flow model that includes contingent interest payments under the following scenarios: 4% contingent interest beginning in 2020 (70%) and 4% contingent interest beginning in 2021 (30%). Should the Company's assessment of these probabilities change, including amendments of certain revenue targets, there could be a change to the fair value of the derivative liability.

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

Balance at December 31, 2018	$	2,142
Change in fair value of derivative liability, recorded as interest expense		461
Balance at September 30, 2019	$	2,603

4. Restricted Cash

The Company is required to maintain a security deposit for its operating lease agreement for the duration of the lease agreement and for its credit cards as long as they are in place. At September 30, 2019 and December 31, 2018, the Company had certificates of deposit for $0.2 million, which represented collateral as security deposits for its operating lease agreement for its facility and its credit cards.

5. Supplemental Balance Sheet Information

Accounts Receivable

Accounts receivable consists of the following (in thousands):

	September 30, 2019	December 31, 2018
Accounts receivable	$ 873	$ 1,786
Unbilled receivables	700	—
Total accounts receivable	$ 1,573	$ 1,786

Inventories

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

	September 30, 2019	December 31, 2018
Raw materials	$ 1,903	$ 639
Work-in-process	1,586	1,713
Finished goods	621	325
Total inventories, net	$ 4,110	$ 2,677

Property and Equipment

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

	September 30, 2019	December 31, 2018
Office and computer equipment	$ 409	$ 409
Software	762	751
Laboratory equipment	4,747	4,636
Furniture	194	200
Manufacturing equipment	672	695
Manufacturing tooling and molds	255	255
T2-owned instruments and components	6,879	6,796
Leasehold improvements	3,497	3,437
Construction in progress	1,698	1,443
	19,113	18,622
Less accumulated depreciation and amortization	(12,799)	(11,307)
Property and equipment, net	$ 6,314	$ 7,315

Construction in progress is primarily comprised of equipment that have not been placed in service. T2-owned instruments and components is comprised of raw materials and work-in-process inventory that are expected to be used or used to produce T2-owned instruments, based on our business model and forecast, and completed instruments that will be used for internal research and development, clinical studies or reagent rental agreements with customers. At September 30, 2019, there were $0.6 million of raw materials and work-in-process inventory in T2-owned instruments and components compared to $0.3 million at December 31, 2018. Completed T2-owned instruments are placed in service once installation procedures are completed and are depreciated over five years. Depreciation expense for T2-owned instruments placed at customer sites pursuant to reagent rental agreements is recorded as a component of cost of product revenue and totaled approximately $0.2 million for the three months ended September 30, 2019 and 2018 and $0.6 million and $0.7 million for the nine months ended September 30, 2019 and 2018, respectively. Depreciation expense for T2-owned instruments used for internal research and development and clinical studies is recorded as a component of research and development expense. Depreciation and amortization expense of $0.5 million and $0.6 million was charged to operations for the three months ended September 30, 2019 and 2018, respectively, and $1.7 million and $1.9 million for the nine months ended September 30, 2019 and 2018, respectively.

There were no property and equipment under finance leases included with property and equipment as of September 30, 2019. Total property and equipment, gross, included $3.6 million for property and equipment recorded under finance leases as of December 31, 2018. Accumulated depreciation and amortization included $2.6 million for property and equipment recorded under finance leases as of December 31, 2018

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Accrued payroll and compensation	$ 2,809	$ 2,940
Accrued research and development expenses	297	359
Accrued professional services	291	576
Operating lease liabilities	1,913	—
Other accrued expenses	3,490	2,198
Total accrued expenses and other current liabilities	$ 8,800	$ 6,073

At September 30, 2019 and December 31, 2018, the Company classified $2.1 million and $1.4 million, respectively, related to a fee associated with the Company's Term Loan Agreement (Note 6), as other accrued expenses in the table above to match the current classification of the associated debt.

6. Notes Payable

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

	September 30, 2019	December 31, 2018
Term loan agreement, net of deferred issuance costs of $2.0 million and $1.8 million, respectively	$ 42,258	$ 41,419
Equipment lease credit facility, net of immaterial deferred issuance costs	—	954
Total notes payable	42,258	42,373
Less: current portion of notes payable	(42,258)	(42,373)
Notes payable, net of current portion	$ —	$ —

The Term Loan Agreement with CRG is classified as a current liability on the balance sheet at September 30, 2019 and December 31, 2018 based on the Company's consideration of the probability of violating the minimum liquidity covenant included in the Term Loan Agreement. The Term Loan Agreement includes a subjective acceleration clause whereby an event of default, including a material adverse change in the business, operations, or conditions (financial or otherwise), could result in the acceleration of the obligations under the Term Loan Agreement. The contractual terms of the agreement, as amended, require quarterly principal payments of $12.0 million commencing March 31, 2022 through maturity December 31, 2022, respectively.

Term Loan Agreement

In December 2016, the Company entered into a Term Loan Agreement (the "Term Loan Agreement") with CRG. The Company initially borrowed $40.0 million pursuant to the Term Loan Agreement, which has a six-year term with four years of interest-only payments (through December 30, 2020), after which quarterly principal and interest payments will be due through the December 30, 2022 maturity date. Interest on the amounts borrowed under the Term Loan Agreement accrues at an annual fixed rate of 11.5%, 3.5% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount. In addition, if the Company achieves certain financial performance metrics, the loan will convert to interest-only until the December 30, 2022 maturity, at which time all unpaid principal and accrued unpaid interest will be due and payable. The Company is required to pay CRG a financing fee based on the loan principal amount drawn. The Company is also required to pay a final payment fee of 8.0% of the principal outstanding upon repayment. The Company is accruing the final payment fee as interest expense and it is included as a current liability at September 30, 2019 and December 31, 2018 on the balance sheet.

The Company may prepay all or a portion of the outstanding principal and accrued unpaid interest under the Term Loan Agreement at any time upon prior notice subject to a certain prepayment fee during the first five years of the term and no prepayment fee thereafter. As security for its obligations under the Term Loan Agreement the Company entered into a security agreement with CRG whereby the Company granted a lien on substantially all of its assets, including intellectual property. The Term Loan Agreement also contains customary affirmative and negative covenants for a credit facility of this size and type, including a requirement to maintain a minimum cash balance. The Term Loan Agreement also requires the Company to achieve certain revenue targets, whereby the Company is required to pay double the amount of any shortfall as an acceleration of principal payments. In March 2019, the Term Loan Agreement was amended to reduce the 2019 minimum revenue target to $9.0 million and eliminate the 2018 revenue covenant. In exchange for the amendment, the Company agreed to reset the strike price of the warrants to purchase a total of 528,958 shares of the Company's common stock, issued in connection with the Term Loan Agreement, from $8.06 per share to $4.35 per share (Note 9).

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

The Term Loan Agreement includes a subjective acceleration clause whereby an event of default, including a material adverse change in the business, operations, or conditions (financial or otherwise), could result in the acceleration of the obligations under the Term Loan Agreement. Under certain circumstances, a default interest rate of an additional 4.0% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default. CRG has not exercised its right under this clause, as there have been no such events. The Company believes the likelihood of CRG exercising this right is remote.

The Company assessed the terms and features of the Term Loan Agreement, including the interest-only period and the acceleration of the obligations under the Term Loan Agreement under an event of default, 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, The Company 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 September 30, 2019 and December 31, 2018 is $2.6 million and $2.1 million, respectively. The Company classified the derivative liability as accrued expenses and other current liabilities on the balance sheet at September 30, 2019 and December 31, 2018 to match the classification of the related Term Loan Agreement.

Equipment Lease Credit Facility

In October 2015, the Company signed a $10.0 million Credit Facility (the "Credit Facility") with Essex Capital Corporation (the "Lessor") to fund capital equipment needs. As one of the conditions of the Term Loan Agreement, the Credit Facility is capped at a maximum of $5.0 million. Under the Credit Facility, Essex will fund capital equipment purchases presented by the Company. The Company will repay the amounts borrowed in 36 equal monthly installments from the date of the amount funded. At the end of the 36 month lease term, the Company has the option to (a) repurchase the leased equipment at the lesser of fair market value or 10% of the original equipment value, (b) extend the applicable lease for a specified period of time, which will not be less than one year, or (c) return the leased equipment to the Lessor.

In April 2016 and June 2016, the Company completed the first two draws under the Credit Facility, of $2.1 million and $2.5 million, respectively. The Company made monthly payments of $67,000 under the first draw and $79,000 under the second draw. The borrowings under the Credit Facility were treated as finance leases and are included in property and equipment on the balance sheet. The amortization of the assets conveyed under the Credit Facility is included as a component of depreciation expense. During the three months ended September 30, 2019, the Company repurchased the equipment for $0.3 million in accordance with the terms of the Credit Facility.

7. Stockholders' Equity

Equity Distribution Agreement

On July 30, 2019, the Company entered into the Sales Agreement with Canaccord, as agent, pursuant to which the Company may offer and sell shares of common stock, for aggregate gross sale proceeds of up to $30.0 million from time to time through Canaccord.

Upon delivery of a placement notice based on the Company's instructions and subject to the terms and conditions of the Sales Agreement, Canaccord may sell the shares by methods deemed to be an "at the market" offering, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, or by any other method permitted by law, including negotiated transactions, subject to the prior written consent of the Company. The Company is not obligated to make any sales of shares under the Sales Agreement. The Company or Canaccord may suspend or terminate the offering of shares upon notice to the other party, subject to certain conditions. Canaccord will act as sales agent on a commercially reasonable efforts basis consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of Nasdaq.

The Company has agreed to pay Canaccord for its services of acting as agent 3% of the gross proceeds from the sale of the shares pursuant to the Sales Agreement. The Company has also agreed to provide Canaccord with customary indemnification for certain liabilities. At September 30, 2019, legal and accounting fees associated with the Sales Agreement were immaterial. Legal and accounting fees are expected to be changed to share capital upon issuance of shares under the Sales Agreement.

During the three months ended September 30, 2019, the Company sold 1,679,387 shares for net proceeds of $1.9 million after expenses in connection with the Sales Agreement.

Purchase Agreement

On July 29, 2019, the Company entered into a $30.0 million Purchase Agreement with Lincoln Park, pursuant to which the Company may sell and issue to Lincoln Park, and Lincoln Park is obligated to purchase, up to $30.0 million in value of its shares of common stock from time to time over a 36-month period starting from the effective date of the respective registration statement.

The Company may direct Lincoln Park, at its sole discretion, and subject to certain conditions, to purchase up to 200,000 shares of common stock on any business day, provided that at least one business day has passed since the most recent purchase. The amount of a purchase may be increased under certain circumstances provided, however, that Lincoln Park's committed obligation under any single purchase shall not exceed $2.0 million. The purchase price of shares of common stock related to the future funding will be based on the then prevailing market prices of such shares at the time of sales as described in the Purchase Agreement.

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

Public Offering

On June 4, 2018, the Company sold 7,015,000 shares of its common stock in a public offering at $7.50 per share, for an aggregate gross cash purchase price of $52.6 million, resulting in net proceeds of $49.2 million after underwriters discount and expenses.

8. Stock-Based Compensation

Stock Incentive Plans

2006 Stock Incentive Plan

The Company's 2006 Stock Option Plan ("2006 Plan") was established for granting stock incentive awards to directors, officers, employees and consultants of the Company. Upon closing of the Company's IPO in August 2014, the Company ceased granting stock incentive awards under the 2006 Plan. The 2006 Plan provided for the grant of incentive and non-qualified stock options and restricted stock grants as determined by the Company's board of directors. Under the 2006 Plan, stock options were generally granted with exercise prices equal to or greater than the fair value of the common stock as determined by the board of directors, expired no later than 10 years from the date of grant, and vest over various periods not exceeding 4 years.

2014 Stock Incentive Plan

The Company's 2014 Incentive Award Plan ("2014 Plan", and together with the 2006 Plan, the "Stock Incentive Plans"), provides for the issuance of shares of common stock in the form of stock options, awards of restricted stock, awards of restricted stock units, performance awards, dividend equivalent awards, stock payment awards and stock appreciation rights to directors, officers, employees and consultants of the Company. Since the establishment of the 2014 Plan, the Company has primarily granted stock options and restricted stock units. Generally, stock options are granted with exercise prices equal to or greater than the fair value of the common stock on the date of grant, expire no later than 10 years from the date of grant, and vest over various periods not exceeding 4 years.

The number of shares reserved for future issuance under the 2014 Plan is the sum of (1) 823,529 shares, (2) any shares that were granted under the 2006 Plan which are forfeited, lapsed 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, 2024, equal to the lesser of (A) 4% of the shares outstanding (on an as-converted basis) on the final day of the immediately preceding calendar year, and (B) such smaller number of shares determined by the Company's Board of Directors. As of September 30, 2019, there were 407,870 shares available for future grant under the Stock Incentive Plans.

Inducement Award Plan

The Company's Amended and Restated Inducement Award Plan ("Inducement Plan"), which was adopted in March 2018 and amended and restated in February 2019, provides for the granting of equity awards to new employees, which includes options, restricted stock awards, restricted stock units, performance awards, dividend equivalent awards, stock payment awards and stock appreciation rights. The aggregate number of shares of common stock which may be issued or transferred pursuant to awards under the Inducement Plan is 1,625,000 shares. Any awards that forfeit, expire, lapse, or are settled for cash without the delivery of shares to the holder are available for the grant of an award under the Inducement Plan. Any shares repurchased by or surrendered to the Company that are returned shall be available for grant of an award under the Inducement Plan. The payment of dividend equivalents in cash in conjunction with any outstanding award shall not be counted against the shares available for issuance under the Inducement Plan. As of September 30, 2019, there were 752,708 shares available for future grant under the Inducement Plan.

Stock Options

During the nine months ended September 30, 2019 and 2018, the Company granted stock options with an aggregate fair value of $3.8 million and $5.5 million, respectively, which are being amortized into compensation expense over the vesting period of the options as the services are being provided.

The following is a summary of option activity under the Stock Incentive Plans and Inducement Plan (in thousands, except share and per share amounts):

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	4,241,833	$ 6.98	7.02	$ 471
Granted	2,683,200	2.11		
Exercised	(938)	2.68		
Forfeited	(373,388)	5.28		
Cancelled	(119,270)	7.81		
Outstanding at September 30, 2019	6,431,437	$ 5.03	7.46	$ 2,148
Exercisable at September 30, 2019	2,996,830	$ 7.30	5.35	$ 257
Vested or expected to vest at September 30, 2019	5,740,731	$ 5.28	7.23	$ 1,791

The weighted-average grant date fair values of stock options granted in the nine month periods ended September 30, 2019 and 2018 were $1.40 per share and $3.55 per share, respectively, and were calculated using the following estimated assumptions:

	Nine Months Ended September 30,	
	2019	2018
Weighted-average risk-free interest rate	1.98%	2.66%
Expected dividend yield	—%	—%
Expected volatility	78%	68%
Expected terms	6.0 years	6.0 years

The total fair values of options that vested during the nine months ended September 30, 2019 and 2018 were $2.4 million and $2.3 million, respectively.

As of September 30, 2019, there was $6.5 million of total unrecognized compensation cost related to non-vested stock options granted under the Stock Incentive Plans and Inducement Plan. Total unrecognized compensation cost will be adjusted for future changes in the estimated forfeiture rate. The Company expects to recognize that cost over a remaining weighted-average period of 2.7 years as of September 30, 2019.

Restricted Stock Units

During the nine months ended September 30, 2019, the Company awarded shares of restricted stock units to certain employees and directors at no cost to them, which cannot be sold, assigned, transferred or pledged during the restriction period. The restricted stock and restricted stock units, excluding any restricted stock units with market conditions, vest through the passage of time, assuming continued employment. Restricted stock units are not included in issued and outstanding common stock until the shares are vested and released. As of December 31, 2018, 78,172 restricted stock units had vested but were not reflected as outstanding shares due to a deferred release date. These restricted stock units are reflected as outstanding shares at September 30, 2019. During the year ended December 31, 2018, an additional 73,172 restricted stock units vested but are not reflected as outstanding shares at September 30, 2019 and December 31, 2018 due to a deferred release date. 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 $1.9 million, which are being amortized into compensation expense over the vesting period of the restricted stock units as the services are being provided.

Included in the nonvested restricted stock units at September 30, 2019 are 755,168 restricted stock units with market conditions, which vest upon the achievement of stock price targets. The compensation cost for restricted stock units with market conditions is

being recorded over the derived service period and was $0.2 million and $0.9 million for the three months ended September 30, 2019 and 2018, respectively, and $1.0 million and $3.6 million for the nine months ended September 30, 2019 and 2018, respectively.

The following is a summary of restricted stock unit activity under the 2014 Plan (in thousands, except share and per share amounts):

	Number of Shares	Weighted-Average Grant Date Fair Value
Nonvested at December 31, 2018	1,198,634	5.04
Granted	589,142	3.23
Vested	(189,129)	6.41
Forfeited	(286,889)	4.41
Cancelled	—	—
Nonvested at September 30, 2019	1,311,758	4.17

As of September 30, 2019, there was $1.6 million of total unrecognized compensation cost related to nonvested restricted stock units granted under the 2014 Plan. Total unrecognized compensation cost will be adjusted for future changes in the estimated forfeiture rate. The Company expects to recognize that cost over a remaining weighted-average period of 2.13 years, as of September 30, 2019.

Stock-Based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Cost of product revenue	$ 7	$ 23	$ 295	$ 408
Research and development	283	409	975	1,271
Selling, general and administrative	862	1,601	3,216	5,561
Total stock-based compensation expense	$ 1,152	$ 2,033	$ 4,486	$ 7,240

For the three months ended September 30, 2019 and 2018, stock-based compensation expenses capitalized as part of inventory or T2Dx instruments and components, respectively, were immaterial. For the nine months ended September 30, 2019, stock-based compensation expenses capitalized as part of inventory or T2Dx instruments and components, respectively, were immaterial. For the nine months ended September 30, 2018 $0.3 million of stock-based compensation expenses were capitalized as part of inventory or T2 instruments and components, respectively.

9. Warrants

In connection with the Term Loan Agreement entered into in December 2016, the Company issued to CRG warrants to purchase a total of 528,958 shares of the Company's common stock. The warrants are exercisable any time prior to December 30, 2026 at a price of $4.35 per share, which was amended in March 2019 from an original price of $8.06 per share, with typical provisions for termination upon a change of control or a sale of all or substantially all of the assets of the Company. The warrants are classified within shareholders' equity, and the proceeds were allocated between the debt and warrants based on their relative fair value. The fair value of the warrants was determined by the Black-Scholes-Merton option pricing model. The fair value of the amended warrants was $0.9 million. The incremental fair value of the modified instrument of $0.1 million was recorded as debt discount and additional paid-in-capital.

In connection with the September 2019 amendment of the Term Loan Agreement, the Company issued to CRG warrants to purchase 568,291 shares of the Company's common stock at an exercise price of $1.55, with typical provisions for termination upon a change of control or a sale of all or substantially all of the assets of the Company. The Company also reduced the exercise price for the warrants previously issued to CRG to $1.55. All of the New Warrants are exercisable any time prior to September 9, 2029. The warrants are classified within shareholders' equity, and the proceeds were allocated between the debt and warrants based on their relative fair value. The fair value of the new and amended warrants was determined by the Black-Scholes-Merton option pricing

model. The incremental fair value of the amended warrants of $0.1 million and the fair value of the New Warrants of $0.7 million were recorded as debt discount and additional paid-in-capital.

10. Net Loss Per Share

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

	Three and Nine Months Ended September 30,	
	2019	2018
Options to purchase common shares	6,431,437	4,236,595
Restricted stock units	1,311,758	1,202,123
Warrants to purchase common stock	1,097,249	528,958
Total	8,840,444	5,967,676

11. Co-Development Agreements

Canon US Life Sciences

On February 3, 2015, the Company entered into a Co-Development Partnership Agreement (the "Co-Development Agreement") with Canon U.S. Life Sciences, Inc. ("Canon") to develop a diagnostic test panel to rapidly detect Lyme disease. On September 21, 2016, Canon became a related party when the Company sold the Canon shares for an aggregate cash purchase price of $39.7 million, which represented 19.9% of the outstanding shares of common stock of the Company.

Under the Co-Development Agreement, the Company recorded revenue of $0.1 million and $0.2 million for the three months ended September 30, 2019 and 2018, respectively. The Company recorded revenue of $0.2 million and $1.5 million during the nine months ended September 30, 2019 and 2018, respectively. The Company expects to record revenue over the next four months.

Allergan Sales, LLC

On November 1, 2016, the Company entered into a Co-Development, Collaboration and Co-Marketing Agreement (the "Allergan Agreement") with Allergan Sales, LLC ("Allergan Sales") to develop (1) a direct detection diagnostic test panel that adds one additional bacteria species to the existing T2Bacteria product candidate (the "T2Bacteria II Panel"), and (2) a direct detection diagnostic test panel for testing drug resistance directly in whole blood (the "T2GNR Panel" and, together with the T2Bacteria II Panel, the "Developed Products"). In addition, both the Company and Allergan Sales will participate in a joint research and development committee and Allergan Sales will receive the right to cooperatively market T2Candida, T2Bacteria, and the Developed Products under the Allergan Agreement to certain agreed-upon customers. The Company achieved the final developmental milestone under the Allergan Agreement in October 2018.

The Company did not record any revenue for the three and nine months ended September 30, 2019 and recorded revenue of $0.7 million and $2.9 million for the three and nine months ended September 30, 2018, respectively, under the Allergan Agreement.

CARB-X

In March 2018, the Company was awarded a grant of up to $2.0 million from CARB-X. The collaboration with CARB-X will be used to accelerate the development of new tests to identify bacterial pathogens and resistance markers directly in whole blood more rapidly than is possible using today's diagnostic tools. The new tests aim to expand the T2Dx instrument product line by detecting 20 additional bacterial species and resistance targets, with a focus on blood borne pathogens on the United States Centers for Disease Control and Prevention ("CDC") antibiotic resistance threat list.

Under this cost-sharing agreement, the Company may be reimbursed up to $1.1 million, with the possibility of up to an additional $0.9 million based on the achievement of certain project milestones. In January 2019, the Company was awarded the $0.9 million reimbursement option.

The Company recorded revenue of $0.1 million and $0.4 million for the three months ended September 30, 2019 and 2018, respectively, under the CARB-X Agreement. The Company recorded revenue of $0.9 million and $0.9 million for the nine months ended September 30, 2019 and 2018, respectively, under the CARB-X agreement. The Company recorded CARB-X revenue as contribution revenue in 2019 upon adoption of a new accounting standard and research revenue in 2018. As the Company has recognized the $0.9 million that was awarded under the reimbursement option, the Company will not recognize any additional revenue under the CARB-X agreement.

US Government Contract

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

The Company recorded revenue of $0.3 million for the three and nine months ended September 30, 2019.

12. Leases

Operating Leases

The Company leases certain office space, laboratory space, and equipment. At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. The Company does not recognize right-of-use assets or lease liabilities for leases determined to have a term of 12 months or less. For new and amended leases beginning in 2019 and after, the Company has elected to account for the lease and non-lease components as a combined lease component.

In August 2010, the Company entered into an operating lease for office and laboratory space at its headquarters in Lexington, Massachusetts. The lease commenced in January 2011, with the Company providing a security deposit of $400,000. In accordance with the operating lease agreement, the Company reduced its security deposit to $180,000 in January 2018, which is recorded as restricted cash in the condensed consolidated balance sheets. In March 2017, the Company entered into an amendment to extend the term to December 2021.

In May 2013, the Company entered into an operating lease for additional office, laboratory and manufacturing space in Wilmington, Massachusetts. In August 2018, the Company entered into an amendment to extend the term to December 2020.

In November 2014, the Company entered into an agreement to rent additional office space in Lexington, Massachusetts. In April 2015, the Company entered into an amendment to extend the term to December 31, 2017. In connection with this agreement, the Company paid a security deposit of $50,000, which is recorded as a component of other assets in the condensed consolidated balance sheets. In May 2015, the Company entered into an amendment to expand existing manufacturing facilities in Lexington, Massachusetts. In September 2017, the Company entered into an amendment to extend the term to December 31, 2021.

In November 2014, the Company entered into a lease for additional laboratory space in Lexington, Massachusetts. The lease term commenced in April 2015 and extended for six years. The rent expense, inclusive of the escalating rent payments, is recognized on a straight-line basis over the lease term. As an incentive to enter into the lease, the landlord paid approximately $1.4 million of the $2.2 million space build-out costs. Prior to the adoption of ASC 842, the incentive was recorded as a component of lease incentives on the condensed consolidated balance sheets and was amortized as a reduction in rent expense on a straight-line basis over the term of the lease. Upon adoption of the new standard the unamortized balance of the lease incentive as of January 1, 2019 was reclassified as a reduction to the initial recognition of the right-of-use asset related to this lease. In connection with this lease agreement, the Company paid a security deposit of $281,000, which is recorded as a component of both prepaid expenses and other current assets and other assets in the condensed consolidated balance sheets.

Operating leases are amortized over the lease term and included in costs and expenses in the condensed consolidated statement of operations and comprehensive loss. Variable lease costs are recognized in costs and expenses in the condensed consolidated statement of operations and comprehensive loss as incurred.

Finance Leases

In October 2015, the Company signed a $10.0 million Credit Facility (the "Credit Facility") to fund capital equipment needs. As one of the conditions of the Term Loan Agreement, the Credit Facility is capped at a maximum of $5.0 million. Under the Credit Facility, the lender will fund capital equipment purchases presented by the Company. The Company will repay the amounts borrowed in 36 equal monthly installments from the date of the amount funded. At the end of the 36 month lease term, the Company has the option to (a) repurchase the leased equipment at the lesser of fair market value or 10% of the original equipment value, (b) extend the applicable lease for a specified period of time, which will not be less than one year, or (c) return the leased equipment to the lessor.

In April 2016 and June 2016, the Company completed the first two draws under the Credit Facility of $2.1 million and $2.5 million, respectively. The Company made monthly payments of $67,000 under the first draw and $79,000 under the second draw. The borrowings under the Credit Facility are treated as finance leases and are included in property and equipment on the balance sheet. The amortization of the assets conveyed under the Credit Facility is included as a component of depreciation expense. During the three months ended September 30, 2019, the Company repurchased the equipment for $0.3 million in accordance with the terms of the Credit Facility.

The following table summarizes the effect of operating and finance lease costs in the Company's condensed consolidated statement of operations and comprehensive loss (in thousands):

Lease cost	Three months ended September 30, 2019	Nine months ended September 30, 2019
Finance lease cost:		
Amortization of right-of-use assets	$ —	$ 235
Interest on lease liabilities	—	36
Operating lease cost	499	1,497
Variable lease cost	163	483
Total lease cost	$ 662	$ 2,251

The following table summarizes supplemental information for the Company's finance and operating leases:

Other information	Nine months ended September 30, 2019
Weighted-average remaining lease term - operating leases (in years)	2.1 years
Weighted-average discount rate - operating leases	11.9%

The minimum lease payments for the next five years and thereafter is expected to be as follows (in thousands):

Maturity of lease liabilities	September 30, 2019 Operating Leases
2019 (excluding the 9 months ended September 30, 2019)	$ 566
2020	2,314
2021	1,951
2022	23
2023	—
Thereafter	—
Total lease payments	$ 4,854
Less: effect of discounting	(551)
Present value of lease liabilities	$ 4,303

The following table summarizes the presentation of the Company's operating leases in its condensed consolidated balance sheets (in thousands):

Leases	Classification	September 30, 2019
Assets		
Operating lease assets	Operating lease assets	3,740
Total lease assets		$ 3,740
Liabilities		
Current		
Operating	Accrued expenses and other current liabilities	$ 1,913
Noncurrent		
Operating	Noncurrent operating lease liabilities	2,390
Total lease liabilities		$ 4,303

Under ASC 840, future minimum non-cancelable lease payments under the Company's operating leases as of December 31, 2018 were as follows (in thousands):

Year ended December 31,	
2019	$ 2,225
2020	2,277
2021	1,926
	$ 6,428

Under ASC 840, rent expense for the years ended December 31, 2018, and 2017 was $2.0 million, and $1.9 million, respectively.

13. Commitments and Contingencies

Leases

Refer to Note 12, Leases, for discussion of the commitments associated with the Company's leases.

License Agreement

In 2006, the Company entered into a license agreement with a third party, pursuant to which the third party granted the Company an exclusive, worldwide, sublicenseable license under certain patent rights to make, use, import and commercialize products and processes for diagnostic, industrial and research and development purposes. The Company agreed to pay an annual license fee ranging from $5,000 to $25,000 for the royalty-bearing license to certain patents. The Company also issued a total of 84,678 shares of common stock pursuant to the agreement in 2006 and 2007, which were recorded at fair value at the date of issuance. The Company is required to pay royalties on net sales of products and processes that are covered by patent rights licensed under the agreement at a percentage ranging between 0.5% - 3.5%, subject to reductions and offsets in certain circumstances, as well as a royalty on net sales of products that the Company sublicenses at 10% of specified gross revenue. Royalties for the nine months ended September 30, 2019 and 2018 were immaterial.

Severance Agreement

On July 30, 2019, the Company announced that founding CEO John McDonough was named Executive Chairman of the Board, effective immediately, and that the Company was undertaking a national search for a new CEO. Once that candidate is identified, Mr. McDonough will become non-executive Chairman of the Board. Mr. McDonough will continue in the role of CEO and Executive Chairman until his successor is in place. A successor has not been named. Transition payments and health benefits under the terms of the agreement are estimated to be approximately $1.0 million, which will be paid over the 15 month period following the successor's start date, and will be classified as selling, general and administrative expense over the anticipated period of the national search, estimated to be 8 months. Such expenses were immaterial for the three and nine months ended September 30, 2019.

