

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

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2020

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: 001-34180



FLUIDIGM CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

State or other jurisdiction of incorporation or organization

77-0513190

I.R.S. Employer Identification No.

2 Tower Place, Ste 2000 South San Francisco, CA
Address of principal executive offices

94080
Zip Code

Registrant's telephone number, including area code: (650) 266-6000

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, \$0.001 par value per share	FLDM	The Nasdaq Global Select 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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 to 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 October 30, 2020, there were 74,119,005 shares of the registrant's common stock, \$0.001 par value per share, outstanding.

FLUIDIGM CORPORATION

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

FLUIDIGM CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 72,345	\$ 21,661
Short-term investments	—	36,978
Accounts receivable (net of allowances of \$324 and \$6, at September 30, 2020 and December 31, 2019, respectively)	17,613	18,981
Grant receivable	7,456	—
Inventories	19,560	13,884
Prepaid expenses and other current assets	5,689	4,592
Total current assets	122,663	96,096
Property and equipment, net	7,531	8,056
Operating lease right-of-use asset, net	38,469	4,860
Other non-current assets	4,904	5,492
Developed technology, net	42,955	46,200
Goodwill	106,455	104,108
Total assets	\$ 322,977	\$ 264,812
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 10,971	\$ 6,510
Accrued compensation and related benefits	9,122	5,160
Operating lease liabilities, current	2,697	1,833
Other accrued liabilities	6,565	7,515
Deferred revenue, current	13,436	11,803
Total current liabilities	42,791	32,821
Convertible notes, net	54,121	53,821
Deferred tax liability	9,041	11,494
Operating lease liabilities, non-current	38,607	4,323
Deferred revenue, non-current	7,684	8,168
Deferred grant income, non-current	18,224	—
Other non-current liabilities	536	573
Total liabilities	171,004	111,200
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000 shares authorized, no shares issued and outstanding at either September 30, 2020 or December 31, 2019	—	—
Common stock: \$0.001 par value, 200,000 shares authorized at September 30, 2020 and December 31, 2019; 74,115 and 69,956 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	74	70
Additional paid-in capital	810,923	777,765
Accumulated other comprehensive loss	(289)	(582)
Accumulated deficit	(658,735)	(623,641)
Total stockholders' equity	151,973	153,612
Total liabilities and stockholders' equity	\$ 322,977	\$ 264,812

See accompanying notes

FLUIDIGM CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue:				
Product revenue	\$ 29,210	\$ 20,666	\$ 65,596	\$ 68,728
Service revenue	6,131	5,630	16,457	15,875
Development revenue	3,180	—	6,180	—
Other revenue	1,340	200	5,303	200
Total revenue	<u>39,861</u>	<u>26,496</u>	<u>93,536</u>	<u>84,803</u>
Costs and expenses:				
Cost of product revenue	12,773	10,520	31,896	33,009
Cost of service revenue	1,769	1,938	4,531	5,403
Research and development	8,128	7,125	25,275	23,362
Selling, general and administrative	22,655	20,729	65,966	65,687
Total costs and expenses	<u>45,325</u>	<u>40,312</u>	<u>127,668</u>	<u>127,461</u>
Loss from operations	(5,464)	(13,816)	(34,132)	(42,658)
Interest expense	(885)	(444)	(2,682)	(3,636)
Loss from extinguishment of debt	—	—	—	(9,000)
Other income (expense), net	107	205	(248)	920
Loss before income taxes	(6,242)	(14,055)	(37,062)	(54,374)
Income tax benefit	243	1,168	2,068	2,269
Net loss	<u>\$ (5,999)</u>	<u>\$ (12,887)</u>	<u>\$ (34,994)</u>	<u>\$ (52,105)</u>
Net loss per share, basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.19)</u>	<u>\$ (0.49)</u>	<u>\$ (0.79)</u>
Shares used in computing net loss per share, basic and diluted	<u>72,486</u>	<u>69,469</u>	<u>71,294</u>	<u>65,792</u>