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

This Quarterly Report on Form 10-Q contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, and Section 21E of the Securities and Exchange Act of 1934, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy, prospective products and product candidates, their expected performance and impact on healthcare costs, marketing clearance from the FDA, reimbursement for our product candidates, research and development costs, timing of regulatory filings, timing and likelihood of success, plans and objectives of management for future operations, availability of funding for such operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described under the sections in this Quarterly Report on Form 10-Q entitled "Item 1A.—Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Quarterly Report on Form 10-Q. These forward looking statements are subject to numerous risks, including, without limitation, the following:

- *our status as an early stage company;*
- *our expectation to incur losses in the future;*
- *the market acceptance of our T2MR technology;*
- *our ability to timely and successfully develop and commercialize our existing products and future product candidates;*
- *the length and variability of our anticipated sales and adoption cycle;*
- *our limited sales history;*
- *our ability to gain the support of leading hospitals and key thought leaders and publish the results of our clinical trials in peer-reviewed journals;*
- *our ability to successfully manage our growth;*
- *our future capital needs and our need to raise additional funds;*
- *the performance of our diagnostics;*
- *our ability to compete in the highly competitive diagnostics market;*
- *our ability to obtain marketing clearance from the FDA or regulatory clearance for new product candidates in the United States or any other jurisdiction;*
- *impacts of and delays caused by future federal government shutdowns;*
- *federal, state, and foreign regulatory requirements, including diagnostic product reimbursements and FDA regulation of our product candidates;*
- *our ability to recruit, train and retain key personnel;*
- *our ability to protect and enforce our intellectual property rights, including our trade secret protected proprietary rights in T2MR;*
- *the impact of security breaches on our information technology systems;*
- *the impact of short sellers on our share price;*
- *our dependence on third parties;*
- *our ability to continue as a going concern;*
- *manufacturing and other product risks;*

- *the impact of the adoption of new accounting standards; and*
- *the Tax Cuts and Jobs Act of 2017 (Tax Reform).*

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 "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2018, as supplemented or amended from time to time under "Item 1A.—Risk Factors" in our Quarterly Reports on Form 10-Q, and elsewhere 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. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Item 1A.—Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Business Overview

We are 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. We are using T2MR to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. T2MR enables rapid detection of pathogens, biomarkers and other abnormalities in a variety of unpurified patient sample types, including whole blood, plasma, serum, saliva, sputum, cerebral spinal fluid and urine, and can detect cellular targets at limits of detection as low as one colony forming unit per milliliter, or CFU/mL. Our initial development efforts target sepsis and Lyme disease, which are areas of significant unmet medical need in which existing therapies could be more effective with improved diagnostics.

On September 22, 2014, we received market clearance from the FDA for our first two products, the T2Dx Instrument and T2Candida, which have the ability to rapidly identify the five clinically relevant species of *Candida*, a fungal pathogen known to cause sepsis, directly from whole blood. On May 24, 2018, we received market clearance from the FDA for T2Bacteria, which runs on the T2Dx Instrument and has the ability to rapidly identify five of the most common and deadly sepsis-causing bacteria (members of the ESKAPE pathogens, as defined in *Our T2Bacteria Panel*) directly from whole blood. We have also developed and sell a research use only *Candida auris* assay for the rapid identification of *Candida auris*, a species of *Candida* that is highly drug resistant. We have developed a T2Resistance Panel for the early and sensitive detection of carbapenemase resistance markers and multiple hospitals are testing this new panel on a "research use only" basis. The T2Resistance Panel received FDA Breakthrough Device designation in February 2019 and we believe this designation will speed our clinical trial. An additional diagnostic application in development is called T2Lyme, which is focused on the detection of the bacteria that cause Lyme disease. Diagnostic applications for additional bacteria species and resistance markers were developed as part of a collaboration with CARB-X, a public-private partnership with the U.S. Department of Health and Human Services, or HHS, and the Wellcome Trust of London, focused on combatting antibiotic resistant bacteria. We anticipate that existing reimbursement codes will support our sepsis and Lyme disease product candidates, and that the anticipated economic savings associated with our sepsis products will be realized directly by hospitals. On August 2, 2019, the Company's T2Bacteria Panel received a New Technology Add-on Payment from CMS, including a stand-alone ICD-10 Code for the T2Bacteria test. In the United States, we have built a direct sales force that is primarily targeting the top 1,200 hospitals with the highest concentration of patients at risk for sepsis-related infections. Internationally, we have primarily partnered with distributors that target large hospitals in their respective international markets.

We believe our sepsis products, which include T2Candida and T2Bacteria, will redefine the standard of care in sepsis management while lowering healthcare costs by improving both the precision and the speed of detection of sepsis-causing pathogens. According to a study published in the Journal of Clinical Microbiology in 2010, targeted therapy for patients with bloodstream infections can be delayed up to 72 hours due to the wait time for blood culture results. In another study published in Clinical Infectious Diseases in 2012, the delayed administration of appropriate antifungal therapy was associated with higher mortality among patients with septic shock attributed to *Candida* infection and, on that basis, the study concluded that more rapid and accurate diagnostic techniques are needed. Due to the high mortality rate associated with *Candida* infections, physicians often will place patients on antifungal drugs while they await blood culture diagnostic results which generally take at least five days to generate a negative test result. Antifungal drugs are toxic and may result in side effects and can cost over $50 per day. The speed to result of T2Candida and

T2Bacteria coupled with its higher sensitivity as compared to blood culture may help reduce the overuse of ineffective, or even unnecessary, antimicrobial therapy which may reduce side effects for patients, lower hospital costs and potentially counteract the growing resistance to antifungal therapy. The administration of inappropriate therapy is a driving force behind the spread of antimicrobial-resistant pathogens, which the United States Centers for Disease Control and Prevention, or the CDC, recently called "one of our most serious health threats." The addition of the use of our products, T2Bacteria and T2Candida, which both run on the T2Dx instrument, with the standard of care for the management of patients suspected of sepsis, enables clinicians to potentially treat 90% of patients with sepsis pathogen infections with the right targeted therapy within the first twelve hours of development of the symptoms of disease. Currently, high risk patients are typically initially treated with broad spectrum antibiotic drugs that typically cover approximately 60% of patients with infections. Of the remaining 40% of patients, approximately 30% of the patients typically have a bacterial infection and 10% typically have *Candida* infections. T2Candida and T2Bacteria are designed to identify pathogens commonly not covered by broad spectrum antibiotic drugs.

We compete with traditional blood culture-based diagnostic companies, including Becton Dickinson & Co. and bioMerieux, Inc., as well as companies offering post-culture species identification using both molecular and non-molecular methods, including bioMerieux, Inc. (and its affiliate, BioFire Diagnostics, Inc.), Bruker Corporation, Accelerate Diagnostics, Luminex, Genmark, Cepheid and Beckman Coulter, a Danaher company. In addition, there may be a number of new market entrants in the process of developing other post-blood culture diagnostic technologies that may be perceived as competitive with our technology. Karius, Inc. offers a lab developed culture independent diagnostic test for the identification of pathogens that has not been cleared by the FDA but may be perceived as competitive with our technology.

We have never been profitable and have incurred net losses in each year since inception. Our accumulated deficit at September 30, 2019 was $362.1 million. 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 initial FDA-cleared products, T2Dx and T2Candida. In addition, we will continue to incur significant costs and expenses as we increase commercialization efforts for our most recent FDA-cleared product, T2Bacteria, and 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, T2Candida, T2Bacteria, and future T2MR-based diagnostics.

Pursuant to the requirements of Accounting Standards Codification (ASC) 205-40, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about our ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued.

We believe that our existing cash and cash equivalents at September 30, 2019, along with funding available through our Sales Agreement with Canaccord and Purchase Agreement with Lincoln Park (Note 7), will be sufficient to allow us to fund our current operating plan at least a year from the issuance of these financial statements. However, because certain elements of our operating plan are outside of our control, including our ability to sell shares under the Sales Agreement and the Purchase Agreement, they cannot be considered probable according to accounting standards. Under ASC 205-40, the future receipt of potential funding from our Co-Development partners and other resources cannot be considered probable at this time because none of the plans are entirely within our control. In addition, we are required to maintain a minimum cash balance under our Term Loan Agreement with CRG (Note 6).

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, should it be necessary, include raising additional funding, earning milestone payments pursuant to our Co- Development agreements, delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels 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 obtain sufficient funding from one or more of these sources or adequately reduce expenditures will be successful, while reasonably possible, is less than probable.

Our Commercial Products and the Unmet Clinical Need

The T2 Biosystems portfolio, including all current products utilizing T2MR technology that run on the T2Dx instrument, represent the only FDA-cleared products that detect and identify sepsis-causing bacterial and fungal pathogens directly from whole blood, without the need for blood culture. All other FDA-cleared products must wait for cells to divide in blood culture to achieve cell titer levels of greater than 1,000,000 CFU/mL. In contrast, the T2Direct Diagnostic products detect pathogens directly as they exist in blood, with limits of detection of 1 to 11 CFU/mL. The result is at least two days faster in time to pathogen identification, as demonstrated by two clinical trials, each including greater than 1,400 patients in addition to many clinical cases and independent studies.

The current standard of care is to treat patients suspected of a bloodstream infection using empiric antimicrobial therapy without diagnostic evidence, and then to revise therapy when diagnostic evidence is available. But as demonstrated by a meta-analysis of 70 studies, the proportion of infected patients receive effective therapy by the empiric approach is only 53.5%. However, the proportion of patients placed on effective therapy after receiving a diagnostic species identification from a blood sample is greater than 95%. We believe this is the principal value of our T2 Biosystems portfolio, to increase the proportion of patients on effective therapy from 55% to 95% within three to five hours, instead of days.

The benefits to clinical care outcomes from faster time to effective therapy include a reduction in average patient length of stay within a hospital, increased hospital cost savings, and reduced mortality. Across three interventional studies, the mean ratio of length of stay reduction to time to effective therapy was 2.7 hours. In other words, for every one hour faster time to effective therapy, patient length of stay was reduced by 2.7 hours. The mean reduction in length of stay from early effective therapy in these studies was up to eight days and an independent economic analysis found a $1,149 cost savings per patient tested with the T2Candida Panel. An independent economic review also found rapid, direct-from-blood diagnostics result in cost savings when sensitivity is greater than 52%, the cost of the test is less than $270, and results are returned within two to seven hours. All of these requirements are met by the T2Direct Diagnostic panels. Additionally, in septic shock patients, every hour delaying effective antimicrobial therapy decreases survival by an estimated 7.6%. In 111,816 patients given a New York State mandated sepsis bundle, the relative probability of death increased by four percent for every hour delay in the administration of effective therapy. In a retrospective analysis of 70 studies, compared to patients given an appropriate empiric antimicrobial therapy, patients given inappropriate empiric antimicrobials showed over two-times higher probability of death. Taken together, T2 Biosystems allow for a reduction in time to effective therapy by multiple days, which are realized as patient and hospital benefits in reduced length of stay, cost of care, and mortality.

Our FDA-cleared products, the T2Dx instrument, T2Candida, and T2Bacteria utilize T2MR to detect species-specific sepsis-causing bacterial and fungal pathogens, directly from whole blood in as few as three hours versus the one to five or more days typically required by blood culture-based diagnostics. This allows the patient to potentially receive the correct treatment in four to six hours versus 24 to 144 hours for blood culture. T2Candida and T2Bacteria run on the T2Dx Instrument and provide high sensitivity with a limit of detection as low as 1 CFU/mL, even in the presence of antimicrobial therapy.

Sepsis is one of the leading causes of death in the United States, claiming more lives annually than breast cancer, prostate cancer and AIDS combined, and it is the most expensive hospital-treated condition. Most commonly afflicting immunocompromised, critical care and elderly patients, sepsis is a severe inflammatory response to a bacterial or fungal infection with a mortality rate of approximately 30%. According to data published by HHS for 2017, the cost of sepsis was over $27 billion in the United States, building on previous data demonstrating that sepsis was responsible for approximately five percent of the total aggregate costs associated with domestic hospital stays. Sepsis is typically caused by one or more of five *Candida* species or over 25 bacterial pathogens, and effective treatment requires the early detection and identification of these specific target pathogens in a patient's bloodstream. Today, sepsis is typically diagnosed through a series of blood cultures followed by post-blood culture species identification. These methods have substantial diagnostic limitations that lead to a high rate of false negative test results, a delay of up to several days in administration of targeted treatment and the incurrence of unnecessary hospital expense. In addition, the Survey of Physicians' Perspectives and Knowledge About Diagnostic Tests for Bloodstream Infections in 2015 reported that negative blood culture results are only trusted by 36% of those physicians. Without the ability to rapidly identify pathogens, physicians typically start treatment of at-risk patients with broad-spectrum antibiotics, which can be ineffective and unnecessary and have contributed to the spread of antimicrobial resistance. According to a study published by Critical Care Medicine in 2006, in sepsis patients with documented hypotension, administration of effective antimicrobial therapy within the first hour of detection was associated with a survival rate of 79.9% and, over the ensuing six hours, each hour of delay in initiation of treatment was associated with an average decrease in survival of 7.6%.

We believe our sepsis products, which include T2Candida and T2Bacteria and the T2Resistance Panel product candidate, will redefine the standard of care in sepsis management while lowering healthcare costs by improving both the precision and the speed of detection of sepsis-causing pathogens. According to a study published in the Journal of Clinical Microbiology in 2010, targeted therapy for patients with bloodstream infections can be delayed up to 72 hours due to the wait time for blood culture results. In another

study published in Clinical Infectious Diseases in 2012, the delayed administration of appropriate antifungal therapy was associated with higher mortality among patients with septic shock attributed to *Candida* infection and, on that basis, the study concluded that more rapid and accurate diagnostic techniques are needed. Our pivotal clinical trial for T2Candida demonstrated that it can deliver actionable results in as few as three hours, with an average time to result during the trial of 4.2 hours, compared to the average time to result of one to six or more days typically required for blood-culture-based diagnostics, which we believe will potentially enable physicians to make treatment decisions and administer targeted treatment to patients in four to six hours versus 24 to 144 hours for blood culture.

The results from our pivotal clinical trial for T2Bacteria, which was recently published in the Annals of Internal Medicine, demonstrated that T2Bacteria can deliver actionable results in an average of 5.4 hours, compared to an average of 60 hours for detecting the same species by blood culture. In addition, T2Bacteria identified 69 patients with bloodstream infections that were missed by the paired blood culture that was simultaneously run. The pivotal study was a study of over 1,400 patient samples collected across 11 hospital and hospital systems across the United States. The investigators concluded the following: (a) T2Bacteria demonstrated accuracy, including overall sensitivity of 90% and overall average specificity of 98%; (b) blood culture species identification results took an average of 3 days while T2Bacteria took an average of only 5.4 hours in the clinical trial, providing results more than 2.5 days faster; (c) 66% of patients in the clinical trial with a bloodstream infection confirmed by T2 and blood culture could have benefited from earlier appropriate antibiotics based on the rapid T2Bacteria result. A separate presentation on T2Bacteria at ASM Microbe 2018 by clinicians at Ochsner Medical Center found the following: (a) T2Bacteria detected 14 infections missed by a paired blood culture – but proven to be a true infection by other cultures; (b) T2Bacteria identified every infection detected by blood culture of the target species (100% sensitivity); and (c) T2Bacteria was accurate in identifying samples without an infection, with 99% average specificity. The authors concluded that the advantages of T2Bacteria over blood culture could make it a valuable tool to enable faster time to targeted antibiotic therapy and reduced use of unnecessary antibiotics. Also at ASM Microbe 2018, clinicians from Northwestern University presented its findings that T2Bacteria was more sensitive when compared to blood culture testing and detected 18 clinically important urinary and respiratory infections that were missed by blood culture. The authors concluded that T2Bacteria may improve patient care by providing clinicians rapid and actionable information for treating patients. In November 2015, the Company presented preliminary data demonstrating the ability of our T2Bacteria product candidate to provide the rapid and sensitive identification of certain sepsis-causing bacteria included in the panel, directly from whole blood. The bacteria species included in T2Bacteria are *Staphylococcus aureus*, *Enterococcus faecium*, *Escherichia coli*, *Klebsiella pneumoniae*, *and Pseudomonas aeruginosa*. The five bacteria species in our T2Bacteria Panel are responsible for about half of all septic infections.

At the 2019 ECCMID conference, several clinical presentations were made on our products. These include a poster and podium presentation by Dr. Tom Walsh from New York Presbyterian / Cornell Hospital highlighting the clinical utility of T2Bacteria in the hematologic malignancy and stem cell transplant patient population. Within his institution, T2Bacteria showed a 75% positive predictive agreement with blood culture and 98% negative predictive agreement and covered 80% of significant species detected by blood culture. T2Bacteria could have potentially influenced care and provided an opportunity to place patients with infections that were diagnosed by T2Bacteria but missed by blood culture on effective therapy faster than with culture dependent methods. Another study presented by Maiken Arendrup from Rigshospitalet, Denmark evaluated the performance of T2Candida, Mannan Ag and blood culture for diagnosis of invasive candidiasis infections across 126 patients. The sensitivity for invasive candidiasis was higher for T2Candida compared to blood culture and Mannan Ag and the positive predictive value was highest for T2Candida. A group from Bambino Gesu Pediatrics Hospital in Rome, Italy presented a comparison of T2Candida, SeptiFast and blood culture in pediatric and neonatal patients showing an 89% concordance between blood culture and T2MR. Data were also presented on the new T2Carba Resistance+ Panel (for research use only or “RUO”) by clinicians at Gemelli Hospital in Rome Italy and by scientists from our company. This data shows that T2MR can be used for detection of resistance genes KPC, NDM, OXA-48, VIM, IMP, and AmpC (CMY-2/DHA) in spiked human whole blood at 5 CFU/mL, as well as in clinical samples from patients with bloodstream infections. The clinical data shows that T2MR results for resistance markers can be available on average 25 hours faster than conventional methods and the T2Carba Resistance Panel has a positive predictive agreement with conventional methods greater than 95%.

There are currently eight interventional studies ongoing and four interventional studies scheduled to begin this year, as well as many observational studies ongoing that are evaluating the clinical impact of our tests. In total, we have over two dozen investigator-initiated clinical studies currently running on our direct-from-blood tests for the purposes of demonstrating their clinical utility.

Our T2Candida Panel

Candida is the fourth leading hospital-acquired bloodstream infection, afflicting more than 135,000 patients per year in the United States, and the most lethal form of common bloodstream infections that cause sepsis, with an average mortality rate of approximately 40%. This high mortality rate is largely due to a delay in providing targeted therapy to the patient due to the elapsed time from *Candida* infection to positive diagnosis. According to a study published in Antimicrobial Agents and Chemotherapy, the *Candida* mortality rate can be reduced to 11% with the initiation of targeted therapy within 12 hours of presentation of symptoms. Additionally, a typical patient with a *Candida* infection averages 40 days in the hospital, including nine days in intensive care,

resulting in an average cost per hospital stay of more than $130,000 per patient. In a study published in the American Journal of Respiratory and Critical Care Medicine, providing targeted antifungal therapy within 24 hours of the presentation of symptoms decreased the length of hospital stay by approximately ten days and decreased the average cost of care by approximately $30,000 per patient.

Our DIRECT pivotal clinical trial was designed to evaluate the sensitivity and specificity of T2Candida on the T2Dx instrument. The DIRECT trial consisted of two patient arms: a prospective arm with 1,501 samples from patients with a possible infection and a seeded arm with 300 samples, also obtained from patients with a possible infection. T2Candida and the T2Dx instrument demonstrated a sensitivity of 91.1 percent and a specificity of 99.4 percent. In addition, the speed to a species-specific positive result with T2Candida was 4.4 hours versus 129 hours with blood culture. A negative result from T2Candida was obtained in just 4.2 hours versus greater than 120 hours with blood culture. The data and other information from the DIRECT pivotal clinical trial was published in January 2015 in Clinical Infectious Diseases.

In April 2015, Future Microbiology published the results of an economic study regarding the use of T2Candida conducted by IMS Health, a healthcare economics company. In that economic study, IMS demonstrated that an average hospital admitting 5,100 patients at risk for *Candida* infections could save approximately $5.8 million annually due to decreased hospital stays for patients, reduction in use of antifungal drugs, and other associated savings. The economic study further showed T2Candida can potentially reduce the costs of care by $26,887 per *Candida* patient and that rapid detection of *Candida* reduces patient deaths by 60.6%. Results from a data analysis of T2Candida for the detection and monitoring of *Candida* infection and sepsis were published comparing aggregated results from the use of T2Candida to blood culture-based diagnostics for the detection of invasive candidiasis and candidemia. The analysis included samples acquired from more than 1,900 patients. Out of 55 prospective patient cases that were tested with T2Candida and blood culture and determined to be positive or likely to be positive for a *Candida* infection, T2Candida detected 96.4% of the patients (53 cases) compared to detection of 60% of the patients (33 cases) with blood culture. During 2016, a number of T2Candida users presented data on their experiences with T2Candida which demonstrated both the clinical and economic benefits of use of T2Candida in the diagnostic regimen. The Henry Ford Health System in Detroit, Michigan reported data on a pre- and post-T2Candida implementation analysis that covered 6 months of clinical experience. The data showed a statistically significant ($p = 0.009$) seven day reduction in median Intensive Care Unit ("ICU") length of stay per positive patient that was identified as positive for *Candida* after implementation of T2Candida and a trend ($p = 0.164$) of total hospital length of stay reduction of four days. The data also showed significant reductions in use of antifungal drugs for negative patients tested with T2Candida. The overall economic savings resulting from these clinical benefits was projected to be approximately $2.3 million on an annualized basis. The Lee Health System in Fort Myers, Florida compared patient and economic experience before and after T2Candida implementation. The data demonstrated that in the post-T2Candida cohort, median length of stay for patients with *Candida* infections was reduced by 7 days when detected by T2Candida while unnecessary antifungal therapy was avoided in 41% of patients tested and was discontinued after one dose in another 15% of patients tested. The average economic savings derived solely from reduction in antifungal drug use was $195 per patient tested, net of the cost of T2Candida. Huntsville Hospital in Huntsville, Alabama, reported that the use of T2Candida resulted in a reduction in the duration of therapy and time to de-escalation in patients that tested negative for *Candida* on T2Candida, yielding net pharmacy savings of approximately $280 per patient tested. T2Candida also detected 56% more positive patients than blood culture. Finally, Riverside Community Hospital in Riverside, California, demonstrated improvements in time to appropriate therapy, increased sensitivity, and rapid discontinuation of antifungal therapy when using T2Candida. Specifically, 83% of patients who tested positive with T2Candida received appropriate therapy within six hours of the blood draw and 100% of patients received appropriate therapy in under nine hours. None of the patients who tested positive had been identified to have been treated with antifungals prior to T2Candida testing. In addition, antifungal therapy was discontinued for 100% of the patients who tested negative with T2Candida.

A study presented at ASM Microbe 2018 found that the T2MR technology provided accurate diagnostic results from patient skin samples for *Candida auris*. The study concluded that T2MR could be used to provide a more rapid detection of Candida auris in patient skin swabs.

Recent publications and presentations continue to demonstrate the clinical utility of T2Candida to assess the presence of disease, and continuation of antifungal therapy and resolution of disease despite negative blood cultures. (Ahuja et al. "Combination Antifungal Therapy for Treatment of Candida Parapsilosis Prosthetic Valve Endocarditis and utility of T2Candida Panel: A Case Series" ID Cases 2019; Chaudhry "Tales from the trenches" ID Week 2018.) Additionally, the Open Forum of Infectious Diseases recently published online "Diagnostic performance of T2Candida among ICU patients with risk factors for invasive candidiasis" by Maiken C. Arendrup reported on a multi-center study on 126 intensive care patients with high risk of invasive candidiasis and sepsis testes with T2Candida, blood culture and Candida Mannan Antigen. In this study the best diagnostic performance was observed for a combination of T2Candida and blood culture. Additionally, the authors note that "T2Candida was superior to blood culture and mannan-antigen and may improve diagnosis of patients with invasive candidiasis."

Our T2Bacteria Panel

On May 24, 2018, we received market clearance from the FDA for T2Bacteria, a multiplex diagnostic panel that runs on the T2Dx and detects five major bacterial pathogens (members of the ESKAPE pathogens, as defined below) associated with sepsis and, in conjunction with T2Candida and standard empiric therapy regimens, may enable the early, appropriate treatment of 90% of sepsis patients. T2Bacteria addresses the same approximately 6.75 million symptomatic high-risk patients as T2Candida and also a new population of patients who are at increased risk for bacterial infections, including an additional two million patients presenting with symptoms of infection in the emergency room setting.

On August 4, 2017 we completed a pivotal clinical study of T2Bacteria, which is a qualitative T2MR assay designed for the direct detection of bacterial species in human whole blood specimens from patients with suspected bacteremia. T2Bacteria is designed to identify five species of bacteria directly from human whole blood specimens: *Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa*, and *Staphylococcus aureus.* Outside of the United States, the CE-marked T2Bacteria identifies all 5 of these species along with a 6th species, *Acinetobacter baumannii*.

The performance characteristics of T2Bacteria were evaluated through a series of analytical studies as well as a multi-center clinical study. The clinical study evaluated the performance of T2Bacteria in comparison to the current standard of care, blood culture. All of the data generated in the analytical studies and the clinical study were submitted to the United States Food and Drug Administration, or FDA, in a 510(k) premarket notification on September 8, 2017. T2Bacteria was cleared by the FDA on May 24, 2018.

The clinical study consisted of two arms, a prospective arm and a seeded arm. In the prospective arm, a total of 1,427 subjects were tested at eleven geographically dispersed and demographically diverse sites in the United States. In the seeded arm, 300 specimens of known bacterial composition were evaluated at three sites. Seeded specimens were prepared by spiking whole blood with multiple strains of the bacterial species detected by T2Bacteria at defined concentrations (CFU/mL). Fifty negative blood samples also were evaluated as part of the seeded arm of the study. In total, 1,777 (1,427 prospective specimens and 350 seeded and negative) clinical samples were tested to evaluate the clinical performance of T2Bacteria.

Recently, poster presentations by Dr. Christopher Voigt at ECCMID 2019 and EIM 2019 reported on the performance of T2Bacteria in the emergency department of Ochsner Medical Center and Tampa General Hospital. Data from 137 emergency department patients were evaluated and relative to blood culture, T2Bacteria showed 100% positive percent agreement and 99.2% negative percent agreement. In addition, for species on T2Bacteria, the T2Bacteria assay detected 4 more positive results associated with infection than blood culture, the average time to identification was 56.6 hours faster than blood culture and T2Bacteria covered 70.5% of all species detected by blood culture. A review of the 16 positive results identified by T2Bacteria records revealed, relative to actual care, T2Bacteria could have potentially allowed for focused therapy in 8 patients, potentially reduced time to a species-directed therapy in 4 patients, and potentially reduced time to effective therapy in 4 patients. In this emergency department population, T2Bacteria appeared to be a more rapid and sensitive detector of bacteremia for the most common ESKAPE pathogens (*E. coli*, *E. faecium*, *S. aureus*, *K. pneumoniae*, and *P. aeruginosa*) and showed the theoretical potential to influence subsequent patient therapy, ranging from antibiotic de-escalation to faster time to effective therapy.

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

Our T2 Biosystems Portfolio

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

We believe our products provide a pathway for more rapid and targeted treatment of infections, potentially reducing the mortality rate by as much as 50-75% if a patient is treated within 12 hours of suspicion of infection and significantly reducing the cost burden of sepsis. Each year, approximately 250,000 patients in the United States die from sepsis. According to a study published by *Critical Care Medicine* in 2006, in sepsis patients with documented hypotension, administration of effective antimicrobial therapy within the first hour of detection was associated with a survival rate of 79.9% and, over the ensuing six hours, each hour of delay in initiation of treatment was associated with an average decrease in survival of 7.6%. According to such study, the survival rate for septic patients who remained untreated for greater than 36 hours was approximately 5%. The toll of sepsis on a patient's health can be severe: more than one-in-five patients die within two years as a consequence of sepsis. Sepsis is also the most prevalent and costly cause of hospital readmissions.

We believe our T2 Biosystems Portfolio addresses a significant unmet need in *in vitro* diagnostics by providing:

- **Limits of Detection as Low as 1 CFU/mL.** T2MR is the only technology currently available that can enable identification of sepsis pathogens directly from a patient's blood sample at limits of detection as low as 1 CFU/mL.
- **Rapid and Specific Results in as Few as Three Hours.** T2MR is the only technology that can enable species-specific results for pathogens associated with sepsis, directly from a patient's blood sample, without the need for blood culture, to deliver an actionable result in three hours.
- **Accurate Results Even in the Presence of Antimicrobial Therapy.** T2MR is the only technology that can reliably detect pathogens associated with sepsis, including slow-growing pathogens, such as *C. glabrata*, directly from a patient's blood sample, even in the presence of an antimicrobial therapy.
- **Easy-to-Use Platform.** T2MR eliminates the need for sample purification or extraction of target pathogens, enabling sample- to-result instruments that can be operated on-site by hospital staff, without the need for highly skilled technicians.

Our T2Dx Instrument

Our FDA-cleared T2Dx instrument is an easy-to-use, fully-automated, benchtop instrument utilizing T2MR for use in hospitals and labs for a broad range of diagnostic tests. To operate the system, a patient's sample tube is snapped onto a disposable test cartridge, which is pre-loaded with all necessary reagents. The cartridge is then inserted into the T2Dx instrument, which automatically processes the sample and then delivers a diagnostic test result. Test results are displayed on screen and printed out.

By utilizing our proprietary T2MR technology for direct detection, the T2Dx instrument eliminates the need for sample purification and analyte extraction, which are necessary for other optical-detection devices. Eliminating these sample processing steps increases diagnostic sensitivity and accuracy, enables a broad menu of tests to be run on a single platform, and greatly reduces the complexity of the consumables. The T2Dx instrument incorporates a simple user interface and is designed to efficiently process up to seven specimens simultaneously.