See accompanying notes

FLUIDIGM CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net loss	\$ (5,999)	\$ (12,887)	\$ (34,994)	\$ (52,105)
Other comprehensive income (loss), net of tax				
Foreign currency translation adjustment	523	(121)	329	(122)
Net change in unrealized gain (loss) on investments	(3)	(14)	(36)	51
Other comprehensive income (loss), net of tax	520	(135)	293	(71)
Comprehensive loss	<u>\$ (5,479)</u>	<u>\$ (13,022)</u>	<u>\$ (34,701)</u>	<u>\$ (52,176)</u>

See accompanying notes

FLUIDIGM CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2019	69,956	\$ 70	\$ 777,765	\$ (582)	\$ (623,641)	\$ 153,612
Issuance of restricted stock, net of shares withheld for taxes, and other	255	—	(146)	—	—	(146)
Cumulative-effect of new accounting standard for Topic 326 Credit Losses	—	—	—	—	(100)	(100)
Stock-based compensation expense	—	—	2,364	—	—	2,364
Acquisition of InstruNor AS	485	1	2,048	—	—	2,049
Net loss	—	—	—	—	(15,980)	(15,980)
Other comprehensive loss, net of tax	—	—	—	(303)	—	(303)
Balance as of March 31, 2020	70,696	\$ 71	\$ 782,031	\$ (885)	\$ (639,721)	\$ 141,496
Issuance of restricted stock, net of shares withheld for taxes, and other	286	—	(116)	—	—	(116)
Issuance of common stock under ESPP	301	—	645	—	—	645
Stock-based compensation expense	—	—	3,633	—	—	3,633
Net loss	—	—	—	—	(13,015)	(13,015)
Other comprehensive income, net of tax	—	—	—	76	—	76
Balance as of June 30, 2020	71,283	\$ 71	\$ 786,193	\$ (809)	\$ (652,736)	\$ 132,719
Issuance of restricted stock, net of shares withheld for taxes, and other	258	1	(124)	—	—	(123)
Issuance of common stock from option exercises	94	—	450	—	—	450
Issuance of common stock from at-the-market offering, net of issuance costs	2,480	2	20,226	—	—	20,228
Equity issuance costs	—	—	(180)	—	—	(180)
Stock-based compensation expense	—	—	4,358	—	—	4,358
Net loss	—	—	—	—	(5,999)	(5,999)
Other comprehensive income, net of tax	—	—	—	520	—	520
Balance as of September 30, 2020	74,115	\$ 74	\$ 810,923	\$ (289)	\$ (658,735)	\$ 151,973

See accompanying notes

FLUIDIGM CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2018	49,338	\$ 49	\$ 631,605	\$ (687)	\$ (558,851)	\$ 72,116
Issuance of common stock on bond conversion	19,460	19	133,279	—	—	133,298
Issuance of restricted stock, net of shares withheld for taxes, and other	140	1	(177)	—	—	(176)
Issuance of common stock from option exercises	53	—	255	—	—	255
Stock-based compensation expense	—	—	2,207	—	—	2,207
Net loss	—	—	—	—	(25,465)	(25,465)
Other comprehensive income, net of tax	—	—	—	10	—	10
Balance as of March 31, 2019	68,991	\$ 69	\$ 767,169	\$ (677)	\$ (584,316)	\$ 182,245
Issuance of restricted stock, net of shares withheld for taxes, and other	183	—	(325)	—	—	(325)
Issuance of common stock from option exercises	130	—	793	—	—	793
Issuance of common stock under ESPP	96	—	641	—	—	641
Stock-based compensation expense	—	—	2,985	—	—	2,985
Net loss	—	—	—	—	(13,753)	(13,753)
Other comprehensive income, net of tax	—	—	—	54	—	54
Balance as of June 30, 2019	69,400	\$ 69	\$ 771,263	\$ (623)	\$ (598,069)	\$ 172,640
Issuance of restricted stock, net of shares withheld for taxes, and other	149	1	(70)	—	—	(69)
Issuance of common stock from option exercises	1	—	1	—	—	1
Stock-based compensation expense	—	—	3,055	—	—	3,055
Net loss	—	—	—	—	(12,887)	(12,887)
Other comprehensive income (loss), net of tax	—	—	—	(135)	—	(135)
Balance as of September 30, 2019	69,550	\$ 70	\$ 774,249	\$ (758)	\$ (610,956)	\$ 162,605