Our T2MR Platform

T2MR is a miniaturized, magnetic resonance-based approach that measures how water molecules react in the presence of magnetic fields. For molecular and immunodiagnostics targets, T2MR utilizes advances in the field of magnetic resonance by deploying particles with magnetic properties that enhance the magnetic resonance signals of specific targets. When particles coated with target-specific binding agents are added to a sample containing the target, the particles bind to and cluster around the target. This clustering changes the microscopic environment of water in that sample, which in turn alters the magnetic resonance signal, or the T2 relaxation signal that we measure, indicating the presence of the target.

We believe that T2MR can also address the significant unmet need associated with Lyme disease, a tick-borne illness that can cause prolonged neurological disease and musculoskeletal disease. For patients with Lyme disease, early diagnosis and appropriate treatment significantly reduces both the likelihood of developing neurological and musculoskeletal disorders, as well as the significant costs associated with treating these complications. Our product candidate, T2Lyme, will identify the bacteria that cause Lyme disease directly from the patient's blood, without the need for blood culture which, for the bacteria associated with Lyme disease, can take several weeks. Our Lyme product candidate is currently in development and we initiated a T2Lyme clinical trial in May 2018.

We have also developed the T2Resistance Panel, a product candidate that detects 13 resistance genes from both gram-positive and gram-negative pathogens. These targets include the most clinically important carbapenem resistance genes (KPC, OXA-48, NDM, VIM, IMP), which are listed on the CDC Urgent Threat list for antibiotic resistance; CTXM-14 and CTXM-15, a major source of extended spectrum beta lactamases (ESBLs); AmpC beta-lactamase genes (CMY, DHA); detection of *vanA/B* resistance genes, which are responsible for vancomycin resistant gram-positive enterococcus; and the detection of the methicillin resistance genes *mecC* and *mecA*, which cause methicillin resistant Staphylococcus aureus (MRSA). Initial clinical performance data demonstrates the carbapenemase targets on the T2Resistance Panel identify these resistance genes with an average time of 5.3 hours compared to an average of 30 hours (and up to 95 hours) with conventional methods. Antibiotic resistance is recognized by the WHO as 'one of the biggest threats to global health, food security, and development today'. We believe the T2Resistance Panel has the potential to prevent the spread of multidrug-resistant organisms and improve patient outcomes by enabling rapid identification of the genes and species associated with antibiotic resistance – enabling the reduction of unnecessary antibiotic use which is the primary cause of antibiotic resistance. Most importantly, these tests can enable more patients to get on the right targeted therapy quicker, potentially reducing mortality and hospitalization cost. Finally, these tests could also be used to accelerate clinical trials for new antibiotics and reduce the time to commercial availability. We expect the T2Resistance Panel to be available for research use only in the United States and receive a CE mark for commercial availability in Europe by the end of 2019.

The T2Dx Instrument also has the ability to ability to enable high-sensitivity, culture-independent detection of pathogens at ultra-high sensitivity in ultra-low concentrations for five biothreat pathogens, including *Bacillus anthracis (anthrax), Burkholderia spp., Rickettsia prowazekii, Francisella tularensis* and *Yersinia pestis*. The U.S. Department of Homeland Security has defined these as biothreat pathogens because they require quick antibiotic treatment and can be difficult to diagnose due to non-distinguishing symptoms, making the development and availability of rapid, high-throughput, high-sensitivity diagnostics for these biothreat pathogens a national priority. Rapid, ultra-high sensitivity diagnosis with T2MR will help discriminate the infected from the non-infected, reducing the spread of disease and impact of a bioweapon event.

In addition, we now have data that demonstrates potential support for a T2MR test panel that could potentially report greater than 40 reported results covering greater than 99% of infections caused by blood-borne bacterial and fungal pathogens. This panel includes "pan-level" channels that detect greater than 250 pathogen species with detection at less than or equal to 10 CFU/mL. Additionally, this panel provides coverage for all blood-borne antibiotic resistance threats identified by the CDC.

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

US Government Contract

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

Financial Overview

Revenue

We generate revenue from the sale of our products, related services, reagent rental agreements and from activities performed pursuant to research and development agreements.

Revenue earned from activities performed pursuant to research and development agreements is reported as research revenue and is recognized over time, using an input method as the work is completed, limited to payments earned. Costs incurred to deliver the services are recorded as research and development expense in the condensed consolidated financial statements. The timing of receipt of cash from the Company's research and development agreements generally differs from when revenue is recognized. Milestones are contingent on the occurrence of future events and are considered variable consideration being constrained until the Company believes a significant revenue reversal will not occur.

Grants received, including cost reimbursement agreements, are assessed to determine if the agreement should be accounted for as an exchange transaction or a contribution. An agreement is accounted as a contribution if the resource provider does not receive commensurate value in return for the assets transferred. Contribution revenue is recognized when all donor-imposed conditions have been met.

Product revenue is derived from the sale of our instruments and related consumable diagnostic tests, predominantly through our direct sales force in the United States, and distributors in geographic regions outside the United States. We do not offer product return or exchange rights (other than those relating to defective goods under warranty) or price protection allowances to our customers, including our distributors. Payment terms granted to distributors are the same as those granted to end-user customers and payments are not dependent upon the distributors' receipt of payment from their end-user customers. 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 the instrument is directly purchased by a customer, the Company recognizes revenue when the related performance obligation is satisfied (i.e. when the control of an instrument has passed to the customer; typically, at shipping point). When the instrument is placed under a reagent rental agreement, the Company's customers generally agree to fixed term agreements, which can be extended, certain of which may include minimum purchase commitments and/or incremental charges on each consumable diagnostic test purchased, which varies based on the volume of test cartridges purchased. Revenue from the sale of consumable diagnostic tests (under a reagent rental agreement), which includes the incremental charge, is recognized upon shipment. Revenue associated with reagent rental consumable purchases is currently classified as variable consideration and constrained until a purchase order is received and related performance obligations have been satisfied (or partially satisfied). The transaction price from consumables purchases is allocated between the lease of the instrument (under a contingent rent methodology as provided for in ASC 842), and the consumables when related performance obligations are satisfied as a component of lease and product revenue.

Direct sales of instruments include warranty, maintenance and technical support services typically for one year following the installation of the purchased instrument ("Maintenance Services"). Maintenance Services are separate performance obligations as they are service based warranties and are recognized straight-line over the service delivery period. After the completion of the initial Maintenance Services period, customers have the option to renew or extend the Maintenance Services typically for additional one-year periods in exchange for additional consideration. The extended Maintenance Services are also service based warranties and classified as separate performance obligations. The Company will recognize the revenue allocated to the extended Maintenance Services performance obligation straight-line over the service delivery period. The Company warrants that consumable diagnostic tests will be free from defects, when handled according to product specifications, for the stated life of the product. To fulfill valid warranty claims, the Company provides replacement product free of charge. Accordingly, the Company accrues warranty expense associated with the estimated defect rates of the consumable diagnostic tests.

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

Our consumable diagnostic tests can only be used with our instruments, and accordingly, as we expect the installed base of our instruments to continue to grow, we expect the following to occur:

- recurring revenue from our consumable diagnostic tests will increase and become subject to lower period-to-period fluctuation;
- consumable revenue will become an increasingly predictable and important contributor to our total revenue; and
- we will gain economies of scale through the growth in our sales, resulting in improving gross margins and operating margins.

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 continue to represent a high percentage of our product revenue as we continue to invest in our manufacturing capabilities, infrastructure and customer service organization and grow our installed customer base. We plan to continue to expand our capacity to support our growth, which will result in higher cost of revenue in absolute dollars. However, we expect cost of product revenue, as a percentage of revenue, to decline as revenue grows in the future.

Research and development expenses

Our research and development expenses consist primarily of costs, incurred for the development of our technology and product candidates, technology improvements and enhancements, clinical trials to evaluate the clinical utility of our product candidates, and laboratory development and expansion, and include salaries and benefits, including stock-based compensation, research-related facility and overhead costs, laboratory supplies, equipment and contract services. Research and development expenses also include costs of delivering products or services associated with research revenue. We expense all research and development costs as incurred.

We anticipate our overall research and development expenses to be flat to a slight increase due to the anticipation of additional research partnerships. Research and development costs include costs to support research partnerships, clinical trials and new product development. We have committed, and expect to commit, significant resources toward developing additional product candidates, improving existing products, conducting ongoing and new clinical trials and expanding our laboratory capabilities.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of costs for our sales and marketing, finance, legal, human resources, business development and general management functions, as well as professional services, such as legal, consulting and accounting services. We expect selling, general and administrative expenses to increase in future periods as we commercialize products and future product candidates and as our needs for sales, marketing and administrative personnel grow. Other selling, general and administrative expenses include facility-related costs, fees and expenses associated with obtaining and maintaining patents, clinical and economic studies and publications, marketing expenses, and travel expenses. We expense all selling, general and administrative expenses as incurred.

Interest expense, net

Interest expense, net, consists primarily of interest expense on our notes payable, changes in fair value of our derivative liability and the amortization of deferred financing costs and debt discount, partially offset by interest earned on our cash and cash equivalents.

Other income, net

Other income, net, consists of dividend and other investment income, and government grant income.

Critical Accounting Policies and Use of Estimates

We have prepared our condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States. Our preparation of these condensed consolidated financial statements requires us to make estimates, assumptions, and judgments that affect the reported amounts of assets, liabilities, expenses, and related disclosures at the date of the condensed consolidated financial statements, as well as revenue and expenses recorded during those periods. We evaluated our estimates and judgments on an ongoing basis. We based our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions.

The items that we disclosed as our critical accounting policies and estimates in Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2018 remained materially consistent, other than the January 1, 2019 adoption of ASC 842, *Leases* ("ASC 842") (Note 2). 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, 2018.

Results of Operations for the Three Months Ended September 30, 2019 and 2018

	Three Months Ended September 30,		
	2019	2018	Change
	(in thousands)		
Revenue:			
Product revenue	$ 1,177	$ 1,218	$ (41)
Research revenue	56	1,248	(1,192)
Contribution revenue	444	—	444
Total revenue	1,677	2,466	(789)
Costs and expenses:			
Cost of product revenue	3,944	3,042	902
Research and development	4,098	2,725	1,373
Selling, general and administrative	5,981	5,873	108
Total costs and expenses	14,023	11,640	2,383
Loss from operations	(12,346)	(9,174)	(3,172)
Interest expense, net	(1,876)	(1,836)	(40)
Other income, net	51	243	(192)
Net loss	$ (14,171)	$ (10,767)	$ (3,404)

Product revenue

Product revenue was $1.2 million for the three months ended September 30, 2019 and 2018.

Research revenue

Research revenue was $0.1 million for the three months ended September 30, 2019, compared to $1.2 million for the three months ended September 30, 2018, a decrease of $1.1 million. The decrease primarily was the result of $0.5 million less revenue recognized related to our Co-Development Agreement with Allergan Sales, which completed in October 2018, and $0.1 million less revenue from services delivered under our Co-Development Agreement with Canon Life Sciences. Research revenue for the three months ended September 30, 2018 included $0.4 million from our cost-sharing agreement with CARB-X. Revenue from our cost-sharing agreement with CARB-X, for the three months ended September 30, 2019, is recorded as contribution revenue, a result of adopting a new accounting standard.

Contribution revenue

Contribution revenue of $0.4 million, for the three months ended September 30, 2019, relates to our cost-sharing agreement with CARB-X and our US Government Contract, which began in September 2019. Revenue related to our cost-sharing agreement with CARB-X, for the three months ended September 30, 2018, was recorded as research revenue.

Cost of product revenue

Cost of product revenue was $3.9 million for the three months ended September 30, 2019, compared to $3.0 million for the three months ended September 30, 2018, an increase of $0.9 million driven primarily by unabsorbed manufacturing overhead capacity offset in part by reduced consumables scrap rates from improved manufacturing processes.

Research and development expenses

Research and development expenses were $4.1 million for the three months ended September 30, 2019, compared to $2.7 million for the three months ended September 30, 2018, an increase of $1.4 million. The increase was driven by higher R&D materials cost of $0.8 million due to increased R&D activity, increased travel of $0.2 and payroll of $0.2 million. Increased travel and payroll are the result of higher headcount. Research and development expense also increased $0.2 million from higher lab expenses associated with research and development projects.

Selling, general and administrative expenses

Selling, general and administrative expenses were $6.0 million for the three months ended September 30, 2019, compared to $5.9 million for the three months ended September 30, 2018, an increase of $0.1 million driven by $0.7 million higher wages and travel associated with the medical science liaison team, $0.5 million of costs to recover from the cyber-attack, $0.2 million for insurance, offset by $0.7 million reduced stock compensation expense due to the vesting of restricted stock units with market conditions, causing acceleration of expense, during the nine months ended September 30, 2018, $0.4 million lower incentive compensation associated with revenue performance, and $0.1 million reductions in tradeshow spending and other expense reductions.

Interest expense, net

Interest expense, net, was $1.9 million for the three months ended September 30, 2019, compared to $1.8 million for the three months ended September 30, 2018, an increase of $0.1 million.

Other income, net

Other income, net, was $0.1 million for the three months ended September 30, 2019 compared to $0.2 million for the three months ended 2018.

Results of Operations for the Nine Months Ended September 30, 2019 and 2018

	Nine Months Ended September 30,		
	2019	2018	Change
	(in thousands)		
Revenue:			
Product revenue	$ 3,765	$ 3,486	$ 279
Research revenue	269	5,222	(4,953)
Contribution revenue	1,232	—	1,232
Total revenue	5,266	8,708	(3,442)
Costs and expenses:			
Cost of product revenue	13,153	9,773	3,380
Research and development	12,047	11,193	854
Selling, general and administrative	19,756	19,238	518
Total costs and expenses	44,956	40,204	4,752
Loss from operations	(39,690)	(31,496)	(8,194)
Interest expense, net	(5,658)	(4,910)	(748)
Other income, net	383	402	(19)
Net loss	$ (44,965)	$ (36,004)	$ (8,961)

Product revenue

Product revenue was $3.8 million for the nine months ended September 30, 2019 compared to $3.5 million for the nine months ended September 30, 2018, an increase of $0.3 million. The increase was driven by higher T2Dx instrument sales.

Research revenue

Research revenue was $0.3 million for the nine months ended September 30, 2019, compared to $5.2 million for the nine months ended September 30, 2018, a decrease of $4.9 million. The decrease was primarily the result of $2.8 million less of revenue recognized related to our Co-Development Agreement with Allergan Sales, which completed in October 2018, and $1.2 million less of revenue recognized under our Co-Development Agreement with Canon US Life Sciences, a result of achieving a $2.0 million milestone during the nine months ended September 30, 2018. Research revenue for the nine months ended September 30, 2018 included $0.9 million from our cost-sharing agreement with CARB-X. Revenue from our cost-sharing agreement with CARB-X for the nine months ended September 30, 2019 is recorded as contribution revenue, a result of adopting a new accounting standard.

Contribution revenue

Contribution revenue of $1.2 million, for the nine months ended September 30, 2019, relates to our cost-sharing agreement with CARB-X of $0.9 million and our US Government Contract of $0.3 million, which began in September 2019. Revenue related to our cost-sharing agreement with CARB-X for the nine months ended September 30, 2018 was recorded as research revenue.

Cost of product revenue

Cost of product revenue was $13.2 million for the nine months ended September 30, 2019, compared to $9.8 million for the nine months ended September 30, 2018, an increase of $3.4 million. The increase in cost was driven by $1.1 million of reagent rental placement costs from higher placements, $0.8 from higher consumables and instrument sales volumes, $0.6 million manufacturing scrap incurred before the improved consumables manufacturing process, $0.5 service repairs to a growing reagent rental instrument base and $0.4 in instrument design change costs.

Research and development expenses

Research and development expenses were $12.0 million for the nine months ended September 30, 2019, compared to $11.2 million for the nine months ended September 30, 2018, an increase of $0.8 million. The increase was attributed to increased payroll expenses of $0.4 million and increased travel expenses of $0.2 million due to higher headcount. Research and development expense also increased $0.2 million from higher lab expenses associated with research and development projects.

Selling, general and administrative expenses

Selling, general and administrative expenses were $19.8 million for the nine months ended September 30, 2019, compared to $19.2 million for the nine months ended September 30, 2018, an increase of $0.6 million. The increase was attributed to increased payroll expenses of $1.8 million and increased travel expenses of $0.4 million due to an increase in medical affairs personnel, $0.5 million for systems restoration from the cyber-attack and $0.2 million for insurance and other expenses. The increase was partially offset by a $2.3 million decrease in stock compensation expense due to the vesting of restricted stock units with market conditions, causing acceleration of expense, during the nine months ended September 30, 2018.

Interest expense, net

Interest expense, net, was $5.7 million for the nine months ended September 30, 2019, compared to $4.9 million for the nine months ended September 30, 2018, an increase of $0.8 million, primarily due to the change in fair value of the derivative.

Other income, net

Other income, net, was $0.4 million for the nine months ended September 30, 2019 and 2018.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception, and as of September 30, 2019 and December 31, 2018 we had an accumulated deficit of $362.1 million and $317.2 million respectively. Having obtained clearance from the FDA and a CE mark in Europe to market the T2Dx, T2Candida, and T2Bacteria, the Company has incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution. The Company may seek to fund its operations through public equity or private equity or debt financings, as well as other sources. However, the Company may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. The Company's failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on the Company's business, results of operations and financial condition and the Company's ability to develop and commercialize T2Dx, T2Candida, T2Bacteria, and other product candidates.

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

Equity Distribution Agreement

On July 30, 2019, the Company entered into an Equity Distribution Agreement (the "Sales 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 $30.0 million from time to time through Canaccord.

Sales of the shares pursuant to the Sales Agreement, if any, may be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act, including sales made directly on or through The Nasdaq Global Market or any other existing trading market for the Shares, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices and/or any other method permitted by law. The Company intends to use the net proceeds from the offering for working capital and general corporate purposes, which may include, among other things, commercialization and research and development expenses and capital expenditures. The Company is not obligated to make any sales of Shares under the Sales Agreement. The Company or Canaccord may suspend or terminate the offering of Shares upon notice to the other party, subject to certain conditions. Canaccord will act as sales agent on a commercially reasonable efforts basis consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of Nasdaq.

The Company has agreed to pay Canaccord for its services of acting as agent 3% of the gross proceeds from the sale of the Shares pursuant to the Sales Agreement. The Company has also agreed to provide Canaccord with customary indemnification and contribution rights. At September 30, 2019, legal and accounting fees associated with the Sales Agreement were immaterial. Legal and accounting fees are expected to be reclassified to share capital upon issuance of shares under the Sales Agreement.

This Quarterly Report on Form 10-Q shall not constitute an offer to sell or a solicitation of an offer to buy any securities, nor shall there be any sale of these securities in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

Purchase Agreement

On July 29, 2019, the Company entered into a $30.0 million purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which the Company may sell and issue to Lincoln Park, and Lincoln Park is obligated to purchase, up to $30.0 million in value of its shares of common stock from time to time over a 36-month period starting from the effective date of the respective registration statement.

The Company may direct Lincoln Park, at its sole discretion, and subject to certain conditions, to purchase up to 200,000 shares of common stock on any business day, provided that at least one business day has passed since the most recent purchase. The amount of a purchase may be increased under certain circumstances provided, however, that Lincoln Park's committed obligation under any single purchase shall not exceed $2.0 million. The purchase price of shares of common stock related to the future funding will be based on the then prevailing market prices of such shares at the time of sales as described in the Purchase Agreement.

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

Plan of operations and future funding requirements

As of September 30, 2019 and December 31, 2018 we had unrestricted cash and cash equivalents of approximately $16.2 million and $50.8 million respectively. Currently, our funds are primarily held in money market funds invested in U.S. government agency securities. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, costs related to our products, clinical trials, laboratory and related supplies, supplies and materials used in manufacturing, legal and other regulatory expenses and general overhead costs.

Until such time as we can generate substantial product revenue, we expect to finance our cash needs, beyond what is currently available or on hand, through a combination of equity offerings, debt financings and revenue from existing and potential research and development and other collaboration agreements. If we raise additional funds in the future, we may need to relinquish valuable rights to our technologies, future revenue streams or grant licenses on terms that may not be favorable to us.

Going Concern

Our ability to continue operations after September 30, 2019 will depend on our ability to obtain additional funding, as to which no assurances can be given. These conditions raise substantial doubt about our ability to continue as a going concern. There can be no assurance that any financing by us can be realized, or if realized, what the terms of any such financing may be, or that any amount that we are able to raise will be adequate.

We believe that our existing cash and cash equivalents at September 30, 2019, along with funding available through our Sales Agreement with Canaccord and Purchase Agreement with Lincoln Park, will be sufficient to allow us to fund our current operating plan at least a year from the issuance of these financial statements. Should our current operating plan not materialize, Management's plans include raising additional funding, earning milestone payments pursuant to the Company's Co- Development agreements, delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels for the Company to continue as a going concern for a period of 12 months from the date the financial statements are issued. Management has concluded the likelihood that its plan to obtain sufficient funding from one or more of these sources or adequately reduce expenditures will be successful, while reasonably possible, is less than probable. The Term Loan Agreement requires us to achieve certain annual revenue targets, whereby we are required to pay double the amount of any shortfall as an acceleration of principal payments, and maintain a minimum liquidity amount. Should we fall short of the revenue target we would seek a waiver of this provision. There can be no assurances that we would be successful in obtaining a waiver. We are also required to maintain a minimum cash balance under our Term Loan Agreement with CRG.

Cash flows

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

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (35,242)	$ (30,450)
Investing activities	(735)	(950)
Financing activities	1,385	49,746
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (34,592)	$ 18,346

Net cash used in operating activities

Net cash used in operating activities was approximately $35.2 million for the nine months ended September 30, 2019, and consisted of a net loss of $44.9 million adjusted for non-cash items including stock-based compensation expense of $4.5 million, depreciation and amortization expense of $1.7 million, non-cash interest expense of $1.8 million, amortization of operating lease right-of-use assets of $1.1 million, a change in the fair value of the derivative instrument of $0.5 million, and a net change in operating assets and liabilities of $0.3 million, primarily related to an increase in accounts payable of $2.7 million due to timing of payments, an increase in accrued expenses of $1.3 million due to timing of interest payments, a decrease in accounts receivable of $0.2 million due to less outstanding instrument invoices and partially offset by a decrease in operating lease liabilities of $1.7 million, a decrease in deferred revenue of $0.1 million, an increase in prepaid expenses and other assets of $0.6 million primarily related to tradeshows and insurance and a $1.5 million increase in instrument inventories to meet anticipated demand.

Net cash used in operating activities was approximately $30.5 million for the nine months ended September 30, 2018, and consisted of a net loss of $36.0 million adjusted for non-cash items including stock-based compensation expense of $7.5 million, depreciation and amortization expense of $1.9 million, non-cash interest expense of $1.7 million, an impairment charge of $0.2 million, offset by a change in the fair value of the derivative instrument of $0.2 million, deferred rent of $0.2 million, and a net change in operating assets and liabilities of $5.3 million, primarily related to an increase in accounts receivable of $1.3 million from increased instrument sales and our cost-sharing agreement with CARB-X, a decrease in accrued expenses and accounts payable of $0.8 million due to clinical, bonus and professional fees, a decrease in deferred revenue of $0.8 million primarily from our Co-Development Agreement with Allergan Sales, LLC, and an increase in prepaid expenses and other assets of $1.3 million.

Net cash used in investing activities

Net cash used in investing activities was approximately $0.7 million for the nine months ended September 30, 2019, and consisted of costs to acquire property and equipment.

Net cash used in investing activities was approximately $1.0 million for the nine months ended September 30, 2018, and consisted of costs to acquire property and equipment.

Net cash used in / provided by financing activities

Net cash provided by financing activities was approximately $1.4 million for the nine months ended September 30, 2019, and consisted of repayments of finance leases of $0.9 million, partially offset by proceeds from issuance of common stock of $0.4 million and $1.9 million proceeds from secondary offering.

Net cash provided by financing activities was approximately $49.7 million for the nine months ended September 30, 2018, and consisted primarily of the net proceeds from the June 2018 public offering of $49.2 million and proceeds from the exercise of stock options of $1.6 million, which were partially offset by $1.1 million of repayments of notes payable.

Borrowing Arrangements

Term Loan Agreement

In December 2016, we entered into a Term Loan Agreement (the "Term Loan Agreement") with CRG. We borrowed $40.0 million pursuant to the Term Loan Agreement, which has a six-year term with four years of interest-only payments (through December 30, 2020), after which quarterly principal and interest payments will be due through the December 30, 2022 maturity date. Interest on the amounts borrowed under the Term Loan Agreement accrues at an annual fixed rate of 11.5%, 3.5% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount. In addition, if we achieve certain financial performance metrics, the loan will convert to interest-only until the December 30, 2022 maturity, at which time all unpaid principal and accrued unpaid interest will be due and payable. We are required to pay CRG a financing fee based on the loan principal amount drawn. We are also required to pay a final payment fee of 8.0% 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 September 30, 2019 and December 31, 2018 on the balance sheet.

We may prepay all or a portion of the outstanding principal and accrued unpaid interest under the Term Loan Agreement at any time upon prior notice subject to a 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 our assets, including intellectual property. The Term Loan Agreement also contains customary affirmative and negative covenants for a credit facility of this size and type. The Term Loan Agreement also requires us to achieve certain revenue targets, whereby we are required to pay double the amount of any shortfall as an acceleration of principal payments.

In connection with the Term Loan Agreement, we issued to CRG warrants to purchase a total of 528,958 shares of common stock in December 2016. The warrants are exercisable any time prior to December 30, 2026 at an original price of $8.06 per share, with typical provisions for termination upon a change of control or sale of all or substantially all of our assets.

In March 2019, the Term Loan Agreement was amended to reduce the 2019 minimum revenue target to $9.0 million and delete the 2018 revenue covenant. In exchange for the amendment, we agreed to reset the strike price of the warrants issued in connection with the Term Loan Agreement, from $8.06 per share to $4.35 per share. The fair value of the warrants was determined by the Black-Scholes-Merton option pricing model, with an amended fair value of $0.9 million. The incremental fair value of the modified instrument of $0.1 million was recorded as debt discount and additional paid-in-capital.

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

amended warrants was determined by the Black-Scholes-Merton option pricing model. The incremental fair value of the amended warrants of $0.1 million and the fair value of the new warrants of $0.7 million were recorded as debt discount and additional paid-in-capital.

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, as there have been no such events. We believe the likelihood of CRG exercising this right is remote.

We assessed the terms and features of the Term Loan Agreement, including the interest-only period and the acceleration of the obligations under the Term Loan Agreement under an event of default, 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 these features are not clearly and closely related to the host instrument, and represent a single compound derivative that is required to be re-measured at fair value on a quarterly basis.

The fair value of the derivative at September 30, 2019 and December 31, 2018 is $2.6 million and $2.1 million, respectively. We classified the derivative liability as accrued expenses and other current liabilities on the balance sheet at September 30, 2019 and December 31, 2018 to match the classification of the related Term Loan Agreement.

Equipment Lease Credit Facility

In October 2015, we signed the $10.0 million Credit Facility (the “Credit Facility”) with Essex Capital Corporation (“Essex”) to fund capital equipment needs. As one of the conditions of the Term Loan Agreement, the Credit Facility is capped at a maximum of $5.0 million. Under the Credit Facility, Essex will fund capital equipment purchases presented by us. We will repay the amounts borrowed in 36 equal monthly installments from the date of the amount funded. At the end of the 36 month lease term, we have the option to (a) repurchase the leased equipment at the lesser of fair market value or 10% of the original equipment value, (b) extend the applicable lease for a specified period of time, which will not be less than one year, or (c) return the leased equipment to the Lessor.

In April 2016 and June 2016, we completed the first two draws under the Credit Facility of $2.1 million and $2.5 million, respectively. We made monthly payments of $67,000 under the first draw and $79,000 under the second draw. The borrowings under the Credit Facility were treated as finance leases and are included in property and equipment on the balance sheet. The amortization of the assets conveyed under the Credit Facility is included as a component of depreciation expense. During the three months ended September 30, 2019, the Company repurchased the equipment for $0.3 million in accordance with the terms of the Credit Facility.

Contractual Obligations and Commitments

On July 30, 2019, the Company announced that founding CEO John McDonough was named Executive Chairman of the Board, effective immediately, and that the Company was undertaking a national search for a new CEO. Once that candidate is identified, Mr. McDonough will become non-executive Chairman of the Board. Mr. McDonough will continue in the role of CEO and Executive Chairman until his successor is in place. A successor has not been named. Transition payments and health benefits under the terms of the agreement are estimated to be approximately $1.0 million, which will be paid over the 15 month period following the successor’s start date, and will be classified as selling, general and administrative expense over the anticipated period of the national search, estimated to be 8 months. Such expenses were immaterial for the three and nine months ended September 30, 2019.

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, 2018.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk related to changes in interest rates. As of September 30, 2019 and December 31, 2018, we had cash and cash equivalents of $16.2 million and $50.8 million, respectively, held primarily in money market funds consisting of U.S. government agency securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate one percent change in interest rates would not have a material effect on the fair market value of our portfolio. As of September 30, 2019 and December 31, 2018, we had no outstanding debt exposed to variable market interest rates.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

Management of the Company, with the participation of the Chief Executive Officer and the Chief Financial Officer, evaluated the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of September 30, 2019. 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 September 30, 2019. 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 September 30, 2019, 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 the quality, frequency and periodic testing of the backup of the Company's Information Systems ("IT") data.

The Company backs up IT data monthly to a tape system and stores the tapes offsite in a secure location for use in data recovery such as in response to the cyber-attack described in this Form on 10-Q. However, Management determined that the frequency of the backup, monthly, presents a potential loss of data that takes an inordinate amount of time to recover, in this instance preventing the Company from filing this report on Form 10-Q timely without filing an extension. Furthermore, Management determined that semi-annual data recovery testing to a secure environment to insure the integrity and recoverability of the data, were not performed. Because these tests were not performed, the Company did not detect flaws in the backup data timely and this flawed data required a lengthy data recovery process which delayed the Company's ability to prepare timely and accurate financial statements. Based upon this evaluation, the Chief Executive Officer and the Chief Financial Officer have concluded that the Company's disclosure controls and procedures were not effective as of September 30, 2019.