See accompanying notes

FLUIDIGM CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2020	2019
Operating activities		
Net loss	\$ (34,994)	\$ (52,105)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,988	3,484
Stock-based compensation expense	10,358	8,292
Amortization of developed technology	8,929	8,400
Amortization of debt discounts, premiums and issuance costs	415	2,130
Lease amortization	1,863	(371)
Loss on extinguishment of debt	—	9,000
Provision for excess and obsolete inventory	680	1,356
Loss on disposal of property and equipment	191	52
Other non-cash items	13	195
Changes in assets and liabilities:		
Accounts receivable, net	967	3,195
Inventories	(6,773)	(3,672)
Prepaid expenses and other assets	(2,395)	(1,338)
Accounts payable	4,996	605
Deferred revenue	1,258	1,592
Other liabilities	(180)	(10,506)
Net cash used in operating activities	(11,684)	(29,691)
Investing activities		
Acquisition, net of cash acquired	(5,154)	—
Purchases of investments	—	(52,719)
Proceeds from RADx grant	11,151	—
Proceeds from sale of investments	5,010	—
Proceeds from maturities of investments	31,800	16,000
Purchases of property and equipment	(2,010)	(2,031)
Net cash provided by (used in) investing activities	40,797	(38,750)
Financing activities		
Proceeds from issuance of common stock from at-the-market offering, net of commissions	20,226	—
Payment of debt and equity issuance costs	(509)	(128)
Proceeds from exercise of stock options	450	1,049
Proceeds from stock issuance from ESPP	645	641
Payments for taxes related to net share settlement of equity awards and other	(387)	(556)
Net cash provided by financing activities	20,425	1,006
Effect of foreign exchange rate fluctuations on cash and cash equivalents	86	(5)
Net increase (decrease) in cash, cash equivalents and restricted cash	49,624	(67,440)
Cash, cash equivalents and restricted cash at beginning of period	23,736	95,401
Cash, cash equivalents and restricted cash at end of period	\$ 73,360	\$ 27,961
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ 86	\$ 3,513
Cash paid for income taxes, net of refunds	\$ 386	\$ 128
Asset retirement obligations	\$ 319	\$ 311

See accompanying notes

FLUIDIGM CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2020

1. Description of Business

Fluidigm Corporation (the Company, Fluidigm, we, our or us) creates, manufactures, and markets technologies and tools for life sciences research, including preparatory and analytical instruments for Mass Cytometry, PCR, Library Prep, Single Cell Genomics, and consumables, including integrated fluidic circuits (IFC), assays, and reagents. Our focus is on the most pressing needs in translational and clinical research, including infectious disease, cancer, immunology and immunotherapy. We sell our instruments, consumables and services to academic institutions, clinical laboratories, and contract research organizations, as well as biopharmaceutical, biotechnology, and agricultural biotechnology companies. The Company was formerly known as Mycometrix Corporation and changed its name to Fluidigm Corporation in April 2001. Fluidigm Corporation was founded in 1999 and is headquartered in South San Francisco, California.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles (U.S. GAAP) and include the accounts of our wholly owned subsidiaries. As of September 30, 2020, we had wholly owned subsidiaries in Singapore, Canada, the Netherlands, Japan, France, the United Kingdom, China, Germany and Norway. All subsidiaries, except for Singapore, use their local currency as their functional currency. The Singapore subsidiary uses the U.S. dollar as its functional currency. All intercompany transactions and balances have been eliminated in consolidation.

Certain prior period amounts in the condensed consolidated statements of income and condensed consolidated statements of cash flows were reclassified to conform with the current period presentation. These reclassifications were immaterial and did not affect prior period total assets, total liabilities, stockholders' equity, total revenue, total costs and expenses, loss from operations or net loss.

Unaudited Interim Financial Information

The accompanying interim condensed consolidated financial statements and related disclosures are unaudited, have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the results of operations for the periods presented.

The year-end condensed consolidated balance sheet was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. The condensed consolidated results of operations for the nine months ended September 30, 2020 are not necessarily indicative of the results to be expected for the full year or for any other year or interim period. The accompanying condensed consolidated financial statements should be read in conjunction with the audited financial statements and the related notes for the year ended December 31, 2019 included in our annual report on Form 10-K, filed with the SEC on February 27, 2020.

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions believed to be reasonable, which together form the basis for making judgments about the carrying values of assets and liabilities. The full extent to which the COVID-19 pandemic impacts our business, results of operations and financial condition will depend on numerous evolving factors including, but not limited to, the magnitude and duration of the pandemic, the extent to which it will impact worldwide macroeconomic conditions, including the speed of recovery, and governmental and business reactions to the pandemic. We assessed certain accounting matters that generally require consideration of forecasted financial information in the context of information available to us and the unknown impact of COVID-19 as of September 30, 2020. These accounting matters included, but were not limited to, our allowance for doubtful accounts and credit losses, inventory and related reserves and the carrying value of goodwill and other long-lived assets. Actual results could differ materially from these estimates and could have a material adverse effect on our condensed consolidated financial statements.

Foreign Currency

Assets and liabilities of non-U.S. subsidiaries that use the local currency as their functional currency are translated into U.S. dollars at exchange rates in effect on the balance sheet date. The adjustments resulting from the foreign currency translations are recorded in accumulated other comprehensive loss, a separate component of stockholders' equity. Income and expense accounts are translated at monthly average exchange rates during the year.

Revenue Recognition

We generate revenue primarily from the sale of our products and services. Product revenue is derived from the sale of instruments and consumables, including IFCs, assays and reagents. Service revenue is derived from the sale of instrument service contracts, repairs, installation, training and other specialized product support services. We also generate revenue from development agreements, license and royalty agreements and grants. Revenue is reported net of any sales, use and value-added taxes we collect from customers as required by government authorities. Research and development cost includes costs associated with development and grant revenue.

We recognize revenue based on the amount of consideration we expect to receive in exchange for the goods and services we transfer to the customer. Our commercial arrangements typically include multiple distinct products and services, and we allocate revenue to these performance obligations based on their relative standalone selling prices. Standalone selling prices (SSP) are generally determined using observable data from recent transactions. In cases where sufficient data is not available, we estimate a product's SSP using a cost plus a margin approach or by applying a discount to the product's list price.

Product Revenue

We recognize product revenue at the point in time when control of the goods passes to the customer and we have an enforceable right to payment. This generally occurs either when the product is shipped from one of our facilities or when it arrives at the customer's facility, based on the contractual terms. Customers generally do not have a unilateral right to return products after delivery. Invoices are generally issued at shipment and generally become due in 30 to 60 days.

We sometimes perform shipping and handling activities after control of the product passes to the customer. We have made an accounting policy election to account for these activities as product fulfillment activities rather than as separate performance obligations.

Service Revenue

We recognize revenue from repairs, maintenance, installation, training and other specialized product support services at the point in time the work is completed. Installation and training services are generally billed in advance of service. Repairs and other services are generally billed at the point the work is completed.

Revenue associated with instrument service contracts is recognized on a straight-line basis over the life of the agreement, which is generally one to three years. We believe this time-elapsed approach is appropriate for service contracts because we provide services on demand throughout the term of the agreement. Invoices are generally issued in advance of service on a monthly, quarterly, annual or multi-year basis. Payments made in advance of service are reported on our condensed consolidated balance sheet as deferred revenue.