We are developing and implementing new control processes and procedures to address this weakness. We have upgraded our tape backup system, we are implementing redundant cloud-based backup processes and we are increasing the frequency of backup to minimize data loss to shorter timeframes of days versus a month. We are implementing a semi-annual data recovery process to a secure environment to ensure data integrity.

(b) Changes in Internal Control over Financial Reporting

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

PART II.
OTHER INFORMATION

Item 1. Legal Proceedings

We may be from time to time subject to various claims and legal actions during the ordinary course of our business. There are currently no claims or legal actions, individually or in the aggregate, that would have a material adverse effect on our results of operations or financial condition.

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2018, which could materially affect our business, financial condition or future results. There have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018.

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

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

On July 30, 2019, the Company announced that founding CEO John McDonough was named Executive Chairman of the Board, effective immediately, and that the Company was undertaking a national search for a new CEO. Once that candidate is identified, Mr. McDonough will become non-executive Chairman of the Board. Mr. McDonough will continue in the role of CEO and Executive Chairman until his successor is in place. A successor has not been named.

Item 6. Exhibits, Financial Statement Schedules

Exhibit Number	Exhibit Description
3.1	Restated Certificate of Incorporation of the Company, as amended (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36571) filed on August 12, 2014)
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 of the Company's Form 8-K (File No. 001-36571) filed on August 12, 2014)
10.1*†	Amendment No. 5 to Term Loan Agreement, dated as of September 10, 2019, by and among the Company, CRG Servicing LLC and the lenders listed on the signature pages thereto
10.2*†	Contract, dated as of September 6, 2019, by and between the Company and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services
31.1*	Certification of principal executive officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of principal financial officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.1*	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, formatted in XBRL: (i) Condensed Consolidated Balance Sheets (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited), (iii) Condensed Consolidated Statements of Cash Flows (unaudited), and (v) Notes of Condensed Consolidated Financial Statements.

* Filed herewith

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Regulation S-K Item 601(b)(10). Such omitted information is not material and would likely cause competitive harm to the registrant if publicly disclosed

** Furnished herewith

SIGNATURES

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

T2 BIOSYSTEMS, INC.

Date: November19, 2019

By: /s/ JOHN MCDONOUGH
John McDonough
Executive Chairman, Chief Executive Officer and Director
(principal executive officer)

Date: November19, 2019

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

EXECUTION VERSION

AMENDMENT NO. 5 TO TERM LOAN AGREEMENT

THIS AMENDMENT NO. 5 TO TERM LOAN AGREEMENT, dated as of September 10, 2019 (this "***Amendment***") is made among T2 BIOSYSTEMS, INC., a Delaware corporation ("***Borrower***"), the other Obligors party hereto, CRG SERVICING LLC, as administrative agent and collateral agent (in such capacities, "***Administrative Agent***") and the lenders listed on the signature pages hereof under the heading "LENDERS" (each, a "***Lender***" and, collectively, the "***Lenders***"), with respect to the Loan Agreement described below.

RECITALS

WHEREAS, Borrower, Administrative Agent and the Lenders are parties to the Term Loan Agreement, dated as of December 30, 2016, with the Subsidiary Guarantors from time to time party thereto (as amended by Amendment No. 1 to Term Loan Agreement, dated as of March 1, 2017, among Borrower, Administrative Agent and the lenders party thereto, as further amended by Amendment No. 2 to Term Loan Agreement, dated as of December 18, 2017, among Borrower, Administrative Agent and the lenders party thereto, as further amended by Amendment No. 3 to Term Loan Agreement, dated as of March 16, 2018, and as further amended by Amendment No. 4 to Term Loan Agreement, dated as of March 13, 2019, among Borrower, Administrative Agent and the lenders party thereto, and as further amended, supplemented or modified to date, the "***Loan Agreement***"); and

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

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

SECTION 1. Definitions; Interpretation.

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

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

SECTION 2. Amendments to Loan Agreement. Subject to **Section 3** of this Amendment, the Loan Agreement is hereby amended as follows:

(a) The following definition in **Section 1.01** of the Loan Agreement is hereby amended and restated in their entirety:

"***Interest-Only Period***" means the period from and including the first Borrowing Date and through and including the twentieth (20th) Payment

Date following the first Borrowing Date; provided that if Borrower achieves the Market Cap Milestone and so long as no Default or Event of Default has occurred and is continuing, the Interest-Only Period shall be extended through and including the twenty-third (23rd) Payment Date following the first Borrowing Date.

(b) **Section 10.02(c)** of the Loan Agreement is hereby amended and restated in its entirety as follows:

(c) during the twelve month period beginning on January 1, 2019, of at least $[****];

(c) **Section 10.02(d)** of the Loan Agreement is hereby amended and restated in its entirety as follows:

(d) during the twenty-four month period beginning on January 1, 2019, of at least $[****];

(d) **Section 10.02(e)** of the Loan Agreement is hereby amended and restated in its entirety as follows:

(e) during the twenty-four month period beginning on January 1, 2020, of at least $[****];

(e) **Annex B** of **Exhibit E** of the Loan Agreement is hereby amended and restated in its entirety by **Annex B to Compliance Certificate** attached hereto as **Exhibit A.**

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

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

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

(c) Borrower and Administrative Agent shall have duly executed and delivered that certain Amendment to Fee Letter;

(d) Borrower shall have delivered to Administrative Agent amendments to each Warrant delivered prior to the date hereof that reduce the Exercise Price (as defined in each such Warrant), in each case in the form attached hereto as **Exhibit B** and duly executed by Borrower;

(e) Borrower shall have delivered to Administrative Agent, for the Lenders, new Warrants, in each case in the form attached hereto as **Exhibit C** and duly executed by Borrower

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

(for such number of shares as indicated opposite each Holder's (as defined in each such Warrant) name on **Schedule I** attached hereto); and

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

SECTION 4. Representations and Warranties; Reaffirmation.

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

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

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

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

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

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

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

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

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

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

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

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

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

SECTION 7. Miscellaneous.

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

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

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

(d) **Integration**. This Amendment constitutes a Loan Document and, together with the other Loan Documents, incorporates all negotiations of the parties hereto with respect to the subject matter hereof and is the final expression and agreement of the parties hereto with respect to the subject matter hereof.

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

(f) **Controlling Provisions**. In the event of any inconsistencies between the provisions of this Amendment and the provisions of any other Loan Document, the provisions of this

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

Amendment shall govern and prevail. Except as expressly modified by this Amendment, the Loan Documents shall not be modified and shall remain in full force and effect.

[Remainder of page intentionally left blank]

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

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

BORROWER:

T2 BIOSYSTEMS, INC.

By: /s/ John McDonough
Name: John McDonough
Title: Chief Executive Officer

[Signature Page to Amendment No. 5 to Term Loan Agreement]

ADMINISTRATIVE AGENT:

CRG SERVICING LLC

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

LENDERS:

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

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

CRG PARTNERS III (CAYMAN) UNLEV AIV I L.P.

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

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

Witness: /s/ Nicole Nesson

Name: Nicole Nesson

CRG ISSUER 2017-1
By CRG SERVICING LLC, acting by power of attorney

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

[Signature Page to Amendment No. 5 to Term Loan Agreement]

Annex B to Compliance Certificate

CALCULATIONS OF FINANCIAL COVENANT COMPLIANCE

I.	**Section 10.01: Minimum Liquidity**	
A.	Amount of unencumbered (other than Liens securing the Obligations and Liens permitted pursuant to **Section 9.02(c)** and **Section 9.02(j)**); *provided* that with respect to case subject to a Lien in connection with Permitted Priority Debt, there is no default under the documentation governing the Permitted Priority Debt) cash and Permitted Cash Equivalent Investments (which for greater certainty shall not include any undrawn credit lines), in each case, to the extent held in an account over which the Lenders have a perfected security interest:	$
B.	The greater of:	$
	(1)$5,000,000 and	
	(2)to the extent Borrower has incurred Permitted Priority Debt, the minimum cash balance required of Borrower by Borrower's Permitted Priority Debt creditors	
	Is Line IA equal to or greater than Line IB?	*Yes: In compliance; No: Not in compliance*
II.	**Section 10.02(a)-(e): Minimum Revenue— Subsequent Periods**	
A.	Revenues during the twelve month period beginning on January 1, 2017	$
	[Is line II.A equal to or greater than $[****]?	*Yes: In compliance; No: Not in compliance]*[1]
B.	Revenues during the twelve month period beginning on January 1, 2019	$
	[Is line II.C equal to or greater than $[****]?	*Yes: In compliance; No: Not in compliance]*[2]
C.	Revenues during the twenty-four month period beginning on January 1, 2019	$

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

[1] Include bracketed entry only on the Compliance Certificate to be delivered within 90 days of the end of 2017 pursuant to Section 8.01(b) of the Loan Agreement.
[2] Include bracketed entry only on the Compliance Certificate to be delivered within 90 days of the end of 2019 pursuant to Section 8.01(b) of the Loan Agreement.

	[Is line II.D equal to or greater than $[****]?	*Yes: In compliance; No: Not in compliance]*[3]
D.	Revenues during the twenty-four month period beginning on January 1, 2020	$
	[Is line II.E equal to or greater than $[****]?	*Yes: In compliance; No: Not in compliance]*[4]

[3] Include bracketed entry only on the Compliance Certificate to be delivered within 90 days of the end of 2020 pursuant to Section 8.01(b) of the Loan Agreement.

[4] Include bracketed entry only on the Compliance Certificate to be delivered within 90 days of the end of 2021 pursuant to Section 8.01(b) of the Loan Agreement.

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

EXHIBIT B

Form of Amendment to Warrant

[See attached.]

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

AMENDMENT NO. 2 TO WARRANT TO PURCHASE SHARES OF COMMON STOCK

THIS AMENDMENT No. 2 TO WARRANT TO PURCHASE SHARES OF COMMON STOCK, dated as of September 10, 2019 (this "***Amendment***"), is made between T2 BIOSYSTEMS, INC., a Delaware corporation (the "***Company***"), and [ ]. (the "***Holder***"), with respect to the Warrant described below.

RECITALS

WHEREAS, the Company and the Holder are parties to the Warrant to Purchase Shares of Common Stock, dated as of December 30, 2016, as amended by the Amendment to Warrant to Purchase Shares of Common Stock, dated as of March 13, 2019 (the "***Warrant***"); and

WHEREAS, the Company and the Holder have agreed to reduce the Exercise Price in connection with an amendment to the Term Loan Agreement.

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

SECTION 1. **Definitions**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Warrant.

SECTION 2. **Amendment**. **Section 1(b)** of the Warrant is hereby amended and restated in its entirety as follows:

(b) ***Exercise Price***. The exercise price per Share shall be equal to $1.55, subject to adjustment pursuant hereto (the "***Exercise Price***").

SECTION 3. **Representations and Warranties; Reaffirmation**.

(a) The Company hereby represents and warrants to the Holder that (i) the Company has full power, authority and legal right to make and perform this Amendment; (ii) this Amendment is within the Company's corporate powers and has been duly authorized by all necessary corporate action and, if required, by all necessary shareholder action; (iii) this Amendment has been duly executed and delivered by the Company and constitutes a legal, valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, except as such enforceability may be limited by (A) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors' rights and (B) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law); and (iv) this Amendment (A) does not require any consent or approval of, registration or filing with, or any other action by, any Governmental Authority (as defined in the Term Loan Agreement) or any third party, except for such as have been obtained or made and are in full force and effect and (B) will not violate (I) the charter, bylaws or other organizational documents of the Company or (II) any applicable law or regulation or any order of any Governmental Authority (as defined in the Term Loan Agreement), other than any such violations in the case of this clause (II) that, individually or in the aggregate, could not reasonably be expected to have a Material Adverse Effect (as defined in the Term Loan Agreement).

(b) The Company hereby ratifies, confirms, reaffirms, and acknowledges its obligations under the Warrant and agrees that the Warrant remains in full force and effect, undiminished by this Amendment, except as expressly provided herein. By executing this Amendment, the Company acknowledges that it has read, consulted with its attorneys regarding, and understands, this Amendment.

SECTION 4. **Governing Law; Jurisdiction and Venue; WAIVER OF JURY TRIAL**.

(a) **Governing Law**. This Amendment and all actions arising out of or in connection with this Amendment shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to the conflicts of law provisions of the State of Delaware, or of any other state.

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

(b) **Jurisdiction and Venue**. The Company agrees that any suit, action or proceeding with respect to this Amendment or any judgment entered by any court in respect thereof may be brought initially in the federal or state courts in Houston, Texas or in the courts of its own corporate domicile and irrevocably submits to the non- exclusive jurisdiction of each such court for the purpose of any such suit, action, proceeding or judgment. This **Section 4(b)** is for the benefit of the Holder only and, as a result, the Holder shall not be prevented from taking proceedings in any other courts with jurisdiction. Nothing herein shall in any way be deemed to limit the ability of the Holder to serve any such process or summonses in any other manner permitted by applicable law. The Company irrevocably waives to the fullest extent permitted by law any objection that it may now or hereafter have to the laying of the venue of any suit, action or proceeding arising out of or relating to this Amendment and hereby further irrevocably waives to the fullest extent permitted by law any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. A final judgment (in respect of which time for all appeals has elapsed) in any such suit, action or proceeding shall be conclusive and may be enforced in any court to the jurisdiction of which the Company is or may be subject, by suit upon judgment.

(c) **WAIVER OF JURY TRIAL**. EACH OF THE HOLDER AND THE COMPANY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATED TO THIS AMENDMENT.

SECTION 5. Miscellaneous.

(a) **No Waiver**. Except as expressly stated herein, nothing contained herein shall be deemed to constitute a waiver of compliance with any term or condition contained in the Warrant or constitute a course of conduct or dealing among the parties. Except as expressly stated herein, the Holder reserves all rights, privileges and remedies under the Warrant. Except as amended hereby, the Warrant remains unmodified and in full force and effect. All references to the Warrant, including in the Term Loan Agreement or any other Loan Document (as defined in the Term Loan Agreement), shall be deemed to be references to the Warrant as amended hereby.

(b) **Severability**. If any provision of this Amendment becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, portions of such provision, or such provision in its entirety, to the extent necessary, shall be severed from this Amendment, and such illegal, unenforceable or void provision shall be replaced with a valid and enforceable provision that will achieve, to the extent possible, the same economic, business and other purposes of the illegal, unenforceable or void provision. The balance of this Amendment shall be enforceable in accordance with its terms.

(c) **Titles and Subtitles**. The titles and subtitles used in this Amendment are used for convenience only and are not to be considered in construing or interpreting this Amendment. All references in this Amendment to sections, paragraphs and exhibits shall, unless otherwise provided, refer to sections and paragraphs hereof and exhibits attached hereto.

(d) **Integration**. The Warrant as amended by this Amendment incorporates all negotiations of the parties hereto with respect to the subject matter hereof and is the final expression and agreement of the parties hereto with respect to the subject matter hereof.

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

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

[Remainder of page intentionally left blank]

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

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

COMPANY:

T2 BIOSYSTEMS, INC.

By Name:
Title:

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

HOLDER:

[SIGNATURE BLOCK TO BE UPDATED FOR EACH APPLICABLE HOLDER]

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

EXHIBIT C

Form of New Warrants

[See attached.]

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

THIS WARRANT AND THE UNDERLYING SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "*ACT*"), OR UNDER THE SECURITIES LAWS OF ANY STATE. THESE SECURITIES MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED EXCEPT AS PERMITTED UNDER THE ACT AND APPLICABLE STATE SECURITIES LAWS IN ACCORDANCE WITH APPLICABLE REGISTRATION REQUIREMENTS OR AN EXEMPTION THEREFROM. THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE ISSUER THAT SUCH OFFER, SALE, TRANSFER, PLEDGE OR HYPOTHECATION OTHERWISE COMPLIES WITH THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS. THIS WARRANT MUST BE SURRENDERED TO THE COMPANY OR ITS TRANSFER AGENT AS A CONDITION PRECEDENT TO THE SALE, TRANSFER, PLEDGE OR HYPOTHECATION OF ANY INTEREST IN ANY OF THE SECURITIES REPRESENTED HEREBY.

WARRANT TO PURCHASE SHARES OF COMMON STOCK OF
T2 BIOSYSTEMS, INC.

Dated as of September 10, 2019 Void after the date specified in Section 8

Warrant to Purchase [ ]Shares of Common Stock (subject to adjustment)

THIS CERTIFIES THAT, for value received, [CRG ENTITY], or its registered assigns (the "***Holder***"), is entitled, subject to the provisions and upon the terms and conditions set forth herein, to purchase from T2 Biosystems, Inc., a Delaware corporation (the "***Company***"), shares of the Company's common stock, par value $0.001 per share (the "***Shares***"), in the amounts, at such times and at the price per share set forth in Section 1. The term "***Warrant***" as used herein shall include this Warrant and any warrants delivered in substitution or exchange therefor as provided herein. This Warrant is issued in connection with the transactions described in the Term Loan Agreement, dated as of December 30, 2016 (as amended by Amendment No. 1 to Term Loan Agreement, dated as of March 1, 2017, among Borrower, Administrative Agent and the lenders party thereto, as further amended by Amendment No. 2 to Term Loan Agreement, dated as of December 18, 2017, among Borrower, Administrative Agent and the lenders party thereto, as further amended by Amendment No. 3 to Term Loan Agreement, dated as of March 16, 2018, as further amended by Amendment No. 4 to Term Loan Agreement, dated as of March 13, 2019, and as further amended by Amendment No. 5 to Term Loan Agreement, dated as of September 10, 2019 (the "***Term Loan Agreement***"), by and between the Company, the Subsidiary Guarantors from time to time party thereto, the Lenders from time to time party thereto and CRG Servicing LLC.

The following is a statement of the rights of the Holder and the conditions to which this Warrant is subject, and to which Holder, by acceptance of this Warrant, agrees:

1. Number and Price of Shares; Exercise Period.

(a) ***Number of Shares.*** Subject to any previous exercise of the Warrant, the Holder shall have the right to purchase up to [_] Shares, as may be adjusted pursuant hereto prior to (or in connection with) the expiration of this Warrant as provided in Section 8.

(b) ***Exercise Price.*** The exercise price per Share shall be equal to $1.55, subject to adjustment pursuant hereto (the "***Exercise Price***").

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

(c) ***Exercise Period.*** This Warrant shall be exercisable, in whole or in part, prior to (or in connection with) the expiration of this Warrant as set forth in Section 8.

2. Exercise of the Warrant.

(a) ***Exercise.*** The purchase rights represented by this Warrant may be exercised at the election of the Holder, in whole or in part, in accordance with Section 1, by:

(i) the tender to the Company at its principal office (or such other office or agency as the Company may designate) of a notice of exercise in the form of Exhibit A (the "***Notice of Exercise***"), duly completed and executed by or on behalf of the Holder, together with the surrender of this Warrant; and

(ii) the payment to the Company of an amount equal to (x) the Exercise Price multiplied by (y) the number of Shares being purchased, by wire transfer or certified, cashier's or other check acceptable to the Company and payable to the order of the Company.

(b) ***Net Issue Exercise.*** In lieu of exercising this Warrant pursuant to Section 2(a)(ii), if the fair market value of one Share is greater than the Exercise Price (at the date of calculation as set forth below), the Holder may elect to receive a number of Shares equal to the value of this Warrant (or of any portion of this Warrant being canceled) by surrender of this Warrant at the principal office of the Company (or such other office or agency as the Company may designate) together with a properly completed and executed Notice of Exercise reflecting such election, in which event the Company shall issue to the Holder that number of Shares computed using the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where:

X = The number of Shares to be issued to the Holder

Y = The number of Shares purchasable under this Warrant or, if only a portion of the Warrant is being exercised, the portion of the Warrant being canceled (at the date of such calculation)

A = The fair market value of one Share (at the date of such calculation)

B = The Exercise Price (as adjusted to the date of such calculation)

For purposes of the calculation above, the fair market value of one Share shall be determined as follows:

(i) if the Shares are traded on any securities exchange or quoted on an established automated over-the-counter market, the fair market value shall be deemed to be the average of the closing prices over a ten (10) Trading Day period ending five (5) Trading Days before the date of calculation; or

(ii) if at any time the Common Stock is not listed on any securities exchange or quoted on an established automated over-the-counter market, the fair market value of Common Stock shall be the price per share which the Company could obtain from a willing buyer (not a current employee or director) for shares of Common Stock sold by the Company, from authorized but unissued shares, as determined in good faith by its Board of Directors, unless the Company shall become subject to a Reorganization, in which case the fair market value of the Common Stock shall be deemed to be the per share value received by the holders of the Company's Common Stock pursuant to such Reorganization.

For purposes hereof, the date of calculation shall be the date the Holder sends to the Company a Notice of Exercise. "***Trading Day***" means a day in which trading in the Shares generally occurs on The Nasdaq Global Market or if the Shares are not then listed on The Nasdaq Global Market, on the principal other U.S. national or

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

regional securities exchange on which the Shares are then listed, or if the Shares are not then listed on a U.S. national or regional securities exchange, on the principal other market on which the Shares are then traded. If the Shares are not so listed or traded, "Trading Day" means any Business Day. "***Business Day***" means any day other than a Saturday, a Sunday or a day on which the Federal Reserve Bank of New York is authorized or required by law or executive order to close or be closed.

(c) ***Exercise Prior to Expiration or Change of Control.*** To the extent this Warrant is not previously exercised as to all Shares subject hereto, and if the fair market value of one Share is greater than the Exercise Price then in effect, this Warrant shall be deemed automatically exercised pursuant to Section 2(b) (even if not surrendered) immediately before its expiration or termination pursuant to Section 8(b) below. For purposes of such automatic exercise, the fair market value of one Share upon such expiration shall be determined pursuant to Section 2(b). To the extent this Warrant or any portion thereof is deemed automatically exercised pursuant to this Section 2(c), the Company agrees to promptly notify the Holder of the number of shares of Common Stock, if any, the Holder is to receive by reason of such automatic exercise.

(d) ***Stock Certificates.*** The rights under this Warrant shall be deemed to have been exercised and the Shares issuable upon such exercise shall be deemed to have been issued immediately prior to the close of business on the date this Warrant is exercised in accordance with its terms, and the person entitled to receive the Shares issuable upon such exercise shall be treated for all purposes as the holder of record of such Shares as of the close of business on such date. As promptly as reasonably practicable on or after such date, the Company shall issue and deliver to the person or persons entitled to receive the same a certificate or certificates (or other reasonably acceptable evidence of issuance if the Company ordinarily registers uncertificated book-entry positions with its transfer agent) for that number of shares issuable upon such exercise. In the event that the rights under this Warrant are exercised in part and have not expired, the Company shall execute and deliver a new Warrant reflecting the number of Shares that remain subject to this Warrant.

(e) ***No Fractional Shares or Scrip.*** No fractional shares or scrip representing fractional shares shall be issued upon the exercise of the rights under this Warrant. In lieu of such fractional share to which the Holder would otherwise be entitled, the Company shall make a cash payment equal to the Exercise Price multiplied by such fraction.

(f) ***Conditional Exercise.*** The Holder may exercise this Warrant conditioned upon (and effective immediately prior to) consummation of any transaction that would cause the expiration of this Warrant pursuant to Section 8 by so indicating in the notice of exercise.

(g) ***Reservation of Stock.*** The Company agrees during the term the rights under this Warrant are exercisable to reserve and keep available from its authorized and unissued shares of common stock of the Company for the purpose of effecting the exercise of this Warrant such number of shares as shall from time to time be sufficient to effect the exercise of the rights under this Warrant; and if at any time the number of authorized but unissued shares of common stock shall not be sufficient for purposes of the exercise of this Warrant in accordance with its terms, without limitation of such other remedies as may be available to the Holder, the Company will use all reasonable efforts to take such corporate action as may be necessary to increase its authorized and unissued shares of common stock of the Company to a number of shares as shall be sufficient for such purposes. The Company represents and warrants that all shares that may be issued upon the exercise of this Warrant will, when issued in accordance with the terms hereof, including the proper exercise of this Warrant, be validly issued, fully paid and nonassessable.

(h) ***Issued Securities***. The Company represents and warrants to the Holder that all issued and outstanding shares of common stock or any other securities of the Company have been duly authorized and that all outstanding shares of common stock of the Company have been validly issued and are fully paid and nonassessable. All outstanding shares of common stock and any other securities were issued in full compliance with all federal and state securities laws. In addition, as of the date immediately preceding the date of this Warrant:

(i) The authorized capital of the Company consists of (A) 200,000,000 shares of common stock, of which 30,482,712 shares are issued and outstanding, and (B) 10,000,000 shares of preferred stock, of which no shares are issued and outstanding.

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

(ii) The Company has reserved 4,538,219 shares of its common stock for issuance under its stock incentive plans, under which (i) 3,980,014 shares are issuable upon the exercise of stock options outstanding on the date hereof and (ii) up to 272,195 shares are issuable under awards of restricted stock units outstanding on the date hereof. The Company has also reserved 134,401 shares of its common stock for issuance pursuant to the Company's employee stock purchase plan. Except as stated above and except for the warrant issued to the Holder pursuant to this Warrant and the other warrants issued on the date hereof in connection with the Term Loan Agreement, there are no other options, warrants, conversion privileges or other rights presently outstanding to purchase or otherwise acquire any authorized but unissued shares of the Company's capital stock or other securities of the Company.

3. **Replacement of the Warrant.** Subject to the receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, on delivery of an indemnity agreement reasonably satisfactory in form and substance to the Company or, in the case of mutilation, on surrender and cancellation of this Warrant, the Company at the expense of the Holder shall execute and deliver, in lieu of this Warrant, a new warrant of like tenor and amount.

4. Transfer of the Warrant.

(a) ***Warrant Register.*** The Company shall maintain a register (the "***Warrant Register***") containing the name and address of the Holder or Holders. Until this Warrant is transferred on the Warrant Register in accordance herewith, the Company may treat the Holder as shown on the Warrant Register as the absolute owner of this Warrant for all purposes, notwithstanding any notice to the contrary. Any Holder of this Warrant (or of any portion of this Warrant) may change its address as shown on the Warrant Register by written notice to the Company requesting a change.

(b) ***Warrant Agent.*** The Company may appoint an agent for the purpose of maintaining the Warrant Register referred to in Section 4(a), issuing the Shares or other securities then issuable upon the exercise of the rights under this Warrant, exchanging this Warrant, replacing this Warrant or conducting related activities.

(c) ***Transferability of the Warrant.*** Subject to the provisions of this Warrant with respect to compliance with the Securities Act of 1933, as amended (the "***Securities Act***") as set forth in Section 5, title to this Warrant may be transferred by endorsement (by the transferor and the transferee executing the assignment form attached as Exhibit B (the "***Assignment Form***")) and delivery in the same manner as a negotiable instrument transferable by endorsement and delivery.

(d) ***Exchange of the Warrant upon a Transfer.*** On surrender of this Warrant (and a properly endorsed Assignment Form) for exchange, subject to the provisions of this Warrant with respect to compliance with the Securities Act and limitations on assignments and transfers, the Company shall issue to or on the order of the Holder a new warrant or warrants of like tenor, in the name of the Holder or as the Holder (on payment by the Holder of any applicable transfer taxes) may direct, for the number of shares issuable upon exercise hereof, and the Company shall register any such transfer upon the Warrant Register. This Warrant (and the securities issuable upon exercise of the rights under this Warrant) must be surrendered to the Company or its warrant or transfer agent, as applicable, as a condition precedent to the sale, pledge, hypothecation or other transfer of any interest in any of the securities represented hereby.

(e) ***Taxes.*** In no event shall the Company be required to pay any tax which may be payable in respect of any transfer involved in the issue and delivery of any certificate in a name other than that of the Holder, and the Company shall not be required to issue or deliver any such certificate unless and until the person or persons requesting the issue thereof shall have paid to the Company the amount of such tax or shall have established to the satisfaction of the Company that such tax has been paid or is not payable.

5. **Compliance with Securities Laws.** By acceptance of this Warrant, the Holder agrees to comply with the following:

(a) ***Restrictions on Transfers.*** Any transfer of this Warrant or the Shares (the "***Securities***") must

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

be in compliance with all applicable federal and state securities laws. The Holder agrees not to make any sale, assignment, transfer, pledge or other disposition of all or any portion of the Securities, or any beneficial interest therein, unless and until the transferee thereof has agreed in writing for the benefit of the Company to take and hold such Securities subject to, and to be bound by, the terms and conditions set forth in this Warrant to the same extent as if the transferee were the original Holder hereunder, and

(i) there is then in effect a registration statement under the Securities Act covering such proposed disposition and such disposition is made in accordance with such registration statement, or

(ii) (A) such Holder shall have given prior written notice to the Company of such Holder's intention to make such disposition and shall have furnished the Company with a reasonable detailed description of the manner and circumstances of the proposed disposition, (B) the transferee shall have made the representations set forth in Section 10 with respect to itself as a Holder and (C) if requested by the Company, such Holder shall have furnished the Company, at the Holder's expense, with (i) evidence reasonably satisfactory to the Company that such disposition will not require registration of such Securities under the Securities Act or (ii) a legal opinion to the effect that the transfer of such Securities may be effected in compliance with the terms of the Securities Act. Notwithstanding the foregoing, compliance with clauses (B) and (C) above shall not be required for any transfer in compliance with Rule 144 or compliance with clause (C) above shall not be required for any transfer by the Holder to any affiliate of the Holder (or any fund or partnership under common control with one of more general partners or managing members of, or shares the same management company with, the Holder) or a transfer by the Holder to any of the Holder's partners, members or other equity owners, or retired partners, members or other equity owners or the estate of any partners, members or other equity owners or retired partners, members or other equity owners.

(b) ***Investment Representation Statement.*** Unless the rights under this Warrant are exercised pursuant to an effective registration statement under the Securities Act that includes the Shares with respect to which the Warrant was exercised or pursuant to Section 2(b) that results in the Shares issued upon exercise being eligible for resale under Rule 144, it shall be a condition to any exercise of the rights under this Warrant that the Holder shall have confirmed the representations set forth in Section 10 hereof.

(c) ***Securities Law Legend.*** Subject to Section 5(e), the Securities shall (unless otherwise permitted by the provisions of this Warrant) be stamped or imprinted with a legend substantially similar to the following (in addition to any legend required by state securities laws):

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR UNDER THE SECURITIES LAWS OF CERTAIN STATES. THESE SECURITIES MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED EXCEPT AS PERMITTED UNDER THE ACT AND APPLICABLE STATE SECURITIES LAWS IN ACCORDANCE WITH APPLICABLE REGISTRATION REQUIREMENTS OR AN EXEMPTION THEREFROM. THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE ISSUER THAT SUCH OFFER, SALE OR TRANSFER, PLEDGE OR HYPOTHECATION OTHERWISE COMPLIES WITH THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS. THIS CERTIFICATE MUST BE SURRENDERED TO THE COMPANY OR ITS TRANSFER AGENT AS A CONDITION PRECEDENT TO THE SALE, TRANSFER, PLEDGE OR HYPOTHECATION OF ANY INTEREST IN ANY OF THE SECURITIES REPRESENTED HEREBY.

(d) ***Instructions Regarding Transfer Restrictions.*** Subject to Section 5(e), the Holder consents to the Company making a notation on its records and giving instructions to any transfer agent in order to implement the restrictions on transfer established in this Section 5.

(e) ***Removal of Legend.*** The legend referring to federal and state securities laws identified in Section 5(c) stamped on a certificate evidencing the Shares and the stock transfer instructions and record notations with respect to such securities shall be removed promptly upon request by the Holder and the Company shall issue a certificate without such legend to the holder of such securities if (i) such securities are registered under the Securities Act, (ii) such securities are eligible for resale under Rule 144, or (iii) such holder provides the Company

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

with an opinion of counsel reasonably acceptable to the Company to the effect that a sale or transfer of such securities may be made without registration or qualification.

(f) ***Compliance with Securities Laws***. The Holder is aware of the restrictions imposed by the United States securities laws on the purchase or sale of securities by any person who has received material, non- public information from the issuer of such securities and on the communication of such information to any other person when it is reasonably foreseeable that such other person is likely to purchase or sell such securities in reliance upon such information.

6. **Adjustments.** Subject to the expiration of this Warrant pursuant to Section 8, the number and kind of shares purchasable hereunder and the Exercise Price therefor are subject to adjustment from time to time, as follows:

(a) ***Merger or Reorganization.*** If at any time there shall be any reorganization, recapitalization, merger or consolidation (a "***Reorganization***") involving the Company (other than as otherwise provided for herein or as would cause the expiration of this Warrant under Section 8) in which shares of the Company's stock are converted into or exchanged for securities, cash or other property, then, as a part of such Reorganization, lawful provision shall be made so that the Holder shall thereafter be entitled to receive upon exercise of this Warrant, the kind and amount of securities, cash or other property of the successor corporation resulting from such Reorganization (collectively, "***Reference Property***"), equivalent in value to that which a holder of the Shares deliverable upon exercise of this Warrant would have been entitled in such Reorganization if the right to purchase the Shares hereunder had been exercised immediately prior to such Reorganization. In any such case, appropriate adjustment (as determined in good faith by the Board of Directors of the successor corporation) shall be made in the application of the provisions of this Warrant with respect to the rights and interests of the Holder after such Reorganization to the end that the provisions of this Warrant shall be applicable after the event, as near as reasonably may be, in relation to any shares or other securities deliverable after that event upon the exercise of this Warrant. Without limiting the foregoing, in connection with any Reorganization, upon the closing thereof, the successor or surviving entity shall assume the obligations of this Agreement. The provisions of this Section 6(a) shall similarly apply to successive Reorganizations.

(b) ***Reclassification of Shares.*** If the securities issuable upon exercise of this Warrant are changed into the same or a different number of securities of any other class or classes by reclassification, capital reorganization or otherwise (other than as otherwise provided for herein) (a "***Reclassification***"), then, in any such event, in lieu of the number of Shares which the Holder would otherwise have been entitled to receive, the Holder shall have the right thereafter to exercise this Warrant for a number of shares of such other class or classes of stock that a holder of the number of securities deliverable upon exercise of this Warrant immediately before that change would have been entitled to receive in such Reclassification, all subject to further adjustment as provided herein with respect to such other shares.

(c) ***Subdivisions and Combinations.*** In the event that the outstanding shares of common stock are subdivided (by stock split, by payment of a stock dividend or otherwise) into a greater number of shares of such securities, the number of Shares issuable upon exercise of the rights under this Warrant immediately prior to such subdivision shall, concurrently with the effectiveness of such subdivision, be proportionately increased, and the Exercise Price shall be proportionately decreased, and in the event that the outstanding shares of common stock are combined (by reclassification or otherwise) into a lesser number of shares of such securities, the number of Shares issuable upon exercise of the rights under this Warrant immediately prior to such combination shall, concurrently with the effectiveness of such combination, be proportionately decreased, and the Exercise Price shall be proportionately increased.

(d) ***Notice of Adjustments.*** Upon any adjustment in accordance with this Section 6, the Company shall give notice thereof to the Holder, which notice shall state the event giving rise to the adjustment, the Exercise Price as adjusted and the number of securities or other property purchasable upon the exercise of the rights under this Warrant, setting forth in reasonable detail the method of calculation of each. The Company shall, upon the written request of any Holder, furnish or cause to be furnished to such Holder a certificate setting forth (i) such adjustments, (ii) the Exercise Price at the time in effect and (iii) the number of securities and the amount, if any, of other property that at the time would be received upon exercise of this Warrant.

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

7. **Notification of Certain Events.** Prior to the expiration of this Warrant pursuant to Section 8, in the event that the Company shall authorize:

(a) the issuance of any dividend or other distribution on the capital stock of the Company (other than (i) dividends or distributions otherwise provided for in Section 6, (ii) repurchases of common stock issued to or held by employees, officers, directors or consultants of the Company or its subsidiaries upon termination of their employment or services pursuant to agreements providing for the right of said repurchase; (iii) repurchases of common stock issued to or held by employees, officers, directors or consultants of the Company or its subsidiaries pursuant to rights of first refusal or first offer contained in agreements providing for such rights; or (iv) repurchases of capital stock of the Company in connection with the settlement of disputes with any stockholder), whether in cash, property, stock or other securities;

(b) the voluntary liquidation, dissolution or winding up of the Company; or

(c) any transaction resulting in the expiration of this Warrant pursuant to Section 8(b);

the Company shall send to the Holder of this Warrant at least ten (10) calendar days prior written notice of the date on which a record shall be taken for any such dividend or distribution specified in clause (a) or the expected effective date of any such other event specified in clause (b) or (c), as applicable. The notice provisions set forth in this section may be shortened or waived prospectively or retrospectively by the consent of the Holder of this Warrant.

8. **Expiration of the Warrant.** This Warrant shall expire and shall no longer be exercisable as of the earlier of:

(a) 5:00 p.m., Pacific time, on September 10, 2029; or

(b) (i) the acquisition of the Company by another entity by means of any transaction or series of related transactions to which the Company is a party (including, without limitation, any stock acquisition, reorganization, merger or consolidation, but excluding any sale of stock for capital raising purposes and any transaction effected primarily for purposes of changing the Company's jurisdiction of incorporation) other than a transaction or series of related transactions in which the holders of the voting securities of the Company outstanding immediately prior to such transaction or series of related transactions receive voting securities of such other surviving or resulting entity (or if the Company or such other surviving or resulting entity is a wholly-owned subsidiary immediately following such acquisition, its parent), or (ii) a sale, lease or other disposition of all or substantially all of the assets of the Company and its subsidiaries taken as a whole by means of any transaction or series of related transactions, except where such sale, lease or other disposition is to a wholly-owned subsidiary of the Company.

9. **No Rights as a Stockholder.** Nothing contained herein shall entitle the Holder to any rights as a stockholder of the Company or to be deemed the holder of any securities that may at any time be issuable on the exercise of the rights hereunder for any purpose nor shall anything contained herein be construed to confer upon the Holder, as such, any right to vote for the election of directors or upon any matter submitted to stockholders at any meeting thereof, or to give or withhold consent to any corporate action (whether upon any recapitalization, issuance of stock, reclassification of stock, change of par value or change of stock to no par value, consolidation, merger, conveyance or otherwise) or to receive notice of meetings, or to receive dividends or subscription rights or any other rights of a stockholder of the Company until the rights under the Warrant shall have been exercised and the Shares purchasable upon exercise of the rights hereunder shall have become deliverable as provided herein.

10. **Representations and Warranties of the Holder.** By acceptance of this Warrant, the Holder represents and warrants to the Company as follows:

(a) ***No Registration.*** The Holder understands that the Securities have not been, and will not be, registered under the Securities Act by reason of a specific exemption from the registration provisions of the Securities Act, the availability of which depends upon, among other things, the *bona fide* nature of the investment intent and the accuracy of the Holder's representations as expressed herein or otherwise made pursuant hereto.

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

(b) ***Investment Intent.*** The Holder is acquiring the Securities for investment for its own account, not as a nominee or agent, and not with a view to, or for resale in connection with, any distribution thereof. The Holder has no present intention of selling, granting any participation in, or otherwise distributing the Securities, nor does it have any contract, undertaking, agreement or arrangement for the same.

(c) ***Investment Experience.*** The Holder has substantial experience in evaluating and investing in private placement transactions of securities in companies similar to the Company, and has such knowledge and experience in financial or business matters so that it is capable of evaluating the merits and risks of its investment in the Company and protecting its own interests.

(d) ***Speculative Nature of Investment.*** The Holder understands and acknowledges that its investment in the Company is highly speculative and involves substantial risks. The Holder can bear the economic risk of its investment and is able, without impairing its financial condition, to hold the Securities for an indefinite period of time and to suffer a complete loss of its investment.

(e) ***Accredited Investor.*** The Holder is an "accredited investor" within the meaning of Regulation D, Rule 501(a), promulgated by the Securities and Exchange Commission and agrees to submit to the Company such further assurances of such status as may be reasonably requested by the Company. The Holder has furnished or made available any and all information requested by the Company or otherwise necessary to satisfy any applicable verification requirements as to "accredited investor" status. Any such information is true, correct, timely and complete.

(f) ***Residency.*** The residency of the Holder (or, in the case of a partnership or corporation, such entity's principal place of business) is correctly set forth on the signature page hereto.

(g) ***Restrictions on Resales.*** The Holder acknowledges that the Securities must be held indefinitely unless subsequently registered under the Securities Act or an exemption from such registration is available. The Holder is aware of the provisions of Rule 144 promulgated under the Securities Act, which permit resale of shares purchased in a private placement subject to the satisfaction of certain conditions, which may include, among other things, the availability of certain current public information about the Company; the resale occurring not less than a specified period after a party has purchased and paid for the security to be sold; the number of shares being sold during any three-month period not exceeding specified limitations; the sale being effected through a "broker's transaction," a transaction directly with a "market maker" or a "riskless principal transaction" (as those terms are defined in the Securities Act or the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder); and the filing of a Form 144 notice, if applicable. The Holder acknowledges and understands that the Company may not be satisfying the current public information requirement of Rule 144 at the time the Holder wishes to sell the Securities and that, in such event, the Holder may be precluded from selling the Securities under Rule 144 even if the other applicable requirements of Rule 144 have been satisfied. The Holder acknowledges that, in the event the applicable requirements of Rule 144 are not met, registration under the Securities Act or an exemption from registration will be required for any disposition of the Securities. The Holder understands that, although Rule 144 is not exclusive, the Securities and Exchange Commission has expressed its opinion that persons proposing to sell restricted securities received in a private offering other than in a registered offering or pursuant to Rule 144 will have a substantial burden of proof in establishing that an exemption from registration is available for such offers or sales and that such persons and the brokers who participate in the transactions do so at their own risk.

(h) ***Authorization***. The Holder has full legal capacity, power and authority to execute and deliver this Warrant and to perform its obligations hereunder. This Warrant constitutes the valid and binding obligations of the Holder, enforceable in accordance with its terms, except as limited by bankruptcy, insolvency or other laws of general application relating to or affecting the enforcement of creditors' rights generally and general principles of equity.

11. Miscellaneous.

(a) ***Amendments.*** Except as expressly provided herein, neither this Warrant nor any term hereof

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

may be amended, waived, discharged or terminated other than by a written instrument referencing this Warrant and signed by the Company and the Holder of this Warrant.

(b) ***Waivers.*** No waiver of any single breach or default shall be deemed a waiver of any other breach or default theretofore or thereafter occurring.

(c) ***Notices.*** All notices and other communications required or permitted hereunder shall be in writing and shall be mailed by registered or certified mail, postage prepaid, sent by facsimile or electronic mail (if to the Holder) or otherwise delivered by hand, messenger or courier service addressed:

(i) if to the Holder, to the Holder at the Holder's address, facsimile number or electronic mail address as shown in the Company's records, as may be updated in accordance with the provisions hereof, or until any such Holder so furnishes an address, facsimile number or electronic mail address to the Company, then to and at the address, facsimile number or electronic mail address of the last holder of this Warrant for which the Company has contact information in its records; or

(ii) if to the Company, to the attention of the Chief Executive Officer or Chief Financial Officer of the Company at the Company's address as shown on the signature page hereto, or at such other current address as the Company shall have furnished to the Holder.

Each such notice or other communication shall for all purposes of this Warrant be treated as effective or having been given (i) if delivered by hand, messenger or courier service, when delivered (or if sent via a nationally-recognized overnight courier service, freight prepaid, specifying next-business-day delivery, one business day after deposit with the courier), or (ii) if sent via mail, at the earlier of its receipt or five days after the same has been deposited in a regularly-maintained receptacle for the deposit of the United States mail, addressed and mailed as aforesaid, or (iii) if sent via facsimile, upon confirmation of facsimile transfer or, if sent via electronic mail, upon confirmation of delivery when directed to the relevant electronic mail address, if sent during normal business hours of the recipient, or if not sent during normal business hours of the recipient, then on the recipient's next business day. In the event of any conflict between the Company's books and records and this Warrant or any notice delivered hereunder, the Company's books and records will control absent fraud or error.

(d) ***Governing Law.*** This Warrant and all actions arising out of or in connection with this Warrant shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to the conflicts of law provisions of the State of Delaware, or of any other state.

(e) ***Jurisdiction and Venue.*** The Company agrees that any suit, action or proceeding with respect to this Agreement or any other Loan Document to which it is a party or any judgment entered by any court in respect thereof may be brought initially in the federal or state courts in Houston, Texas or in the courts of its own corporate domicile and irrevocably submits to the non-exclusive jurisdiction of each such court for the purpose of any such suit, action, proceeding or judgment. This Section 11(e) is for the benefit of the Holder only and, as a result, Holder shall not be prevented from taking proceedings in any other courts with jurisdiction. Nothing herein shall in any way be deemed to limit the ability of the Holder to serve any such process or summonses in any other manner permitted by applicable law. The Company irrevocably waives to the fullest extent permitted by law any objection that it may now or hereafter have to the laying of the venue of any suit, action or proceeding arising out of or relating to this Warrant and hereby further irrevocably waives to the fullest extent permitted by law any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. A final judgment (in respect of which time for all appeals has elapsed) in any such suit, action or proceeding shall be conclusive and may be enforced in any court to the jurisdiction of which the Company is or may be subject, by suit upon judgment.

(f) ***Titles and Subtitles.*** The titles and subtitles used in this Warrant are used for convenience only and are not to be considered in construing or interpreting this Warrant. All references in this Warrant to sections, paragraphs and exhibits shall, unless otherwise provided, refer to sections and paragraphs hereof and exhibits attached hereto.

(g) ***Severability.*** If any provision of this Warrant becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, portions of such provision, or such provision in its entirety, to the

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

extent necessary, shall be severed from this Warrant, and such illegal, unenforceable or void provision shall be replaced with a valid and enforceable provision that will achieve, to the extent possible, the same economic, business and other purposes of the illegal, unenforceable or void provision. The balance of this Warrant shall be enforceable in accordance with its terms.

(h) ***Waiver of Jury Trial.*** **EACH OF THE HOLDER AND THE COMPANY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATED TO THIS WARRANT.**

(i) ***California Corporate Securities Law.*** THE SALE OF THE SECURITIES THAT ARE THE SUBJECT OF THIS WARRANT HAS NOT BEEN QUALIFIED WITH THE COMMISSIONER OF CORPORATIONS OF THE STATE OF CALIFORNIA AND THE ISSUANCE OF SUCH SECURITIES OR THE PAYMENT OR RECEIPT OF ANY PART OF THE CONSIDERATION THEREFOR PRIOR TO SUCH QUALIFICATION IS UNLAWFUL, UNLESS THE SALE OF SECURITIES IS EXEMPT FROM QUALIFICATION BY SECTION 25100, 25102, OR 25105 OF THE CALIFORNIA CORPORATIONS CODE. THE RIGHTS OF ALL PARTIES TO THIS WARRANT ARE EXPRESSLY CONDITIONED UPON THE QUALIFICATION BEING OBTAINED, UNLESS THE SALE IS SO EXEMPT.

(j) ***Saturdays, Sundays and Holidays.*** If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall be a Saturday, Sunday or U.S. federal holiday, then such action may be taken or such right may be exercised on the next succeeding day that is not a Saturday, Sunday or U.S. federal holiday.

(k) ***Rights and Obligations Survive Exercise of the Warrant.*** Except as otherwise provided herein, the rights and obligations of the Company and the Holder under this Warrant shall survive exercise of this Warrant.

(l) ***Entire Agreement.*** Except as expressly set forth herein, this Warrant (including the exhibits attached hereto) constitutes the entire agreement and understanding of the Company and the Holder with respect to the subject matter hereof and supersede all prior agreements and understandings relating to the subject matter hereof.

(*signature page follows*)

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

The Company and the Holder sign this Warrant as of the date stated on the first page.

COMPANY:

T2 BIOSYSTEMS, INC.

By Name:
Title:

Address for Notices: 101
Hartwell Avenue,
Lexington, MA 02421 Attn: [ ]
Tel.: [ ]
Fax: [ ]
Email: [ ]

AGREED AND ACKNOWLEDGED,

HOLDER:

[APPLICABLE CRG SIGNATURE BLOCK TO BE USED ON EACH WARRANT]:

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

EXHIBIT A NOTICE OF EXERCISE

TO: T2 BIOSYSTEMS, INC. (the "*Company*")

Attention: CHIEF FINANCIAL OFFICER

(1) **Exercise.** The undersigned elects to purchase the following pursuant to the terms of the attached warrant:
Number of shares:

Type of security:

(2) **Method of Exercise.** The undersigned elects to exercise the attached warrant pursuant to:

[ ] A cash payment, and tenders herewith payment of the purchase price for such shares in full, together with all applicable transfer taxes, if any.

[ ] The net issue exercise provisions of Section 2(b) of the attached warrant.

(3) **Conditional Exercise.** Is this a conditional exercise pursuant to Section 2(f):

[ ] Yes **[ ]** No

If "Yes," indicate the applicable condition:

(4) **Stock Certificate.** Please issue a certificate or certificates representing the shares in the name of:

[ ] The undersigned

[ ] Other—Name:

Address:

(5) **Unexercised Portion of the Warrant.** Please issue a new warrant for the unexercised portion of the attached warrant in the name of:

[ ] The undersigned

[ ] Other—Name:

Address:

[ ] Not applicable

(6) **[Investment Intent.** The undersigned represents and warrants that the aforesaid shares are being acquired for investment for its own account and not with a view to, or for resale in connection with, the distribution thereof, and that the undersigned has no present intention of selling, granting any participation in, or

otherwise distributing the shares, nor does it have any contract, undertaking, agreement or arrangement for the same, and all representations and warranties of the undersigned set forth in Section 10 of the attached warrant are true and correct as of the date hereof.][1]

([6][7]) **Consent to Receipt of Electronic Notice.** Subject to the limitations set forth in §232(e) of the General Corporation Law of the State of Delaware (the "***DCGL***"), the undersigned consents to the delivery of any notice to stockholders given by the Company under the DGCL or the Company's certificate of incorporation or bylaws by (i) facsimile telecommunication to the facsimile number provided below (or to any other facsimile number for the undersigned in the Company's records), (ii) electronic mail to the electronic mail address provided below (or to any other electronic mail address for the undersigned in the Company's records), (iii) posting on an electronic network together with separate notice to the undersigned of such specific posting or (iv) any other form of electronic transmission (as defined in the DGCL) directed to the undersigned. This consent may be revoked by the undersigned by written notice to the Company and may be deemed revoked in the circumstances specified in DGCL §232.

_____
(*Print name of the warrant holder*)

_____
(*Signature*)

_____
(*Name and title of signatory, if applicable*)

_____
(*Date*)

_____
(*Fax number*)

_____
(*Email address*)

EXHIBIT B ASSIGNMENT FORM

ASSIGNOR: _____

COMPANY: T2 BIOSYSTEMS, INC.

WARRANT: THE WARRANT TO PURCHASE SHARES OF COMMON STOCK ISSUED ON DECEMBER 30, 2016 (THE "***WARRANT***")

DATE: _____

(1) **Assignment.** The undersigned registered holder of the Warrant ("***Assignor***") assigns and transfers to the assignee named below ("***Assignee***") all of the rights of Assignor under the Warrant, with respect to the number of shares set forth below:

Name of Assignee: _____

Address of Assignee: _____

_____

Number of Shares Assigned: _____

and does irrevocably constitute and appoint _____ as attorney to make such transfer on the books of T2 Biosystems, Inc., maintained for the purpose, with full power of substitution in the premises.

(2) **Obligations of Assignee.** Assignee agrees to take and hold the Warrant and any shares of stock to be issued upon exercise of the rights thereunder (the "***Securities***") subject to, and to be bound by, the terms and conditions set forth in the Warrant to the same extent as if Assignee were the original holder thereof.

(3) **[Investment Intent.** Assignee represents and warrants that the Securities are being acquired for investment for its own account, not as a nominee or agent, and not with a view to, or for resale in connection with, the distribution thereof, and that Assignee has no present intention of selling, granting any participation in, or otherwise distributing the shares, nor does it have any contract, undertaking, agreement or arrangement for the same, and all representations and warranties set forth in Section 10 of the Warrant are true and correct as to Assignee as of the date hereof.][2]

Assignor and Assignee are signing this Assignment Form on the date first set forth above.

ASSIGNOR **ASSIGNEE**

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

(*Print name of Assignor*)	(*Print name of Assignee*)
(*Signature of Assignor*)	(*Signature of Assignee*)
(*Print name of signatory, if applicable*)	(*Print name of signatory, if applicable*)
(*Print title of signatory, if applicable*)	(*Print title of signatory, if applicable*)
Address:	Address:

SCHEDULE I

NEW WARRANT SHARES

Holder	**Number of Shares of Common Stock subject to the Warrants**
CRG Partners III L.P.	98,314
CRG Partners III – Parallel Fund "A" L.P.	48,305
CRG Partners III Parallel Fund "B" (Cayman) L.P.	214,814
CRG Partners III (Cayman) LEV AIV L.P.	191,344
CRG Partners III (Cayman) UNLEV AIV I L.P.	15,514
TOTAL	568,291

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

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES 1 | 58

2. CONTRACT (Proc. Inst. Ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
75A50119C00053	See Block 20A	OS246197

2275655. ISSUED BY	CODE	ASPR-BARDA	6. ADMINISTERED BY (If other than Item 5)	CODE	ASPR-BARDA02
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201			US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MANAGEMENT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515		

7. NAME AND ADDRESS OF CONTRACTOR (No., Street, City, Country, State and ZIP Code)	8. DELIVERY	
T2 Biosystems, Inc. 101 Hartwell Ave., Lexington, MA 02421	☐ FOB ORIGIN ☒ OTHER (See below)	
	9. DISCOUNT FOR PROMPT PAYMENT	
	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN	ITEM
CODE 143 3521	FACILITY CODE	

11. SHIP TO/MARK FOR	CODE		12. PAYMENT WILL BE MADE BY	CODE	PSC
			PSC Program Support Center 7700 Wisconsin Ave Bethesda MD 20814		

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:	14. ACCOUNTING AND APPROPRIATION DATA
☐ 10 U.S.C. 2304(c)( ) ☐ 41 U.S.C. 253 (c)( )	See Schedule

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				
	15G. TOTAL AMOUNT OF CONTRACT			▶	$5,978,993

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES	
X	A	SOLICITATION/CONTRACT FORM	1	X	I	CONTRACT CLAUSES	50
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	3			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
X	C	DESCRIPTION/SPECS./WORK STATEMENT	10	X	J	LIST OF ATTACHMENTS	58
X	D	PACKAGING AND MARKING	11			PART IV - REPRESENTATIONS AND INSTRUCTIONS	
X	E	INSPECTION AND ACCEPTANCE	12		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	16				
X	G	CONTRACT ADMINISTRATION DATA	31		L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
X	H	SPECIAL CONTRACT REQUIREMENTS	37		M	EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. ☐ CONTRACTOR'S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return* _____ *copies to issuing office.*) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (*Attachments are listed herein.*)

18. ☒ SEALED-BID AWARD (*Contractor is not required to sign this document.*) Your bid on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER (Type or print)	20A. NAME OF CONTRACTING OFFICER
John McDonough	Carl A. Newman

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
BY: /s/ John McDonough (Signature of person authorized to sign)	9/5/2019	BY: /s/ Carl A. Newman (Signature of the Contracting Officer)	9/6/2019

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is NOT usable

STANDARD FORM 26 (Rev. 5/2011)
Prescribed by GSA - FAR (48 CFR) 53.214(a)

CONTRACT TABLE OF CONTENTS

PART I – THE SCHEDULE	**1**
SECTION B – SUPPLIES OR SERVICES AND PRICE/COSTS	1
SECTION C – DESCRIPTIONS/SPECIFICATIONS/WORK STATEMENT	7
SECTION D – PACKAGING, MARKING, & SHIPPING	9
SECTION E – INSPECTION AND ACCEPTANCE	10
SECTION F – DELIVERIES OR PERFORMANCE	11
SECTION G – CONTRACT ADMINISTRATION DATA	26
SECTION H – SPECIAL CONTRACT REQUIREMENTS	32
PART II – CONTRACT CLAUSES	**46**
SECTION I – CONTRACT CLAUSES	46
PART III – LIST OF DOCUMENTS, EXHIBITS, AND OTHER ATTACHMENTS	**53**
SECTION J – LIST OF ATTACHMENTS	53

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The Pandemic and All Hazards Preparedness Act (PAHPA) of 2006 established the Biomedical Advanced Research and Development Authority (BARDA) and was reauthorized under the PAHPA of 2013 to support development and acquisition of medical countermeasure (MCMs) to prevent or treat the medical consequences of chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza (PI), and emerging infectious diseases (EID). These MCMs include vaccines, therapeutics, diagnostics, and medical devices. Additionally, BARDA is entrusted to foster innovation of technologies that enable better manufacturing, testing, and utilization of these medical countermeasures.

Antimicrobial resistant (AMR) and biodefense microbial threat (biothreat) pathogens are serious and emerging threats to the U.S. civilian, military and pediatric populations. These opportunistic pathogens cause devastating and potentially incurable infections in high-risk groups such as patients undergoing complex surgery, in long-term hospital care, and the immunocompromised. A 2013 CDC report classified 18 pathogens resistant to antimicrobial drugs as threats to modern society and identified the major cause of resistance as the inappropriate use of antimicrobial drugs, leading to the CARB initiative by the U.S. government in 2015. Improvements to antimicrobial stewardship present an opportunity to slow and even stop natural AMR development. In particular, there is a major need for high sensitivity and rapid diagnostics, sufficient to quickly identify infected patients even with low titer level infections and inform therapy decisions. Next generation diagnostics have the unique potential to triage patients onto the correct therapy faster, reducing the spread of resistance and improving patient outcomes.

The overall objective of this contract is to advance the development of “Rapid, high-throughput, multiplexed detection of biothreat species ID and resistance genes using T2MR” as a rapid type of countermeasure to diagnose bacterial biothreat pathogens and bacterial antibiotic resistance threats. The scope of work for this contract includes: program management activities, assay development activities including microbiology, nucleic acid amplification, detection, and optimization, instrument development activities, controls development, assay migration and on-instrument optimization, consumables and instrument manufacturing, regulatory and quality activities, equipment validation, and biosafety level 3 (BSL-3) biocontainment verification studies, clinical studies and FDA submission. The R&D effort for the product “Rapid, high- throughput, multiplexed detection of biothreat species ID and resistance genes using T2MR” will progress in specific stages that cover the base performance segment (I) to be labeled Contract Line Item Number (CLIN) 0001 and option segments (I to VII) to be labeled CLINs 0002 to CLINs 0008 as specified in this contract.

Except for the stand-alone work segment labeled CLIN 0008, the contractor must complete specific tasks required in each of the discrete work segments for consideration to proceed onto subsequent segments. The program is divided into eight segments for contractual organization (Base and Options 1-7).

The Government has determined a Bona Fide Need for each non-severable discrete work segment which will conclude upon the completion of a defined task or defined tasks that provide(s) independent merit and value to the Government. The Contractor's success in completing the required tasks under the work segments must be demonstrated through the Deliverables and Milestones specified under Article F of this contract. As set forth in the Contract WBS Milestones/Deliverables and Technical Deliverables chart under Article F of this contract, the GO/NO GO Contract Milestones and Decision Gates will constitute the basis for the Government’s decision, at its sole discretion, to exercise any follow-on option period(s).

The base and option period segments under Contract Line Item (CLIN) 0001 are event driven work segments rather than time driven CLINs. The funds for each independent, non-severable discrete work segment (requirement), regardless of duration, shall only be used for the scope of work covered in each discrete work segment (i.e., the base period work segment and each option work segment). It is possible that more than one option period (requirement), may be awarded at one time and that individual CLINs may overlap and/or proceed concurrently.

B.2 BASE PERIOD

1. The total estimated cost of the base period of this contract, excluding fee, is $ $5,978,993.

2. The Contractor shall maintain records of all contract costs and such records shall be subject to FAR 52.215-2 (Oct 2010), Audit and Records – Negotiation and incorporated by reference into the contract in SECTION I.

3. The amount currently obligated will cover base performance of the contract through July 8, 2020.

CLIN	Period of Performance	Supplies/Services	Not To Exceed Total
0001	Base Period [****]	[****]	$5,978,993

B.3. OPTION PERIODS

B.3.1 COST REIMBURSMENT OPTIONS

a. The contract includes optional, cost reimbursement CLINs 0002 through 0008. The Government may exercise Option Periods in accordance with FAR 52.217-9 Option to Extend the Term of the Contract (March 2000), as set forth in Section I of the contract.

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

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

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

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

Option	CLIN	Period of Performance	Supplies/Services	Not to Exceed Total
1	0002	[****]	**Option 1 Period**: [****]	$[****]
2	0003	[****]	**Option 2 Period:** [****]	$[****]
3	0004	[****]	**Option 3 Period:** [****]	$[****]
4	0005	[****]	**Option 4 Period:** [****]	$[****]
5	0006	[****]	**Option 5 Period:** [****]	$[****]
6	0007	[****]	**Option 6 Period:** [****]	$[****]
7	0008	[****]	**Option 7 Period:** [****]	$[****]
		TOTALS	**Only option years**	$[****]
		TOTALS	**Base + options**	$[****]

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

B.4 ESTIMATED COST - COST SHARING

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

B.5. LIMITATIONS APPLICABLE TO DIRECT COSTS

a. Items Unallowable Unless Otherwise Provided

Notwithstanding the clauses and unless authorized in writing by the Contracting Officer or set forth in the Statement of Work, the cost of the following items or activities shall be unallowable as direct costs:

1) Acquisition, by purchase or lease, of any interest in real property;

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

2) Special rearrangement or alteration of facilities;

3) Accountable Government Property (see the HHS Contracting Guide for Control for Government Property incorporated by Section G.9. of this contract);

Note: this includes the lease or purchase of any item of general purpose office furniture or office equipment regardless of dollar value.

4) Purchase or lease of scientific instruments or equipment over $10,000 except for instruments and equipment specifically included in the Statement of Work;

5) Travel to attend general scientific meetings/conferences;

6) Printing Costs (as defined in the Government Printing and Binding Regulations);

7) Overtime (premium) compensation

8) Entering into certain types of subcontracting arrangements. Note that most consulting agreements require CO's written consent.

9) Patient care costs (see Section J-List of Attachments);

10) Light Refreshment and Meal Expenditures - Requests to use contract funds to provide light refreshments and/or meals to either federal or nonfederal employees must be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, at least six (6) weeks in advance of the event and are subject to "HHS Policy on Promoting Efficient Spending: Use of Appropriate Funding for Conferences and Meetings, Food and Promotional Items and Printing and Publications." The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provide; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshments and/or meals costs; (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals; and (e) if the event will be held at a government facility.

B.6. ADVANCE UNDERSTANDINGS

a. Person-in-Plant

With seven (7) days advance notice to the Contractor in writing from the Contracting Officer, the Government may place a man-in-plant in the Contractor's or Subcontractor's facility, who shall be subject to the Contractor's or Subcontractor's policies and procedures regarding security and facility access at all times while in the Contractor's or Subcontractor's facility.

The Government's representative shall be provided reasonable access, during normal business hours, of the production areas being utilized in performance on the Contract. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a contractor or subcontractor plant.

An article substantially similar to this Person-in-Plant article shall be incorporated into any subcontract for experimental or manufacturing work.

b. Security

No security plan is required at this point for this effort. It is anticipated that a security waiver will be approved.

c. Subcontracts

Prior written consent from the Contracting Officer in the form of Contracting Officer Authorization (COA) is required for any subcontract that:

- Is of the cost-reimbursement type and exceeds $150,000; or
- Is of the fixed price type and exceeds $150,000 or 5% of the contract, whichever is less.

The Contracting Officer shall request appropriate supporting documentation in order to review and determine authorization, pursuant with FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, the Contractor shall provide a copy of the signed, executed subcontract and consulting agreement to the Contracting Officer within ten (10) calendar days.

Note: Consulting services are treated as subcontracts and subject to the 'consent to subcontract' provisions set forth in this Section.

d. Overtime Compensation

No overtime (premium) compensation is authorized under the subject contract.

e. Sharing of contract deliverables within United States Government (USG)

In an effort to build a robust medical countermeasure pipeline through increased collaboration, the Government may share technical deliverables with Government entities responsible for Medical Countermeasure Development. In accordance with recommendations from the Public Health Emergency Medical Countermeasure Enterprise Review, agreements established in the Integrated Portfolio Advisory Committee (PAC) Charter, and agreements between BARDA and the Department of Defense, the National Institutes of Health, the Centers for Disease Control, and the Food and Drug Administration, BARDA may share technical deliverables and test results created in the performance of this Contract with colleagues within the Integrated Portfolio. This advance understanding does not authorize the Government to share financial information outside of the United States Government.

The Contractor is advised to review the terms of FAR 52.227-14, Rights in Data – General, regarding the government's rights to deliverables submitted during performance as well as the government's rights to data contained within those deliverables.

f. Approval of Human and Animal Protocols

The Contractor shall submit all human and animal protocols and human informed consent documents as referenced under this Contract to the COR for review and approval **prior** to seeking other approvals (Institutional Review Board, Human Use Committee, Institutional Animal Care and Use Committee). The Government requires no fewer than eight (8) business days to perform a review. The Contractor shall take this review time into account and submit protocols as early as possible to avoid delays. The Government's comments and feedback shall be addressed prior to approval. The COR will review and provide approval of protocols. Human informed consents shall also be submitted and reviewed with any human protocol.

g. Rights in Data

The contract will incorporate the FAR Clause 52.227-14, Rights in Data—General. The Contractor is advised to review the terms of FAR 52.227-14, Rights in Data, regarding the government's rights to deliverables submitted during performance as well as the government's rights to data contained within those deliverables.

h. Invoice Submission during end of Fiscal Year

The government will not accept invoices for processing from Sep 6th through Oct 5th because of end of year fiscal requirements. Any invoices received from September 6th through October 5th will be canceled and returned to the Contractor for resubmission beginning on October 6th.

i. Cost Sharing

1. This is a cost-sharing contract. Monies shall be provided for the total cost of performance from the BARDA and T2 Biosystems, Inc.
2. The Government shall provide monies in an amount not to exceed $5,978,993. The Contractor's share is estimated at $2,875,256.
3. The Contractor shall maintain records of all contract costs (including costs claimed by the Contractor as being its share) and such records shall be subject to the **Audit and Records- Negotiation** and **Final Decisions on Audit Findings** clauses of the General Clauses.
4. Costs contributed by the Contractor shall not be charged to the Government under any other contract, grant, or cooperative agreement (including allocation to other grants, contracts, or cooperative agreements as part of an independent research and development program). The Contractor shall report the organization's share of the costs expended by category, on the Financial Report of Individual Project/Contract as referenced in the CONTRACT FINANCIAL REPORT Article in SECTION G of this contract.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Work attached to this contract as Attachment 1 (Section J-List of Attachments).

C.2. REPORTING REQUIREMENTS

Refer to Section F.2 for specific instructions regarding Reporting Requirements.

C.3. PROJECT MEETING CONFERENCE CALLS

A conference call between the Contract Officer, the Contracting Officer's Representative (COR) and designees and the Contractor's Project Leader/delegate and designees shall occur bi-weekly or as otherwise mutually agreed upon by the Government and the Contractor or determined by the Contracting Officer. During this call the Contractor's Project Leader/delegate and designees will discuss the activities since the last call, any problems that have arisen and the activities planned until the next call takes place. The Contractor's Project Leader/delegate may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the Contracting Officer's Representative. Electronic copy of conference call meeting minutes/summaries shall be provided via e-mail to the CO, COR, and uploaded in eRoom by the Contractor within five (5) business days after the conference call is held.

C.4. PROJECT MEETINGS

The Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the COR. These meetings may include face-to-face meetings with BARDA in Washington,
D.C. and at work sites of the Contractor and its subcontractors. Such meetings may include, but are not limited to, meetings of the Contractor (and subcontractors invited by the Contractor) to discuss study designs, site visits to the Contractor's and subcontractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor must provide data, reports, and presentations to groups of outside experts (subject to appropriate protections for Contractor confidential or proprietary data) and Government personnel as required by the COR in order to facilitate review of contract activities.

a. Kickoff Meeting

The Contractor and Government shall conduct a kickoff meeting within 45 calendar days after contract award to review HHS procedures, processes and expectations. Contractor shall provide an itinerary/agenda no later than 5 business days before meeting. Minutes from the kickoff meeting must be provided within 10 business days of the event.

b. Quarterly and Ad-Hoc Meetings

At the discretion of the CO or COR, the Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the Contracting Officer's Representative. These meetings may be conducted via teleconferences or face-to-face meetings in Washington, D.C. or at work sites of the Contractor and its subcontractors. Such meetings may include, but are not limited to, meetings of the Contractor (and subcontractors invited by the Contractor) to discuss study designs, site visits to the Contractor's and subcontractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor must provide data, reports, and presentations to groups of outside experts (subject to appropriate protections for Contractor's confidential or proprietary data) and Government personnel as required by the Contracting Officer's Representative, giving reasonable prior notice of such requirement to Contractor, in order to facilitate review of contract activities.

Contractor shall provide itinerary/agenda at least 5 business days in advance of face-to-face meeting.

c. Face-to-Face Project Review Meetings

The Contractor shall, at a time to be determined later, present a comprehensive review of contract progress to date in a face-to-face meeting in Washington, DC. The Contractor will be responsible for updating the BARDA program on technical progress under the Statement of Work. Presentation must be delivered seven (7) business days prior to the scheduled meeting.

C.5 RISK MANAGEMENT

The Contractor shall establish and maintain an active, enterprise-wide risk management system as well as a specific risk management plan that includes the SOPs governing risk management, a description of the risk management activities required to oversee the project across its range of scope, and the processes for reviewing completed risk mitigations. The Contractor shall complete risk management documentation for the program as applicable, such as:

1. Preliminary hazard analyses as necessary for each product component
2. Design, user, and process FMEA plans
3. Risk control plans to verify the proposed mitigations

C.6 REGULATORY ACTIVITIES

The Contractor shall provide the COR the opportunity to review and comment upon any draft documents, including draft pre-submission packages, and meeting requests, to be submitted to the FDA or other regulatory agency. The Contractor shall provide the COR with five (5) business days for review and comments. An acceptable version shall be provided to the COR prior to FDA submission.

The Contractor shall provide the COR initial draft minutes and final draft minutes of any - meeting with the FDA and other regulatory agencies.

The Contractor shall communicate the dates and times of any meeting with the FDA and other regulatory agencies to the COR and ensure participation for appropriate COR and BARDA SME staff to attend the meetings.

The Contractor shall forward Standard Operating Procedures (SOPs) upon request from Contracting Officer’s Representative /Contracting Officer.

The Contractor shall work to support BARDA in development of FDA submissions and meeting for seeking a Pre-Emergency Use Authorization if deemed necessary by BARDA. The support may require the Contractor to develop unique deliverables other than the ones related to the SOW for submission to the FDA by BARDA.

The Contractor shall support FDA audits. Within thirty (30) calendar days of an FDA audit of Contractor or subcontractor facilities, the Contractor shall provide copies of the audit findings, final report, and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

C.7 QUALITY

The Contractor shall establish and maintain a Quality Management System with sufficient content to include but not limited to the elements contained in the Code of Federal Regulations Title 21 Part 820.

The Contractor shall establish routine internal reviews, documentation, and evidence of the ability to maintain, and adhere to the Code of Federal Regulations Title 21 Part 820.

The Contractor shall contract for an independent audit of its system quality system adherence, resolve any issues noted by the auditor, and provide the audit findings and resolutions to the Government.

SECTION D – PACKAGING, MARKING, AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications and Section F. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition

Unless otherwise specified by the CO, delivery of reports to be furnished to the Government under this contract (including invoices) shall be delivered to the CO and COR electronically along with a concurrent email notification to the CO and COR (as defined in Section F.3. Electronic Submission) summarizing the electronic delivery.

SECTION E – INSPECTION AND ACCEPTANCE

E.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

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

FAR Clause **Title and Date**

FAR 52.246-3, Inspection of Supplies – Cost-Reimbursement (May 2001) FAR 52.246-5,
Inspection of Services - Cost-Reimbursement (April 1984)
FAR 52.246-9, Inspection of Research and Development (Short Form) (April 1984) FAR 52.246-16,
Responsibility for Supplies (April 1984)

E.2. DESIGNATION OF GOVERNMENT PERSONNEL

For the purpose of this Section E, the designated Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer. The COR will assist in resolving technical issues that arise during performance. The COR however is not authorized to change any contract terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance.

E.3. INSPECTION, ACCEPTANCE AND CONTRACT MONITORING

Inspection and acceptance of the product, services, and documentation called for herein shall be accomplished by the Contracting Officer or a duly authorized representative. Delivery, technical inspection and acceptance will take place at a location designated by the Contracting Officer or at:

Office of the Assistant Secretary for Preparedness and Response Biomedical
Advanced Research and Development Authority O'Neill House Office Building
Washington, DC 20515

a. Site Visits and Inspections

At the discretion of the Government and independent of activities conducted by the Contractor, with 48 hours' notice to the Contractor, the Government reserves the right to conduct site visits and inspections related to this Contract on an as needed basis during normal business hours, including collection of product samples and intermediates held at the location of the Contractor, or its subcontractor. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable costs subject to the Allowable cost requirements in FAR Subpart 31.2. The Contractor shall coordinate these visits and shall have the opportunity to accompany the Government on any such visits. Under time-sensitive or critical situations, the Government reserves the right to suspend the 48 hour notice to the Contractor. The areas included under the site visit could include, but are not limited to: security, regulatory and quality systems, manufacturing processes and cGMP/GLP/GCPcompliance related to activities funded under this Contract.

If the Government, Contractor, or other party identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government for review and acceptance:

- If issues are identified during the audit, the Contractor shall submit a report to the CO and COR within five (5) business days detailing the finding and corrective action(s) of the audit.
- COR and CO will review the report and provide a response to the Contractor within ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

SECTION F – DELIVERIES OR PERFORMANCE

F.1. ESTIMATED PERIOD OF PERFORMANCE

The estimated period of performance for this contract shall be consistent with the dates set forth in the Base Period in Section B.2. If the Government exercises the Options Period(s) pursuant to the Option Clause in Section I.3 of the contract, the period of performance shall be increased as shown in the table in Section B.3.

F.2. DELIVERABLES

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

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

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

All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double- sided, on at least 30 percent post-consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b). Hard copies of deliverables and reports furnished to the Government under the resultant Contract (including invoices) shall be addressed as follows:

HHS/ASPR/BARDA/CMA:

ATTN: Carl Newman (Contracting Officer)
U.S. Department of Health & Human Services
Office of the Assistant Secretary for Preparedness and Response Biomedical
Research and Development Authority (BARDA) Contract Management and
Acquisition (CMA)
O’Neill House Office Building Room
Number: 21C06 Washington, DC
20515
Email: carl.newman@hhs.gov

HHS/ASPR/BARDA:

ATTN: Ivan Silva (COR)
U.S. Department of Health & Human Services
Office of the Assistant Secretary for Preparedness and Response Biomedical Advanced
Research & Development Authority (BARDA) O’Neill House Office Building
Room Number: 21J23 Washington,
DC 20515 Email:
ivan.silva@hhs.gov

Contract Data Requirements List (CDRLs)

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
01	Kickoff Meeting	The Contractor shall complete a Kickoff meeting after contract award	• Within 45 calendar days after contract award. • Materials: Contractor shall provide itinerary and agenda to CO and COR at least 5 business days in advance of meeting. CO approves and the COR distributes itinerary and agenda within 3 business days. • Due out: Contractor provides meeting minutes to CO and COR within 5 business days after the meeting. The CO and COR reviews, comments, and the CO approves minutes within 10 business days of the event.
02	Quarterly Meetings	At the discretion of the government the Contractor shall hold recurring teleconference or face-to-face Project Review Meetings up to four per year either in Washington D.C or at work sites of the Contractor or subcontractors. Face-to-face meetings shall alternate between Washington DC and Contractor, sub-contractor sites. The meetings will be used to discuss contract progress in relation to the Program Management deliverables described below as well as study designs, technical, regulatory, and ethical aspects of the program.	• Materials: Contractor shall provide itinerary and agenda to CO and COR at least 5 business days in advance of site visit. The COR approves and distributes itinerary and agenda within 3 business days. • Due out: Contractor provides meeting minutes to the CO and the COR within 5 business days after the meeting. The CO and COR reviews, comments, and the CO approves minutes within 10 business days.
03	Biweekly Teleconference Meetings	The Contractor shall participate in teleconferences every two weeks with the CO and the COR to discuss the performance of the contract.	• Materials: Contractor provides agenda to the CO and COR no later than 2 business days in advance of meeting. The COR approves and distributes agenda prior to meeting. • Due out: Contractor provides meeting minutes to the CO and COR within 5 business days following the meeting. The CO and COR reviews, comments, and the COR approves minutes within 10 business days following the meeting.
04 (Monthly) 05 (Annual)	Monthly & Annual Technical Progress Reports	The Monthly and Annual Technical Progress report shall address each of the below items and be cross- referenced to the Work Breakdown Structure (WBS), Statement of Work (SOW), Integrated Master Schedule	• Due: Monthly Reports shall be submitted on the 25th day of the month after the end of each month with an Annual Report submitted on the 30th calendar day of the final month of each

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
		(IMS), and Contract Performance Report (CPR). 1. An Executive Summary highlighting the progress, issues and relevant manufacturing, non- clinical, clinical and regulatory activities. The Executive Summary should highlight only critical issues for that reporting period and resolution approach; limited to 2-3 pages. 2. Progress in meeting contract milestones – broken out by subtasks within each milestone, overall project assessment, problems encountered and recommended solutions. The reports shall detail the planned and actual progress during the period covered, explaining occurrences of any differences between the two and the corrective steps. 3. The reports shall also include a three-month rolling forecast of the key planned activities, referencing the WBS/IMS. 4. A tracking log of progress on regulatory submissions with the FDA number, description of submission, date of submission, status of submission and next steps. 5. Estimated and Actual Expenses. 6. This report shall also contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.	contract year for the previous twelve calendar months. • When the 25th or 30th falls on a weekend or a US Holiday, the reports will be due the next business day. • Monthly progress reports are not required for the periods when the Annual Report(s) and Final Report are due. The CO and the COR will review the monthly reports and provide feedback within 5 business days of receiving the report. The CO approves acceptance of monthly and annual reports.
06	Risk Management	The Contractor shall provide a Risk Management Plan that outlines the	• Due: Within 90 days of contract award.

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
	Plan	impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance.	• Due out: Contractor provides updated Risk Management Plan in Monthly Progress Report. The COR shall provide Contractor with written comments in response submitted plan. Contractor must address, in writing, all commercially reasonable concerns raised by the COR within 20 business days of Contractor's receipt of COR's concerns for CO approval.
07	Deviation Notification and Mitigation Strategy	Process for changing IMS activities associated with cost and schedule. Contractor shall notify BARDA of significant changes the IMS defined as increases in cost above 5% or schedule slippage of more than 30 days, which would require a PoP extension. Contractor shall provide a high-level management strategy for risk mitigation.	• Due: As needed and communicated by the COR/CO.
08	Go/No-Go In-Process Review (IPR) or Decision Gate Presentation	Contractor shall provide a presentation detailing technical progress made towards completion of Go/No-Go decision gate milestones following a prescribed template provided by BARDA prior to the IPR.	• Materials: Contractor shall provide presentation materials to the CO and COR 10 business days prior to the In- Process Review (IPR). Contractor shall submit written justification of progress towards satisfying Go/No-Go criteria. After reviewing, the CO and COR will provide a written response within 10 business days.
09	Incident Report	Contractor shall communicate and document all critical programmatic concerns, risks, or potential risks with the CO and COR.	• Due: Within 48 hours of activity or incident or within 24 hours for a security activity or incident via email or telephone, with written follow- up to the CO and COR. Additional updates due within 48 hours of additional developments. • Due out: Contractor shall submit, within 5 business days, a Corrective Action Plan (if deemed necessary by either party) to address any potential issues. If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by the CO, within 5 business days of receiving such concerns in writing.

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
10	Draft and Final Reports for Clinical and Non- Clinical Studies	Contractor shall provide Draft and Final Clinical/Non-Clinical Study Reports to the CO and COR for review and comment.	• Draft - within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA. Subcontractor prepared reports received by the Contractor shall be submitted to the CO and COR for review and comment no later than 5 business days after receipt by Contractor. The CO shall provide written comments to the Draft Final Report for Clinical and Non-Clinical Studies within 15 business days after the submission. • Final - due 30 calendar days after receiving comments on the Draft Final Report for Clinical and Non-Clinical Studies. If corrective action is recommended, Contractor must address, in writing, all reasonable concerns raised by the CO in writing. Contractor shall consider revising reports to address CO's recommendations prior to FDA submission. • Final FDA submissions shall be provided to the CO and COR concurrently or no later than 5 business days after submission to the FDA.
11	Standard Operating Procedures	The Contractor shall make internal and, to the extent possible, subcontractor Standard Operating Procedures (SOPs) available for review electronically.	Upon request from the CO.
12	FDA Correspondence	The Contractor shall memorialize any correspondence between Contractor and FDA and submit to the CO and COR. All documents shall be duly marked as either "Draft" or "Final".	• Due: Contractor shall provide written summary of any FDA correspondence within 5 business days of correspondence.
13	FDA Meetings	The Contractor shall forward the dates and times of any meeting with the FDA to the CO and COR and make arrangements for appropriate government staff to attend the FDA meetings. Government staff shall include up to a maximum of four people (COR, CO and up to 2 subject matter experts).	• Contractor shall schedule upcoming FDA meetings, so at a minimum the CO, COR, and RQA persons from BARDA can attend. Additionally, a pre-meeting needs to be held with BARDA to review slides and discuss meeting strategies.

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
			• Contractor shall notify the CO and COR of upcoming FDA meeting within 24 hours of scheduling. • The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to the CO and COR within 5 business days of receipt. All documents shall be duly marked as either “Draft” or “Final”.
14	FDA Submissions	The Contractor shall provide the CO and COR the opportunity to review and comment upon all draft submissions before submission to the FDA. Contractor shall provide the CO and COR with an electronic copy of the final FDA submission. All documents shall be duly marked as either “Draft” or “Final”.	• Due: Contractor shall submit draft FDA submissions to the CO and COR at least 15 business days prior to FDA submission. The CO and COR will provide feedback to Contractor within 10 business days of receipt. • Due out: If corrective action is recommended, the Contractor must address, in writing, its consideration of all concerns raised by the CO. • The Contractor shall consider revising their documents to address CO’s concerns and/or recommendations prior to FDA submission. • Final FDA submissions shall be submitted to the CO and COR concurrently or no later than 5 calendar day of its submission to CDER.
15	FDA Audits	In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the Government with an exact copy (non- redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution	• Contractor shall notify the CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice. • Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA or third party.

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
		and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.	• Within 10 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.
16	QA Audit Reports	BARDA Quality group and /or their qualified representatives reserves the right to participate in QA audits. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non- conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to the CO and COR. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.	• Contractor shall notify the CO and COR 10 days in advance of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications. • Contractor shall notify the CO and COR within 5 business days of report completion.
17	BARDA Audit	Contractor shall accommodate periodic or ad hoc site visits by the CO and COR. Contractor shall also accommodate any 'for cause' audit if and when there are potential issues identified in the program during the period of performance. Such issues include but are not limited to stability failures, GLP issues etc. If the CO, COR, Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the CO and COR.	• If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and corrective action(s) within 10 business days of the audit. • Due out: The CO and COR will review the report and provide a response to the Contractor with 10 business days. Once corrective action is completed, the Contractor will provide a final report to the CO and COR.
18	Technical Documents	Upon request, Contractor shall provide CO and COR with deliverables from the following contract funded activities: process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The	• Contractor shall provide technical document within 10 business days of COR's request. Contractor can request additional time on an as needed basis. • If corrective action is recommended by the COR, the Contractor must address, in writing, concerns raised by the

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
		CO and COR reserve the right to request within the PoP a non- proprietary technical document for distribution within the Government.	COR to the COR and CO in writing.
19	Raw Data or Data Analysis	Contractor shall provide raw data and/or data analysis to the CO and COR upon request. Contractor shall address and adjudicate all concerns from BARDA review of the data/analysis and amend the reports as required.	• Contractor shall provide data or data analysis to the CO and COR within 20 business days of request. • Contractor shall amend the reports if required and adjudicate all comments.
20	Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to the CO and COR for review prior to submission.	• Contractor must submit all manuscript or scientific meeting abstract to the CO and COR within 30 days for manuscripts and 15 days for abstracts. • Contractor must address in writing all concerns raised by the CO and COR in writing. • Final submissions shall be submitted to the CO and COR concurrently or no later than five (5) calendar days after its submission.
21	Press Releases	Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases.	• With the exception of ad-hoc press releases required by applicable law or regulations, Contractor shall ensure that the CO and COR has received and approved an advanced copy of any draft press release to this contract not less than 2 business days prior to the issuance of the press release. The CO shall reply with comments within 1 business day of receipt of the draft press release. Should no comments be forthcoming from the CO by end of the 1st business day, Contractor will be permitted to issue the press release • If corrective action is required, the Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. • Any final press releases shall be submitted to the CO and COR no later than 1 (one) calendar day prior to its release.

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
22	Integrated Master Schedule (IMS)-Gantt	The Contractor shall provide an IMS including WBS, critical path, and milestones.	• Due: Contractor shall provide the draft IMS-Gantt within 90 days of contract award with final due 8 months after award and updated monthly as part of the Monthly Progress Report. • Contractor must address, in writing, all concerns raised by the COR in writing and provide response to the CO and COR.
23	Draft and Final Technical Progress Report	A Draft Final Technical Progress Report containing a summation of the work performed and the results obtained for the entire contract PoP. The draft report shall be duly marked as 'Draft'. The Final Technical Progress Report incorporating feedback received from the CO and COR and containing a summation of the work performed and the results obtained for the entire contract PoP. The final report shall document the results of the entire contract. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. The final report shall be duly marked as 'Final'.	• Due: Contractor shall provide a draft Technical Progress Report 75 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP. • Subcontractor prepared reports received by the Contractor shall be submitted to the CO and COR for review and comment no later than 5 business days after receipt by the Contractor. • Due out: the CO shall provide feedback on draft report within 15 calendar days of receipt, which the Contractor shall consider incorporating into the Final Report. • Contractor shall submit, with the Final Technical Progress Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.
24	Draft and Final Study Protocols	Contractor shall provide all Draft and Final Study Protocols to the COR for evaluation. (The CO and COR reserves the right to request within the period of performance a non-proprietary Study Protocol for distribution within the US Government.	• The Contractor will submit all proposed protocols to the CO and COR at least 10 business days prior to study start. If corrective action is required, the Contractor must address in writing all concerns raised by the CO and COR to the satisfaction of the COR before study execution and provide the CO and COR a revised draft protocol that addresses the CO's comments and requested changes. • After receiving the revised Study Protocol that satisfies

CDRL#	Deliverable	Description	Reporting Procedures and Due Dates
			the COR, the CO will approve the revised Study Protocol and will provide a written approval to the Contractor that provides authorization to the Contractor to execute the specific study. • Contractor shall not proceed with any study protocol until the COR gives its approval and the Contractor has provided the CO and COR with a final and approved Study Protocol.
25	Clinical Study Status Update	Contractor shall provide COR with a status update of clinical studies that are actively enrolling patients to include by study site: cumulative enrollment; new enrollments; screen failures; patients dropped from study; AE and SAEs; activation or inactivation of study sites; investigator appointments or changes; and status of IRB/IEC review/approval/renewal. Contractor will provide proposed format for the COR's review and approval.	• Update will be submitted by e-mail or other electronic format to be provided by the COR by the end of the 25th business day of each new month. • When the 25th falls on a weekend or US Holiday, the update will be due the next business day. • Updates, to the extent they are available, will be presented during biweekly teleconferences. • If no changes have occurred since the prior update only a simple statement that there is no new data is required.

NOTE: Pursuant to federal law, no Government personnel shall publish, divulge, disclose, or otherwise make known to any non-Government entity any Contractor data marked according to FAR 52.227-14, unless permitted to do so by law or regulation.

Detailed Description of Select Contract Deliverables

A. Monthly and Annual Progress Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with this Section F of this contract, and in the Statement of Work, attached to this contract (see Section J-List of Attachments).

i. Monthly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The Contractor shall submit a Monthly Progress Report according to the dates set forth in the summary table ("Summary of Contract Deliverables") under this Section. The progress report shall conform to the requirements set forth in the Deliverables Chart in Section F of this contract.

The format should include:

- A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission;
- SECTION I – EXECUTIVE SUMMARY
- SECTION II - PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g., evaluating, and managing subcontractor performance, and personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - For each activity related to Gantt chart, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project.
- SECTION II Part D: PROPOSED WORK - A summary of work proposed related to Gantt chart for the next reporting period and preprints/reprints of papers and abstracts.
- SECTION III: Estimated and Actual Expenses.
  a. This Section of the report shall contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level.
  b. This Section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.

  A Monthly Progress Report will not be required in the same month that the Annual Progress Report is submitted.

ii. Annual Progress Report

This report shall include a summation of the results of the entire contract work for the period covered. Monthly Progress Reports shall not be submitted in the same month when an Annual Progress Report is due. Furthermore, an Annual Progress Report will not be required for the period when the Final Report is due. The first Annual Progress Report shall be submitted in accordance with the date set forth in the table ("Summary of Contract Deliverables") under Section F.2. of this contract. The progress report shall conform to the requirements set forth in the Deliverables Chart in Section F of this contract.

Each Annual Progress Report shall include:

- A Cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and email address; and the date of submission;
- SECTION I: EXECUTIVE SUMMARY - A brief overview of the work completed, and the major accomplishments achieved during the reporting period.
- SECTION II: PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A high level summary of critical meetings, etc. that have taken place during the reporting period. Include progress on administration and management to critical factors of the project (e.g. regulatory compliance audits and key personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - A detailed description of the work performed structured to follow the activities and decision gates outlined at the Integrated Baseline Review and as described in the Integrated Master Schedule. The Report should include a description of any problems (technical or financial) that occurred or were identified during the reporting period, and how these problems were resolved.
- SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next year period to include an updated Gantt Chart.

Contractor also should include the following in the Annual Progress Report:

1. Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period; and
2. A summary of any Subject Inventions per the requirements under FAR Clause 52.227-11.

iii. Draft Final Report and Final Report

These reports are to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Report and Final Report shall be submitted in accordance with the Deliverables Chart in Section F of the contract. An Annual Progress Report will not be required for the period when the Final Report is due. The Draft Final Report and the Final Report shall be submitted in accordance with the dates set forth in the table (“Summary of Contract Deliverables”) under SECTION F.2. of this contract. The report shall conform to the following format:

1. Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date.
2. SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.
3. SECTION II: RESULTS - A detailed description of the work performed related to WBS and Gantt chart, the results obtained, and the impact of the results on the scientific and/or public health community including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance and a summary of all inventions.

Draft Final Report: The Contractor is required to submit the Draft Final Report to the Contracting Officer's Representative and Contracting Officer. The Contracting Officer's Representative and Contracting Officer will review the Draft Final Report and provide the Contractor with comments in accordance with the dates set forth in Section F.2. of the contract.

Final Report: The Contractor will deliver the final version of the Final Report on or before the completion date of the contract. The final version shall include or address the COR's and CO's written comments on the draft report. Final Report shall be submitted on or before the completion date of the contract.

iv. Summary of Salient Results

The Contractor shall submit, with the Final Report, a summary of salient results achieved during the performance of the contract.

v. Audit Reports

Within thirty (30) calendar days of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP, GCP guidelines, the Contractor shall provide copies of the audit report (so long as received from the FDA) and a plan for addressing areas of nonconformance to FDA regulations and guidelines for GLP, GMP, or GCP guidelines as identified in the final audit report and as related to activities funded under this contract.

vi. Periodic Document Review

Upon request, Contractor shall provide CO and COR with the following contract funded documents as specified below but not limited to: Process Development Reports; Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, Contractor/Subcontractor Standard Operating Procedures (SOP's), Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the Period of Performance a non-proprietary technical document for distribution within the Government. Contractor shall provide technical document within 10 business days of CO or COR request. Contractor can request additional time on an as needed basis. If edits are recommended, the Contractor must address, in writing, concerns raised by BARDA in writing.

vii. Risk Management Plan

The Contractor shall provide a Risk Management Plan that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance.

- Due within 180 days of contract award
- Contractor provides updated Risk Management Plan in Monthly Progress Report
- The COR shall provide Contractor with a written list of concerns in response plan submitted

Contractor must address, in writing, all concerns raised by COR within 20 business days of Contractor's receipt of COR's concerns.

B. Deliverables Arising from FDA Correspondence

i. FDA Meetings

The Contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people (COR, CO and up to 2 subject matter experts).

- Contractor shall notify BARDA of upcoming FDA meeting within 24 hours of scheduling.
- The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to the CO and COR within 5 business days of receipt. All documents shall be duly marked as either “Draft” or “Final.”

ii. FDA Submissions

The Contractor shall provide the COR all documents submitted to the FDA.
Contractor shall provide the COR with an electronic copy of the final FDA submission. All documents shall be duly marked as either “Draft” or “Final.”

- If draft documents are submitted to the COR for review, the COR will provide feedback to Contractor within 10 business days of receipt.
- If BARDA reviews draft documents, the Contractor shall revise their documents to address BARDA’s written concerns and/or recommendations prior to FDA submission.
- Final FDA submissions shall be submitted to the CO and COR concurrently or no later than 5 calendar days of their submission to FDA.

iii. FDA Audits

In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the CO and COR with an exact copy

(non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) within five (5) business days after the Contractors receipt of those documents. The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

- Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice.
- Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA, Subcontractor, or third party.
- Within 15 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

iv. Other FDA Correspondence

The Contractor shall memorialize any correspondence between Contractor and FDA as related to activities funded under this contract and submit to BARDA. All documents shall be duly marked as either “Draft” or “Final.” Contractor shall provide written summary of any FDA correspondence within 5 business days of correspondence.

F.3. ELECTRONIC SUBMISSION

For electronic delivery, the Contractor shall upload documents to the appropriate folder on https://eroom.bardatools.hhs.gov/eRoom (“eRoom”) which is the designated Government file sharing system. The Government shall provide two contractor representatives authorized log in access to the file share program. Each representative must complete a mandatory training provided by the Government prior to gaining user access. A notification email should be sent to the CO and COR upon electronic delivery of any documents.

F.4. SUBJECT INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. A final invention statement (see FAR
27.303 (b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

Reports and documentation submitted to the Contracting Officer shall be sent to the address set forth in Section G – Contract Administration Data.

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

F.5. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. The full text of each clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html.

FAR 52.242-15, Stop Work Order (August 1989), Alternate 1 (April 1984)

SECTION G - CONTRACT ADMINISTRATION DATA

G.1. CONTRACTING OFFICER

The following Contracting Officers (CO) will represent the Government for the purpose of this contract: Carl Newman (Contracting Officer)
U.S. Department of Health & Human Services
Office of the Assistant Secretary for Preparedness and Response (ASPR) Biomedical Advanced Research and Development Authority (BARDA) Contract Management and Acquisition (CMA)
O'Neill House Office Building Room Number: 21C06 Washington, DC 20515
202-205-1156 (Office)
carl.newman@hhs.gov

1) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.
2) The Contracting Officer is the only person with the authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimburse to the Contractor of any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract.
3) No information other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the US Government, other otherwise, shall be considered grounds for deviation from any stipulation of this contract.
4) The Government may unilaterally change its CO designation, after which it will notify the Contractor in writing of such change.

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

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

ATTN: Ivan Silva (COR)
U.S. Department of Health & Human Services
Office of the Assistant Secretary for Preparedness and Response Biomedical Advanced Research & Development Authority (BARDA) O'Neill House Office Building
Room Number: 21J23 Washington,
DC 20515 Email: ivan.silva@hhs.gov

The COR is responsible for:

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

G.3. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in Section I of this contract, the following individuals are considered to be essential to the work being performed hereunder:

Name	Title
[****]	[****]
[****]	[****]

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) and qualifications of the individual proposed as a substitute to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the contractor or Government. At a minimum, the key personnel should include the project manager, principal investigator, radiation biologist, quality control manager, quality assurance director, regulatory lead, and manufacturing lead.

G.4. CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Financial Report of Individual Project/Contract shall be submitted by the Contractor to the CO with a copy to the COR in accordance with the instructions for completing this form, which accompany the form, in an original and one electronic copy, not later than the 30th business day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories), which shall be reported within the total contract, are discussed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise stated in the instructions for completing this form, all columns A through J, shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the first full three calendar months following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

e. The listing of expenditure categories to be reported is incorporated as a part of this contract and can be found under Section J entitled, "Financial Report of Individual Project/Contract,".

f. Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

g. Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests and Contract Financial Reporting, and be sent to the following points of contact:

CO	COR	PSC
Carl Newman(Contracting Officer) HHS/ASPR/BARDA/CMA O'Neill House Office Building Room Number: 21C06 Washington, DC 20515 Email: carl.newman@hhs.gov	Ivan Silva COR HHS/ASPR/BARDA O'Neill House Office Building Room Number: 21J23 Washington, DC 20515 202- 260-0761 (Office) ivan.silva@hhs.gov	PSC_Invoices@psc.hhs.gov & "e-Room"

The Contractor agrees to immediately notify the CO in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10%) of the estimated costs for the base period or any option period(s) (See estimated costs under Section B) and the reasons for the variance. These requirements are in addition to the specified requirements of FAR Clause 52.232-20, Limitation of Cost that is incorporated by reference under Section I.1 which states;

Limitation of Cost (Apr 1984)

- The parties estimate that performance of this contract, exclusive of any fee, will not cost the Government more than (1) the estimated cost specified in the Schedule or, (2) if this is a cost-sharing contract, the Government's share of the estimated cost specified in the Schedule. The Contractor agrees to use its best efforts to perform the work specified in the Schedule and all obligations under this contract within the estimated cost, which, if this is a cost-sharing contract, includes both the Government's and the Contractor's share of the cost.
- The Contractor shall notify the Contracting Officer in writing whenever it has reason to believe that—
- The costs the Contractor expects to incur under this contract in the next 60 days, when added to all costs previously incurred, will exceed 75 percent of the estimated cost specified in the Schedule; or
- The total cost for the performance of this contract, exclusive of any fee, will be either greater or substantially less than had been previously estimated.
- As part of the notification, the Contractor shall provide the Contracting Officer a revised estimate of the total cost of performing this contract.
- Except as required by other provisions of this contract, specifically citing and stated to be an exception to this clause—
- The Government is not obligated to reimburse the Contractor for costs incurred in excess of (i) the estimated cost specified in the Schedule or, (ii) if this is a cost-sharing contract, the estimated cost to the Government specified in the Schedule; and
- The Contractor is not obligated to continue performance under this contract (including actions under the Termination clause of this contract) or otherwise incur costs in excess of the estimated cost specified in the Schedule, until the Contracting Officer (i) notifies the Contractor in writing that the estimated cost has been increased and (ii) provides a revised estimated total cost of performing this contract. If this is a cost-sharing contract, the increase shall be allocated in accordance with the formula specified in the Schedule.
- No notice, communication, or representation in any form other than that specified in paragraph (d)(2) of this clause, or from any person other than the Contracting Officer, shall affect this contract's estimated cost to the Government. In the absence of the specified notice, the Government is not obligated to reimburse the Contractor for any costs in excess of the estimated cost or, if this is a cost-sharing contract, for any costs in excess of the estimated cost to the Government specified in the Schedule, whether those excess costs were incurred during the course of the contract or as a result of termination.

- If the estimated cost specified in the Schedule is increased, any costs the Contractor incurs before the increase that are in excess of the previously estimated cost shall be allowable to the same extent as if incurred afterward, unless the Contracting Officer issues a termination or other notice directing that the increase is solely to cover termination or other specified expenses.
- Change orders shall not be considered an authorization to exceed the estimated cost to the Government specified in the Schedule, unless they contain a statement increasing the estimated cost.
- If this contract is terminated or the estimated cost is not increased, the Government and the Contractor shall negotiate an equitable distribution of all property produced or purchased under the contract, based upon the share of costs incurred by each.

h. The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e- mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

i. An electronic copy of the payment request shall be uploaded into the designated eRoom (as defined in Section F.3 ELECTRONIC SUBMISSION) and an e-mail notification of the upload will be provided to the CO and COR.

j. All invoice submissions shall be in accordance with FAR Clause 52.232-25, Prompt Payment (Oct 2008).

k. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget.

The Contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

1. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), and amount claimed.
2. Fringe Benefits - Cite rate and amount
3. Overhead - Cite rate and amount
4. Materials & Supplies - Include detailed breakdown when total amount is over $10,000.
5. Travel - Identify travelers, dates, destination, purpose of trip, and total breaking out amounts for transportation (plane, car etc), lodging, M&IE. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel.
6. Consultant Fees - Identify individuals, amounts and activities. Cite appropriate COA
7. Subcontracts - Attach subcontractor invoice(s). Cite appropriate COA
8. Equipment - Cite authorization and amount. Cite appropriate COA
9. Other Direct Costs - Include detailed breakdown when total amount is over $10,000.
10. G&A - Cite rate and amount.
11. Total Cost (and applicable cost-shared ratio)
12. Fixed Fee (if applicable)
13. Total Cost Plus Fixed Fee

Additional instructions and an invoice template are provided in Section J-List of Attachments,

Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for Cost- Reimbursement Contracts. All invoices must be signed by a representative of the contractor authorized to certify listed charges are accurate and comply with government regulations. Invoices shall be signed and submitted electronically (in accordance with Section F.3 Electronic Submission).

If applicable, the Contractor shall convert any foreign currency amount(s) in the monthly invoice to U.S. dollars each month, on the 1st of the month, using the foreign exchange rate index published on www.federalreserve.gov. Payment of invoices is subject to the U.S. dollar limits within the Total Costs of CLIN 0001 in Section B of the contract.

The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-33, Payment by Electronic Funds Transfer–System for Award Management, in Section I requires the Contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

G.5. REIMBURSEMENT OF COST

The Government shall reimburse the Contractor the cost determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with FAR Clause 52.216-7, Allowable Cost and Payment incorporated by reference in Section I, Contract Clauses, of this contract, and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

a) All direct materials and supplies that are used in performing the work provided for under the contract, including those purchased for subcontracts and purchase orders.

b) All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.

c) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.

G.6. INDIRECT COST RATES

Pursuant to FAR Part 42.704, the following provisional rates are established and incorporated into the contract for interim reimbursement of indirect costs (include specific CLINS or Base period if needed) pending the establishment of final indirect cost rates in accordance with FAR 52.216-7. The provisional rates may be revised retroactively or prospectively during contract performance by mutual agreement of the contracting officer, or cognizant auditor and the contractor at either party's request, to prevent substantial overpayment or underpayment.

Rate Type	Provisional Rate	Ceiling	Allocation Base
Fringe Benefits	[****]%	[****]%	Total Salaries and Wages
Overhead	[****]%	[****]%	Total Direct Costs

b. Notwithstanding the provisions of FAR 42.704, ceilings are hereby established on indirect costs reimbursable under this contract. Therefore, the Government will not be obligated to pay any additional amounts if the final indirect cost rates developed by the cognizant audit activity based on actual allowable costs exceed the ceiling rates set forth above. In the event the final indirect cost rates are less than the above- established ceiling rates, the negotiated final rates shall be reduced to conform to the lower rates.

c. In accordance with FAR Part 5.216-7(d), the contractor shall submit an adequate final indirect cost rates proposal to the contracting officer and the cognizant auditor within the six-month period following the end of each of its fiscal years during the period of contract performance. The contracting officer may grant, in writing, reasonable extensions, for exceptional circumstances only, when requested in writing by the contractor.

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

G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, an interim evaluation shall be submitted annually.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address: https://www.cpars.csd.disa.mil/.

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact that will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

G.8. CONTRACT COMMUNICATIONS/CORRESPONDENCE (JULY 1999)

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting the contract number from Page 1 of the contract.

G.9. GOVERNMENT PROPERTY

In addition to the requirements of the Government Property clause incorporated in Section I of this contract, the Contractor shall comply with the provisions of HHS Publication, "HHS Contracting Guide for Control of Government Property," which is incorporated into this contract by reference. This document can be accessed at:

https://archive.org/details/contractorsguide00unit

Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

Notwithstanding the provisions outlined in the HHS Publication, "HHS Contracting Guide for Control of Government Property," which is incorporated in this contract in paragraph 1 above, the Contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for submitting summary reports required under this contract, as directed by the Contracting Officer or his/her designee. This form is attached to this contract (see Section J- List of Attachments). Title will vest in the Government for equipment purchased as a direct cost.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The Contractor, depending upon the nature of the work, is responsible for following the provisions below in conducting its own work under this contract. The Contractor also is responsible for incorporating these provisions into any subcontract awarded, if applicable to the specific nature of the work in the subcontract. Accordingly, those provisions shall be flowed-down as applicable.

H.1 CLINICAL AND NON-CLINICAL TERMS OF AWARD

BARDA has a responsibility to obtain documentation concerning mechanisms and procedures that are in place to protect the safety of participants and animals in BARDA funded clinical trials and non-clinical studies. Therefore, the Contractor shall develop a protocol for each clinical trial *and* non-clinical study funded under this contract and submit all such protocols and protocol amendments to the Contracting Officer's Representative (COR) for evaluation and comment.

Approval by the COR is required before work under a protocol may begin. The COR comments will be forwarded to the Contractor within ten (10) business days. The Contractor must address, in writing, all concerns (*e.g.* study design, safety, regulatory, ethical, and conflict of interest) noted by the COR.

If the draft protocols are to be submitted to the FDA, the COR review shall occur before submission, pursuant to the terms set forth by Section F.2 of this contract. The Contractor shall revise their protocols to address BARDA's concerns and recommendations prior to FDA submission. The Contractor must provide BARDA with a copy of FDA submissions, within the time frame set forth by Section F.2 of this contract.

Execution of clinical and non-clinical studies requires written authorization from the Government. The Government will provide written authorization to the Contractor upon either 1) receiving documentation in which all COR comments have been satisfactorily addressed; or 2) receiving documentation that the FDA has reviewed and commented on the protocol.

The Government shall have unlimited rights to all protocols, data resulting from execution of these protocols, and final reports funded by BARDA under this contract, as set forth in the FAR clauses referenced in PART II of this contract. The Government reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form to ensure the Government has the ability to review and distribute the deliverables as the Government deems necessary. Important information regarding performing human subject research is available at https://www.niaid.nih.gov/research/clinical- research.

Any updates to technical reports are to be addressed in the Monthly and Annual Progress Reports. The Contractor shall advise the Contracting Officer's Representative or designee in writing and via electronic communication in a timely manner of any issues potentially affecting contract performance.

1. **Non-Clinical Terms of Award**

   This contract does not involve the use of animals.

2. **Clinical Terms of Award**

These Clinical Terms of Award detail an agreement between the Government and the Contractor; they apply to all grants and contracts that involve clinical research.

BARDA shall have unlimited rights to all protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this contract, as defined in Rights in Data Clause in FAR 52.227-14. BARDA reserves the right to request that the Contractor provide any contract deliverable in a without any restrictive legends to ensure BARDA has the ability to review and distribute the deliverables, as BARDA deems necessary.

a. Safety and Monitoring Issues

i. Institutional Review Board or Independent Ethics Committee Approval

Within 30 days of award and then with the annual progress report, the Contractor must submit to the COR a copy of the current IRB-or IEC-approved informed consent document, documentation of continuing review and approval and the OHRP federal wide assurance number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter clinical trial or study), each institution's IRB or IEC must review and approve the protocol. They must also provide BARDA initial and annual documentation of continuing review and approval, including the current approved informed consent document and federal wide number.

The Contractor must ensure that the application as well as all protocols is reviewed by their IRB or IEC.

To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor must provide the COR copies of documents related to all major changes in the status of ongoing protocols, including the following:

- All amendments or changes to the protocol, identified by protocol version number, date, or both and dates it is valid.
- All changes in informed consent documents, identified by version number, dates, or both and dates it is valid.
- Termination or temporary suspension of patient accrual.
- Termination or temporary suspension of the protocol.
- Any change in IRB approval.
- Any other problems or issues that could affect the participants in the studies.

The Contractor must notify the COR and CO of any of the above changes within five (5) working days by email or fax, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IRB and a copy of any responses from the IRB or IEC.

If a clinical protocol has been reviewed by an institutional biosafety committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if
any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

ii. Data and Safety Monitoring Requirements

BARDA strongly recommends independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trial of licensed products; and clinical research of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms. Phase III clinical trials must be reviewed by an independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform BARDA of any upcoming site visits and/or audits of CRO facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of CROs as BARDA deems necessary.

A risk is minimal where the probability and magnitude of harm or discomfort anticipated

in the proposed research and not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For examples, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination (45 CFR 46.102I).

Final decisions regarding the type of monitoring to be used must be made jointly by BARDA and the Contractor before enrollment starts. Discussions with the responsible BARDA Project Officer regarding appropriate safety monitoring and approval of the final monitoring plan by BARDA must occur before patient enrollment begins and may include discussions about the appointment of one of the following.

- **Independent Safety Monitor** – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.

- **Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC)** – a small group of independent investigators and biostatisticians who review data from a particular study.

- **Data and Safety Monitoring Board** – an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may be required to use an established BARDA DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) For Oversight of Clinical Trials Policy

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and *curriculum vitae* from all members must be submitted to and approved by the COR before enrollment starts. The Contractor will also ensure that the monitors and board members report any conflicts of interest and the Contractor will maintain a record of this. The Contractor will share conflict of interest reports with the CO and COR.

Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to the BARDA within thirty (30) days of reviews or meetings.

iii. **BARDA Protocol Review Process Before Patient Enrollment Begins** The COR has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must ensure the following (as applicable) are in place at each participating institution, prior to patient accrual or enrollment:

- IRB- or IEC-approved clinical research protocol identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria.
- Documentation of IRB or IEC approval, including OHRP federal wide number, IRB or IEC registration number, and IRB and IEC name.
- IRB- or IEC- approved informed consent document, identified by version number, date, or both and dates it is valid.
- Plans for the management of side effects.
- Procedures for assessing and reporting adverse events.
- Plans for data and safety monitoring (see above) and monitoring of the clinical study site, pharmacy, and laboratory.
- Documentation that the Contractor and all study staff responsible for the design or

conduct of the research have received training in the protection of human subjects.

Documentation to demonstrate that each of the above items are in place shall be submitted to the COR) for evaluation and comment in conjunction with the protocol. Execution of clinical studies requires written authorization from the COR in accordance with this Section of this contract.

iv. Investigational New drug or Investigational Device Exemption Requirements

Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

Exceptions must be granted in writing by FDA. If the proposed clinical trial will be performed under an IND or IDE, the Contractor must provide BARDA with the name and institution of the IND or IDE sponsor, the date the IND or IDE was filed with FDA, the FDA IND or IDE number, any written comments from FDA, and the written responses to those comments.

Unless FDA notifies Contractor otherwise, The Contractor must wait thirty (30) calendar days from FDA receipt of an initial IND or IDE application before initiating a clinical trial.

The Contractor must notify BARDA if the FDA places the study on clinical hold and provide BARDA any written comments from FDA, written responses to the comments, and documentation in writing that the hold has been lifted. The Contractor must not use grant or contract funds during a clinical hold to fund clinical studies that are on hold. The Contractor must not enter into any new financial obligations related to clinical activities for the clinical trial on clinical hold.

v. Required Time-Sensitive Notification

Under an IND or IDE, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Contractor must submit copies to the responsible Contracting Officer's Representative (COR) as follows:

i. Expedited safety report of unexpected or life-threatening experience or death:
A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven (7) days after the IND sponsor's receipt of the information, must be submitted to the COR within 24 hours of FDA notification.

ii. Expedited safety reports of serious and unexpected adverse experiences: A copy of any report of unexpected and serious adverse experience
associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 days after the IND sponsor's receipt of the information, must be submitted to the COR within 24 hours of FDA notification. For medical devices, adverse events should be reported under the MedWatch (MDR) program with reporting timelines of 5 days for serious adverse events or 30 days for reportable events.

iii. IDE reports of unanticipated adverse device effect:

A copy of any reports of unanticipated adverse device effect submitted to FDA

must be submitted to the COR within 24 hours of FDA notification.

iv. Expedited safety reports: Sent to the COR concurrently with the report to FDA.

v. Other adverse events documented during the course of the trial should be included in the annual IND or IDE report and reported to BARDA annually.

In case of problems or issues, the Contracting Officer's Representative will contact the Contractor within ten (10) business days by email or fax, followed within thirty (30) calendar days by an official letter to the Contractor's Project Manager, with a copy to the institutions' office of sponsored programs, listing issues and appropriate actions to be discussed.

vi. Safety reporting for research not performed under an IND or IDE.

Final decisions regarding ongoing safety reporting requirements for research not performed under an IND or IDE must be made jointly by the Contracting Officer's Representative and the Contractor.

H.2. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (December 2015)

a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current federal wide Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

c. Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FW' via designation as agents of the institution of via individual investigator agreements (see OHRP website at: http//:www.hhs.gov/ohrp/policy/guidanceonalternativeofwa.pdf).

d. If at any time during the performance of this contract, the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.

H.3. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable Federal, State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP- approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990- 0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

H.4. RESEARCH INVOLVING HUMAN FETAL TISSUE

All research involving human fetal tissue shall be conducted in accordance with the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://grants1.nih.gov/grants/guide/notice-files/not93- 235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

The Contractor shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Contractor.

H.5. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs should report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800- 447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services TIPS HOTLINE
P.O. Box 23489 Washington, D.C. 20026

H.6. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

H.7. IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will be required to provide certain data generated under this contract to the Department of

Health and Human Services (DHHS). DHHS reserves the right to review any other data determined by DHHS to be relevant to this contract. The Contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

H.8. EXPORT CONTROL NOTIFICATION

Contractors are responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and foreign access to their proposed technologies. Contractors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 CRF Parts 120-130) and /or the Department of Commerce regarding the Export Administration Regulations (15 CRF Parts 730-774).

H.9. CONFLICT OF INTEREST

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR 2.101 and Subpart 9.5, and that the Contractor has disclosed all such relevant information. Prior to commencement of any work, the Contractor agrees to notify the Contracting Officer promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the Contracting Officer any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification shall be made within five (5) working days. The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor shall promptly make a full disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the Contracting Officer of any contrary action to be taken. Remedies include termination of this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the Contracting Officer, the Government may terminate the contract for default, debar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

H.10. NEEDLE DISTRIBUTION

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

H.11. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

H.12. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

The Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

H.13. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

H.14. ACCESS TO DOCUMENTATION/DATA

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all data documenting Contractor performance; all data generated; all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion documents, and all Offeror commitments and responses.
Contractor shall provide the Government with an electronic copy of all correspondence and submissions to the FDA within 5 business days of receipt. The Government shall acquire unlimited rights to all data funded or furnished without proprietary restrictions under this contract in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14.

H.15. EPA ENERGY STAR REQUIREMENTS

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment), all microcomputers, including personal computers, monitors, and printers that are purchased using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant.

This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with the network environment. In addition, the equipment will run commercial off-the-shelf software both before and after recovery from its energy conservation mode.

H.16. ACKNOWLEDGMENT OF FEDERAL FUNDING

Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

Publication and Publicity

No information related to data obtained under this contract shall be released or publicized without providing BARDA with at least thirty (30) days advanced notice and an opportunity to review the proposed release or publication.

In addition to the requirements set forth in HHSAR Clause 352.227-70, Publications and Publicity incorporated by reference in Section I of this contract, Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state:

(1) The percentage and dollar amounts of the total program or project costs financed with Federal money and;

(2) The percentage and dollar amount of the total costs financed by non-governmental sources. For purposes of this contract “publication” is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, including any manuscript or scientific meeting abstract. Any publication containing data generated under this contract must be submitted for BARDA review no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts

before submission for public presentation or publication. Contract support shall be acknowledged in all such publications substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50119C00053."

Press Releases

Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. With the exception of ad-hoc press releases required by applicable law or regulations, the Contractor shall ensure that the COR has received an advance copy of any press release related to the contract not less than two (2) business days prior to the issuance of the press release.

The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50119C00053."

H.17. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES AND HHSAR 352.203-70 ANTI-LOBBYING (December 2015)

Pursuant to the HHS annual appropriations acts, except for normal and recognized executive- legislative relationships, the Contractor shall not use any HHS contract funds for:

(a) Publicity or propaganda purposes;

(b) The preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any state or local legislature

itself; or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any state or local government, except in presentation to the executive branch of any state or local government itself; or

(c) Payment of salary or expenses of the Contractor, or any agent acting for the Contractor, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body, other than for normal and recognized executive-
legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government.

(d) The prohibitions in subSections (a), (b), and (c) above shall include any activity to advocate or promote any proposed, pending, or future federal, state, or local tax increase, or any proposed, pending, or future requirement for, or restriction on, any legal consumer product, including its sale or marketing, including, but not limited to, the advocacy or promotion of gun control.

H.18. PRIVACY ACT APPLICABILITY

Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 CFR Part 5b, Privacy Act Regulations, may be obtained at https://www.gpo.gov/fdsys/granule/CFR-2007-title45-vol1/CFR-2007-title45-vol1- part5b

The Project Officer is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.

The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200. This document may be obtained at the following link: http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm

H.19. LABORATORY LICENSE REQUIREMENTS

The Contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended) (42 U.S.C. 263a and 42 CFR Part 493). This requirement shall also be included in any subcontract for services under the contract.

H.20. QUALITY ASSURANCE (QA) AUDIT REPORTS

BARDA reserves the right to participate in QA audits as related to activities funded under this contract. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications.
- Contractor shall notify the COR and CO within five (5) business days of report completion.

H.21. BARDA AUDITS

Contractor shall accommodate periodic or reasonable ad hoc site visits during normal business hours by the Government with forty-eight (48) hours advance notice. If the Government, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government.

- If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and corrective action(s) within 10 business days of the audit.
- COR and CO will review the report and provide a response to the Contractor with ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

H.22. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

The Contractor shall not use contract funds to employ workers described in Section 274A (h)(3) of the Immigration and National Act, which reads as follows:

"(3) Definition of unauthorized alien – As used in this Section, the term 'unauthorized alien' with respect to the employment of an alien at a particular time, that the alien is not at that time either an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

H.23. NOTIFICATION OF CRITICAL PROGRAMMATIC CONCERNS, RISKS, OR POTENTIAL RISKS

If any action occurs that creates a cause for critical programmatic concern, risk, or potential risk to BARDA or the Contractor and Incident Report shall be delivered to BARDA.

- Within 48 hours of activity or incident or within 24 hours for a security related activity or incident, Contractor must notify BARDA.
- Additional updates due to COR and CO within 48 hours of additional developments.
- Contractor shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues.

If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by BARDA within 5 business days.

H.24. DISSEMINATION OF INFORMATION (May 2004)

Other than scientific and technical Sections for which the contractor can assert a copyright under FAR Clause 52.227-14 I no information related to data obtained under this contract shall be released or publicized without the prior written consent of the Contracting Officer. In the event that the contractor seeks to publicize data through a scientific or technical Section, the contractor shall provide BARDA, through the COR, with a minimum of thirty (30) business days to review the Section prior to publication.

H.25. REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this contract until the Contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (https://www.ecfr.gov/cgi- bin/retrieveECFR?gp=&SID=8a4be60456973b5ec6bef5dfeaffd49a&r=PART&n=42y1.0.1.6.61) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the contracting officer, the Contractor shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and

applicable laws, regulations, and policies. For the purpose of security risk assessments, the Contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the contract.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at https://www.selectagents.gov/regulations.html

H.26. MANUFACTURING STANDARDS

The Good Manufacturing Practice Regulations (GMP)(21 CFR Parts 820) will be the standard to be applied for manufacturing, processing, packaging, storage and delivery of this product.

If at any time during the life of the contract, the Contractor fails to comply with GMP in the manufacturing, processing, packaging, storage, stability and other testing of the manufactured drug substance or product and delivery of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by the FDA, the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If, within the thirty (30) calendar day period, the Contractor fails to take such an action to the satisfaction of the Government Project Officer, or fails to provide a remediation plan that is acceptable to the COR, then the contract may be terminated.

H.27. IN-PROCESS REVIEW

In Process Reviews (IPR) will be conducted at the discretion of the Government to discuss the progression of the milestones. The Government reserves the right to revise the milestones and budget pending the development of the project. Deliverables such as an overall project summary report and/or slides will be required when the IPRs are conducted. The Contractor's success in completing the required tasks under each work segment must be demonstrated through the Deliverables and Milestones specified under Section F. Those deliverables will constitute the basis for the Government's decision, at its sole discretion, to proceed with the work segment, or institute changes to the work segment, or terminate the work segment.

IPRs may be scheduled at the discretion of the Government to discuss progression of the contract. The Contractor shall provide a presentation following a prescribed template which will be provided by the Government at least 30 business days prior to the IPR. Subsequently, the contractor will be requested to provide a revised/final presentation to the Contracting Officer at least 10 business days prior to the IPR.

H.28. HUMAN SUBJECTS

The Contractor shall submit all human clinical protocols and informed consent documents to BARDA for review and comment prior to submission to another entity.

Research involving human subjects shall not be conducted under this contract until the study protocol has been approved by the Department of Health and Human Services, written notice of such approval has been provided by the CO, and the Contractor has provided to the CO a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self-designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

H.29. SHARING RESEARCH DATA

The Contractor's data sharing plan, due date to be determined at contract award, is hereby incorporated by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

BARDA endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers.

BARDA recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS- published documentation on the Health Information Privacy at http://www.hhs.gov/ocr/privacy/index.html). The rights and privacy of people who participate in BARDA-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

H.30. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, HHSAR 352.270-13 (December 2015)

a. The Contractor shall not use any funds obligated under this contract for any abortion.
b. The Contractor shall not use any funds obligated under this contract for the following:
    i. The creation of a human embryo or embryos for research purposes; or
    ii. Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury of death greater than that allowed for research on fetuses in utero under 45 CFR part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).
c. The term ``human embryo or embryos'' includes any organism, not protected as a human subject under 45 CFR part 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes of human diploid cells.
d. The Contractor shall not use any Federal funds for the cloning of human beings.

H.31. PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM ASPR FUNDED RESEARCH

All ASPR-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, of any peer-reviewed scientific publications resulting from research supported in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response. ASPR defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and ASPR. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

H.32. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

The Contractor shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under BARDA contracts) will not be biased by any conflicting financial interest. 45 CFR Part 94 is available at the following Web site: https://www.ecfr.gov/cgi-bin/text- idx?tpl=/ecfrbrowse/Title45/45cfr94_main_02.tpl

As required by 45 CFR Part 94, the Contractor shall, at a minimum:

a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in BARDA-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the BARDA-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.

c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

If a conflict of interest is identified, the Contractor shall report to the Contracting Officer, the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the BARDA-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in BARDA-funded research, including a review of all records pertinent to compliance with 45 CFR Part 94. The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular conflict of interest will bias the objectivity of the BARDA-funded research to such an extent that further corrective action is needed or that the Contractor has not managed, reduced, or eliminated the conflict of interest. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an investigator with a conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

PART II – CONTRACT CLAUSES
SECTION I – CONTRACT CLAUSES
I.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

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

General Clauses for Cost-Reimbursement Research and Development Contract

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

Reg	Clause	Date	Clause Title
FAR	52.202-1	Nov 2013	Definitions
FAR	52.203-3	Apr 1984	Gratuities
FAR	52.203-5	May 2014	Covenant Against Contingent Fees
FAR	52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	May 2014	Anti-Kickback Procedures
FAR	52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-11	Sept 2007	Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions
FAR	52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Oct 2015	Contractor Code of Business Ethics and Conduct
FAR	52.203-14	Oct 2015	Display of Hotline Poster(s)
FAR	52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
FAR	52.204-1	Dec 1989	Administrative Matters Provisions and Clauses
FAR	52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
FAR	52.204-5	Oct 2014	Women-Owned Business (Other Than Small Business)
FAR	52.204-7	Oct 2016	System for Award Management
FAR	52.204-10	Oct 2016	Reporting Executive Compensation and First-Tier Subcontract Awards
FAR	52.204-13	Oct 2016	System for Award Management Maintenance
FAR	52.204-16	Jul 2016	Commercial and Government Entity Code Reporting
FAR	52.204-17	Jul 2016	Ownership of Control or Offeror
FAR	52.204-18	Jul 2015	Commercial and Government Entity Code Maintenance
FAR	52.207-1	May 2006	Notice of Standard Competition
FAR	52.209-5	Oct 2015	Certification Regarding Responsibility Matters
FAR	52.209-6	Oct 2015	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
FAR	52.209-9	Jul 2013	Updates of Publicly Available Information Regarding Responsibility Matters
FAR	52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations
FAR	52.210-1	Apr 2011	Market Research
FAR	52.211-5	Aug 2000	Material Requirements
FAR	52.215-2	Oct 2010	Audit and Records – Negotiation
FAR	52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format

Reg	Clause	Date	Clause Title
FAR	52.215-10	Aug 2011	Price Reduction for Defective Cost or Pricing Data
FAR	52.215-11	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data —Modifications.
FAR	52.215-12	Oct 2010	Subcontractor Certified Cost or Pricing Data
FAR	52.215-13	Oct 2010	Subcontractor Certified Cost or Pricing Data—Modifications
FAR	52.215-14	Oct 2010	Integrity of Unit Prices (Over the Simplified Acquisition Threshold
FAR	52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
FAR	52.215-16	June 2003	Facilities Capital Cost of Money
FAR	52.215-17	Oct 1997	Waiver of Facilities Capital Cost of Money
FAR	52.215-18	Jul 2005	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-20	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data
FAR	52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data – Modifications
FAR	52.215-22	Oct 2009	Limitations on Pass-Through Charges—Identification of Subcontract Effort
FAR	52.215-23	Oct 2009	Limitations on Pass-Through Charges
FAR	52.216-7	Aug 2018	Allowable Cost and Payment
FAR	52.216-8	Jun 2011	Fixed Fee
FAR	52.219-8	Nov 2018	Utilization of Small Business Concerns
FAR	52.219-9	Aug 2016	Small Business Subcontracting Plan
FAR	52.219-10	Oct 2014	Incentive Subcontracting Program
FAR	52.219-14	Jan 2017	Limitations on Subcontracting
FAR	52.219-16	Jan 1999	Liquidated Damages – Subcontracting Plan
FAR	52.219-28	Jul 2013	Post-Award Small Business Program Representation
FAR	52.222-3	Jun 2003	Convict Labor
FAR	52.222-21	Apr 2015	Prohibition of Segregated Facilities
FAR	52.222-24	Feb 1999	Pre-award On-Site Equal Opportunity Compliance Evaluation
FAR	52.222-25	Apr 1984	Affirmative Action Compliance
FAR	52.222-26	Sept 2016	Equal Opportunity
FAR	52.222-35	Oct 2015	Equal Opportunity for Veterans ($150,000 or more)
FAR	52.222-36	Jul 2014	Equal Opportunity for Workers with Disabilities
FAR	52.222-37	Feb 2016	Employment Reports on Veterans
FAR	52.222-38	Feb 2016	Compliance with Veterans' Employment Reporting Requirements
FAR	52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
FAR	52.222-50	Mar 2015	Combating Trafficking in Persons
FAR	52.222-54	Oct 2015	Employment Eligibility Verification
FAR	52.222-59	Dec 2016	Compliance With Labor Laws (Executive Order 13673)
FAR	52.222-60	Oct 2016	Paycheck Transparency (Executive Order 13673)
FAR	52.222-61	Dec 2016	Arbitration of Contractor Employee Claims (Executive Order 13673)
FAR	52.222-62	Jan 2017	Paid Sick Leave Under Executive Order 13706
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-18	Aug 2011	Encouraging Contractor Policy to Ban Text Messaging While Driving
FAR	52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
FAR	52.225-25	Aug 2018	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certifications

Reg	Clause	Date	Clause Title
FAR	52.226-1	Jun 2000	Utilization of Indian Organizations and Indian-Owned Economic Enterprises.
FAR	52.227-1	Dec 2007	Authorization and Consent, Alternate 1 (APR 1984)
FAR	52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-3	Apr 1984	Patent Indemnity
FAR	52.227-11	May 2014	Patent Rights – Ownership by the Contractor
FAR	52.227-14	May 2014	Rights in Data – General
FAR	52.227-14 Alt. II	Dec 2007	Rights in Data – General – Limited Rights Notice
FAR	52.227-15	Dec 2007	Representation of Limited Rights Data and Restricted Computer Software
FAR	52.227-16	June 1987	Additional Data Requirements
FAR	52.228-7	Mar 1996	Insurance – Liability to Third Persons
FAR	52.230-2	Oct 2015	Cost Accounting Standards
FAR	52.230-3	Oct 2015	Disclosure and Consistency of Cost Accounting Practices
FAR	52.230-6	Jun 2010	Administration of Cost Accounting Standards
FAR	52.230-7	Apr 2005	Proposal Disclosure—Cost Accounting Practice Changes
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-17	May 2014	Interest
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	May 2014	Assignment of Claims
FAR	52.232-25	Jan 2017	Prompt Payment
FAR	52.232-33	Jul 2013	Payment by Electronic Funds Transfer–System for Award Management
FAR	52.232.39	Jun 2013	Unenforceability of Unauthorized Obligations
FAR	52.232-40	Dec 2013	Providing Accelerated Payments to Small Business Subcontractors
FAR	52.233-1	May 2014	Disputes
FAR	52.233-3	Aug 1996	Protest After Award, Alternate 1 (Jun 1985)
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	May 2014	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.243-2	Aug 1987	Changes – Cost-Reimbursement Alternate V (Apr 1984)
FAR	52.244-2	Oct 2010	Subcontracts, Alternate 1 (Jun 2007)
FAR	52.244-5	Dec 1996	Competition in Subcontracting
FAR	52.244-6	Aug 2018	Subcontracts for Commercial Items
FAR	52.245-1	Apr 2012	Government Property
FAR	52.245-9	Apr 2012	Use and Charges
FAR	52.246-23	Feb 1997	Limitation of Liability
FAR	52.249-6	May 2004	Termination (Cost-Reimbursement)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR	352.203-70	Dec 2015	Anti-Lobbying
HHSAR	352.208-70	Dec 2015	Printing and Duplication
HHSAR	352.211-3	Dec 2015	Paperwork Reduction Act
HHSAR	352.219-70	Dec 2015	Mentor-Protégé Program
HHSAR	352.219-71	Dec 2015	Mentor-Protégé Program Reporting Requirements
HHSAR	352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
HHSAR	352.223-70	Dec 2015	Safety and Health
HHSAR	352.224-70	Dec 2015	Privacy Act
HHSAR	352.224-71	Dec 2016	Confidential Information
HHSAR	352.227-70	Dec 2015	Publications and Publicity
HHSAR	352.231-70	Dec 2015	Salary Rate Limitation
HHSAR	352.233-71	Dec 2015	Litigation and Claims
HHSAR	352.237-75	Dec 2015	Key Personnel
HHSAR	352.239-74	Dec 2015	Electronic and Information Technology Accessibility
HHSAR	352.270-9	Dec 2015	Non-discrimination for Conscience

I.2. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR Clause 52.217-8 Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days of end of period of performance.

FAR Clause 52.217-9, Option to Extend the Term of the Contract (Mar 2000)

The Government may extend the term of this contract by written notice to the Contractor within 15 days provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

- If the Government exercises this option, the extended contract shall be considered to include this option clause.
- The total duration of this contract, including the exercise of any options under this clause, shall not exceed 10 years.

FAR Clause 52.219-28, Post-Award Small Business Program Representation (July 2013)

a. *Definitions* . As used in this clause--

Long-term contract means a contract of more than five years in duration, including options.

However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend services, or other appropriate authority.

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is "not dominant in its field of operation" when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

b. If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall re-represent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and
(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

c. The Contractor shall represent its size status in accordance with the size standard in effect at the time of this re-representation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at http://www.sba.gov/content/table-small-business-size- standards

d. The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

e. Except as provided in paragraph (g) of this clause, the Contractor shall make the representation required by paragraph (b) of this clause by validating or updating all its representations in the Representations and Certifications Section of the System for Award Management (SAM) and its other data in SAM, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

f. If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

g. If the Contractor does not have representations and certifications in SAM, or does not have a representation in SAM for the NAICS code applicable to this contract, the Contractor is required to complete the following representation and submit it to the contracting office, along with the contract number and the date on which the representation was completed:

The Contractor represents that it [X] is, [ ] is not a small business concern under NAICS Code 541714 assigned to contract number 75A50119C00053.

FAR 52.204-21 Basic Safeguarding of Covered Contractor Information Systems (Jun 2016)

(a) *Definitions*. As used in this clause--

“Covered contractor information system” means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

“Federal contract information” means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public Web sites) or simple transactional information, such as necessary to process payments.

“Information” means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

“Information system” means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

“Safeguarding” means measures or controls that are prescribed to protect information systems.

(b) Safeguarding requirements and procedures.

(1) The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

(iii) Verify and control/limit connections to and use of external information systems.

(iv) Control information posted or processed on publicly accessible information systems.

(v) Identify information system users, processes acting on behalf of users, or devices.

(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.

(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

(xii) Identify, report, and correct information and information system flaws in a timely manner.

(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.

(xiv) Update malicious code protection mechanisms when new releases are available.

(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) *Other requirements*. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

(c) *Subcontracts*. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS
SECTION J - LIST OF ATTACHMENTS
The following documents are attached and incorporated in this contract:

1. **Statement of Work**

   Statement of Work, dated 07/22/2019, [****] pages

2. **Invoice/Financing Request Instructions for AMCG Cost-Reimbursement Type Contracts,**

   Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for AMCG Cost-Reimbursement Type Contracts, 2 pages.

3. **Sample Invoice, 1 page**

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

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

6. **Inclusion Enrollment Report**

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

7. **Research Patient Care Costs**

   Research Patient Care Costs, 1 page.

8. **Report of Government Owned, Contractor Held Property**

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

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

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

ATTACHMENT 1

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

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

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

Topic Area of Interest No. [7.2.4 & 7.3.3] Statement of Work DATED July 22, 2019 (Diagnostics/Devices Product Development)

STATEMENT OF WORK

BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA) BROAD
AGENCY ANNOUNCEMENT (BAA) BAA-18-100-SOL-00003

ADVANCED RESEARCH AND DEVELOPMENT OF CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR MEDICAL COUNTERMEASURES

RAPID, HIGH-THROUGHPUT, MULTIPLEXED DETECTION OF BIOTHREAT SPECIES ID AND RESISTANCE GENES USING T2MR
AREA OF INTEREST NUMBERS 7.2.4 AND 7.3.3
CONTRACTUAL STATEMENT OF WORK
[****]

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

ATTACHMENT #2

INVOICE/FINANCING REQUEST INSTRUCTIONS - FOR COST-REIMBURSEMENT TYPE CONTRACTS

Format: Payment requests shall be submitted on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.

Number of Copies: Payment requests shall be submitted in the quantity specified in the Invoice Submission Instructions in SECTION G of the Contract Schedule.

Frequency: Payment requests shall not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract. Small business concerns may submit invoices/financing requests more frequently than every two weeks when authorized by the Contracting Officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by pre-contract cost provisions. **Billing of Costs Incurred:** If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall site the amount(s) and month(s) in which it incurred such costs.

Contractor's Fiscal Year: Payment requests shall be prepared in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

Currency: All government contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approval: Costs requiring the Contracting Officer's approval, including those set forth in an Advance Understanding in the contract, shall be identified and reference the Contracting Officer's Authorization (COA) Number. In addition, the Contractor shall show any cost set forth in an Advance Understanding as a separate line item on the payment request.

Invoice/Financing Request Identification: Each payment request shall be identified as either:

(a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice:** The completion invoice shall be submitted promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and it completes all performance provisions.

(c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request.

(a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in SECTION G of the Contract Schedule.

(b) **Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number:** Show the Contractor's name and address exactly as they appear in the contract, along with the name, title, phone number, and e-mail address of the person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. Provide the Contractor's Vendor Identification Number (VIN), and Data Universal Numbering System (DUNS) number or DUNS+4. The DUNS number must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i.e., name, address, point of contact, VIN, and DUNS).

(c) **Invoice/Financing Request Number:** Insert the appropriate serial number of the payment request. Include numbering in format of year_month #.

(d) **Date Invoice/Financing Request Prepared:** Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (if applicable).

(f) **Effective Date:** Insert the effective date of the contract or if billing under an order, the effective date of the order.

(g) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fixed-fee. If billing under an order, insert the total estimated cost of the order, exclusive of fixed-fee. For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

(h) **Total Fixed-Fee:** Insert the total fixed-fee (where applicable) or the portion of the fixed-fee applicable to a particular invoice as defined in the contract.

(i) **Two-Way/Three-Way Match:** Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in SECTION G of the Contract Schedule.

(j) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in SECTION G of the Contract Schedule.

(k) **Central Point of Distribution:** Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in SECTION G of the Contract Schedule.

(l) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(m) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(n) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fixed- fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(o) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(1) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract. List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), breakdown by task performed by personnel, and amount claimed.

(2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect costs.

(3) **Accountable Personal Property:** Include any property having a unit acquisition cost of $5,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost see the HHS *Contractor's Guide for Control of Government Property (https://archive.org/details/contractorsguide00unit)* (e.g. personal computers). Note this is not permitted for reimbursement without pre- authorization from the CO.

On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. Include reference to the following (as applicable):

- Item number for the specific piece of equipment listed in the Property Schedule, and

- COA number, if the equipment is not covered by the Property Schedule.

The Contracting Officer may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

(4) **Materials and Supplies:** Include all consumable material and supplies regardless of amount. Detailed line-item breakdown (e.g. receipts, quotes, etc.) is required.

(5) **Premium Pay:** List remuneration in excess of the basic hourly rate.

(6) **Consultant Fee:** List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.

(7) **Travel:** Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(8) **Subcontract Costs:** List subcontractor(s) by name and amount billed. Provide subcontract invoices/receipts as backup documentation. If subcontract is of the cost-reimbursement variety, detailed breakdown will be required. Regardless, include backup documentation (e.g. subcontractor invoices, quotes, etc.).

(9) **Other:** Include all other direct costs not fitting into an aforementioned category. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(p) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed, if applicable.

(q) **Indirect Costs:** Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.

(r) **Fixed-Fee:** Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract.

(s) **Total Amounts Claimed:** Insert the total amounts claimed for the current and cumulative periods.

(t) **Adjustments:** Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(u) **Grand Totals**

(v) **Certification of Salary Rate Limitation:** If required by the contract (see Invoice Submission Instructions in the Contract Schedule), the Contractor shall include the following certification at the bottom of the payment request:

“I hereby certify that the salaries billed in this payment request are in compliance with the HHS Salary Rate Limitation Provisions in Section H of the contract.”

**Note the Contracting Officer may require the Contractor to submit detailed support for costs claimed on payment requests. Every cost must be determined to be allocable, reasonable, and allowable per FAR Part 31.

Attachment 3 - SAMPLE INVOICE/PAYMENT REQUEST AND CONTRACT FINANCIAL REPORT

(a) Designated Billing Office Name and Address: DHHS/OS/ASPR/AMCG Attn: Contracting Officer US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MGMT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515 (b) Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number: ABC CORPORATION 100 Main Street Anywhere, USA Zip Code Name, Title, Phone Number, and E-mail Address of person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. **VIN:**_____ **DUNS or DUNS+4:** _____	(c) Invoice/Financing Request No.: _____ (d) Date Invoice Prepared: _____ (e) Contract No. and Order No. (if applicable): (f) Effective Date: _____ (g) Total Estimated Cost of Contract/Order: _____ (h) ☐ Total Fixed-Fee (if applicable): _____ (i) ☐ Two-Way Match: _____ Three-Way Match: _____ (j) Office of Acquisitions: _____ (k) Central Point of Distribution: _____

(l) This invoice/financing request represents reimbursable costs for the period from_____to_____

	Cumulative Percentage of Effort/Hrs.		Amount Billed				
Expenditure Category* A	Negotiated B	Actual C	(m) Current D	(n) Cumulative E	Cost at Completion F	Contract Amount G	Variance H
(o) Direct Costs:							
(1) Direct Labor							
(2) Fringe Benefits							
(3) Accountable Property							
(4) Materials & Supplies							
(5) Premium Pay							
(6) Consultant Fees							
(7) Travel							
(8) Subcontracts							
(9) Other							
Total Direct Costs							
(p) Cost of Money							
(q) Indirect Costs							
(r) Fixed Fee							
(s) Total Amount Claimed							
(t) Adjustments							
(u) Grand Totals							

I certify that all payments are for appropriate purposes and in accordance with the contract.

_____ _____

(Name of Official) (Title)

* Attach details as specified in the contract

Attachment 4

FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT	**Project Task:**	**Contract No.:**	**Date of Report:**	**0990-0134** **0990-0131**
Note: Complete this Form in Accordance with Accompanying Instructions.	**Reporting Period:**	**Contractor Name and Address:**		

Expenditure Category	**Percentage of Effort/Hours**		**Cumulative Incurred Cost at End of Prior Period**	**Incurred Cost-- Current Period**	**Cumulative Cost to Date (D + E)**	**Estimated Cost to Complete**	**Estimated Cost at Completion (F + G)**	**Negotiated Contract Amount**	**Variance (Over or Under) (I - H)**
	Negotiate	**Actual**							
A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**

Attachment 5
INSTRUCTIONS FOR COMPLETING
"FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT" GENERAL INFORMATION

Purpose. This Quarterly Financial Report is designed to: (1) provide a management tool for use by the Government in monitoring the application of financial and personnel resources to the BARDA funded contracts; (2) provide contractors with financial and personnel management data which is usable in their management processes; (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actual performance and projections with prior estimates on individual elements of cost and personnel; and (4) obtain contractor's analyses of cause and effect of significant variations between actual and prior estimates of financial and personnel performance.

REPORTING REQUIREMENTS

Scope. The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award. The Government may require the contractor to provide detailed documentation to support any element(s) on one or more financial reports.

Number of Copies and Mailing Address. An original and two (2) copies of the report(s) shall be sent to the contracting officer at the address shown on the face page of the contract, no later than 30 working days after the end of the period reported. However, the contract may provide for one of the copies to be sent directly to the Contracting Officer’s Representative.

REPORTING STATISTICS

A modification which extends the period of performance of an existing contract will not require reporting on a separate quarterly report, except where it is determined by the contracting officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only a funding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

Definitions and Instructions for Completing the Quarterly Report. For the purpose of establishing expenditure categories in Column A, the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

(1) **Key Personnel.** Include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.

(2) **Personnel--Other.** List as one amount unless otherwise required by the contract.

(3) **Fringe Benefits.** Include allowances and services provided by the contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.

(4) **Accountable Personal Property.** Include nonexpendable personal property with an acquisition cost of $1,000 or more and with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report of Accountable Property," must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See "Contractor's Guide for Control of Government Property."

(5) **Supplies.** Include the cost of supplies and material and equipment charged directly to the contract, but excludes the cost of nonexpendable equipment as defined in (4) above.

(6) **Inpatient Care.** Include costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.

(7) **Outpatient Care.** Include costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.

(8) **Travel.** Include all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and consultants shall be shown separately. Identify foreign and domestic travel separately. If required by the contract, the following

information shall be submitted: (i) Name of traveler and purpose of trip; (ii) Place of departure, destination and return, including time and dates; and (iii) Total cost of trip.

(9) **Consultant Fee.** Include fees paid to consultant(s). Identify each consultant with effort expended, billing rate, and amount billed.

(10) **Premium Pay.** Include the amount of salaries and wages over and above the basic rate of pay.

(11) **Subcontracts.** List each subcontract by name and amount billed.

(12) **Other Costs.** Include any expenditure categories for which the Government does not require individual line item reporting. It may include some of the above categories.

(13) **Overhead/Indirect Costs.** Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(14) **General and Administrative Expense.** Cite the rate and the base. In the case of nonprofit organizations, this item will usually be included in the indirect cost.

(15) **Fee.** Cite the fee earned, if any.

(16) Total Costs to the Government.

PREPARATION INSTRUCTIONS

These instructions are keyed to the Columns on the Quarterly Report.

Column A--Expenditure Category. Enter the expenditure categories required by the contract.

Column B--Percentage of Effort/Hours Negotiated. Enter the percentage of effort or number of hours agreed to during contract negotiations for each labor category listed in Column A.

Column C--Percentage of Effort/Hours-Actual. Enter the cumulative percentage of effort or number of hours worked by each employee or group of employees listed in Column A.

Column D--Cumulative Incurred Cost at End of Prior Period. Enter the cumulative incurred costs up to the end of the prior reporting period. This column will be blank at the time of the submission of the initial report.

Column E--Incurred Cost-Current Period. Enter the costs which were incurred during the current period.

Column F--Cumulative Incurred Cost to Date. Enter the combined total of Columns D and E.

Column G--Estimated Cost to Complete. Make entries only when the contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column H--Estimated Costs at Completion. Complete only if an entry is made in Column G.

Column I--Negotiated Contract Amount. Enter in this column the costs agreed to during contract negotiations for all expenditure categories listed in Column A.

Column J--Variance (Over or Under). Complete only if an entry is made in Column H. When entries have been made in Column H, this column should show the difference between the estimated costs at completion (Column H) and negotiated costs (Column I). When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column J by Column I, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications. List any modification in the amount negotiated for an item since the preceding report in the appropriate cost category. **Expenditures Not Negotiated.** List any expenditure for an item for which no amount was negotiated (e.g., at the discretion of the contractor in performance of its contract) in the appropriate cost category and complete all columns except for I. Column J will of course show a 100 percent variance and will be explained along with those identified under J above.

Attachment 6
INCLUSION ENROLLMENT REPORT

This report format should NOT be used for data collection from study participants

Study Title:				
Total Enrollment:	**Protocol Number:**			
Contract Number:				
PART A. TOTAL ENROLLMENT REPORT:Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			
	Females	**Males**	**Unknown or Not Reported**	**Total**
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				
PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	**Females**	**Males**	**Unknown or Not Reported**	**Total**
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				
*These totals must agree **These totals must agree				

Attachment 7 - Research Patient Care Costs

Research Patient Care Costs

(a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.

(b) Research patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine research patient care costs. Research patient care rates or amounts shall be established by the Secretary of HHS or his/her duly authorized representative.

(c) Prior to submitting an invoice for research patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payors (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for research patient care.

(d) The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.

(e) Only those charges not recoverable from third party payors or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

Attachment 8 - Report of Government Owned, Contractor Held Property

REPORT OF GOVERNMENT OWNED, CONTRACTOR HELD PROPERTY							
CONTRACTOR:					**CONTRACT NUMBER:**		
ADDRESS:					**REPORT DATE:**		
ADDRESS1:							
ADDRESS2:					**FISCAL YEAR:**		
CITY:							
STATE:							
ZIP:							
CLASSIFICATION	**BEGINNING OF PERIOD**		**ADJUSTMENTS**			**END OF PERIOD**	
	#ITEMS	VALUE	GFP ADDED	CAP ADDED	DELETIONS	#ITEMS	VALUE
LAND >=$25K							
LAND <$25K							
OTHER REAL >=$25K							
OTHER REAL <$25K							
PROPERTY UNDER CONST >=$25K							
PROPERTY UNDER CONST <$25K							
PLANT EQUIP >=$25K							
PLANT EQUIP <$25K							
SPECIAL TOOLING >=$25K							
SPECIAL TOOLING <$25K							
SPECIAL TEST EQUIP >=$25K							
SPECIAL TEST EQUIP <$25K							
AGENCY PECULIAR >=$25K							
AGENCY PECULIAR <$25K							
MATERIAL >=$25K (CUMULATIVE)							
PROPERTY UNDER MFR >=$25K							
PROPERTY UNDER MFR <$25K							
SIGNED BY:							
SIGNATURE			DATE SIGNED:				
NAME PRINTED			Email				
TITLE			TELEPHONE				

Report of Government Owned, Contractor Held Property (Rev 10/2014)

ATTACHMENT 9: Deliverables:
[****]

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

Exhibit 31.1

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

I, John McDonough, certify that:

1. I have reviewed this quarterly report on Form 10-Q/A 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 McDonough
John McDonough
President, Chief Executive Officer and Director
(principal executive officer)

Date: November 19, 2019

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/A of T2 Biosystems, Inc.;

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

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

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

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

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

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

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

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

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

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

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

Date: November 19, 2019

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/A for the period ending September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John McDonough, 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 McDonough
John McDonough
President and Chief Executive Officer
(principal executive officer)

Date: November 19, 2019

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/A for the period ending September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John M. Sprague, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

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

Date: November 19, 2019

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.