Development Revenue

The Company has entered and may continue to enter into development agreements with third parties that provide for up-front and periodic milestone payments. Our development agreements may include more than one performance obligation. At the inception of the contract, we assess whether each obligation represents a separate performance obligation or whether such obligations should be combined as a single performance obligation. The transaction price for each development agreement is determined based on the amount of consideration we expect to be entitled to for satisfying all performance obligations within the agreement.

We assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. In arrangements where we satisfy performance obligation(s) over time, we recognize development revenue typically using an input method based on our costs incurred relative to the total expected cost which determines the extent of our progress toward completion. As part of the accounting for these arrangements, we must develop estimates and assumptions that require judgment to determine the transaction price and progress towards completion. We review our estimate of the transaction price and progress toward completion based on the best information available to recognize the cumulative progress toward completion as of the end of each reporting period, and make revisions to such estimates as necessary.

We may also generate revenue from development or collaboration agreements that do not include upfront or milestone-based payments and generally recognize revenue on these types of agreements based on the timing of development activities.

Other Revenue

Other revenue consists of license and royalty revenue and grant revenue. We recognize revenue from license agreements when the license is transferred to the customer and the customer is able to use and benefit from the license. For contracts that include sales-based royalties, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied.

In March 2020, we entered into an agreement to settle intellectual property infringement claims, in which we received a \$3.5 million payment in exchange for a perpetual license under certain Fluidigm intellectual property. The settlement is considered a multiple-element arrangement with each element accounted for individually. Accordingly, \$3.1 million of the proceeds was recognized as license revenue and \$0.4 million was offset against legal costs.

We receive grants from various entities to perform research and development activities over contractually defined periods. Revenue is generally recognized provided that the conditions under which the grants were provided have been met and any remaining performance obligations are perfunctory.

Contract Costs

Incremental sales commission costs incurred to obtain instrument service contracts are capitalized and amortized to selling, general and administrative expense over the life of the contract, which is generally one to three years. As a practical expedient, we expense sales commissions associated with product support services that are delivered in less than one year as they are incurred. Sales commissions associated with the sale of products are expensed as they are incurred. To date, capitalized contract costs have been immaterial.

Product Warranties

We generally provide a one-year warranty on our instruments. We accrue for estimated warranty obligations at the time of product shipment. We periodically review our warranty liability and record adjustments based on the terms of warranties provided to customers, and historical and anticipated warranty claim experience. This expense is recorded as a component of cost of product revenue in the condensed consolidated statements of operations.

Significant Judgments

Applying the revenue recognition practices discussed above often requires significant judgment. Judgment is required when identifying performance obligations, estimating SSP and allocating purchasing consideration in multi-element arrangements, determining the transaction price and progress towards completion on development arrangements and estimating the future amount of our warranty obligations. Moreover, significant judgment is required when interpreting commercial terms and determining when control of goods and services passes to the customer. Any material changes created by errors in judgment could have a material effect on our operating results and overall financial condition.

Accounts Receivable

Trade accounts receivable are recorded at net invoice value. We review our exposure to accounts receivable and provide allowances of specific amounts if collectability is no longer reasonably assured based on historical experience and specific customer collection issues. We evaluate such allowances on a regular basis and adjust them as needed.

Concentrations of Business and Credit Risk

Financial instruments that potentially subject us to credit risk consist of cash, cash equivalents, investments, and accounts receivable. Our cash, cash equivalents, and investments may consist of deposits held with banks, money market funds, and other highly liquid investments that may at times exceed federally insured limits. Cash equivalents and investments are financial instruments that potentially subject us to concentrations of risk. Under our investment policy, we invest primarily in securities issued by the U.S. government. The goals of our investment policy, in order of priority, are as follows: preserve capital, meet liquidity needs, and optimize returns.

We generally do not require collateral to support credit sales. To reduce credit risk, we perform credit evaluations of our customers. One customer from whom we derived development revenue exceeded 10% of revenue for the three and nine months ended September 30, 2020. No other customer represented more than 10% of total revenue for the three and nine months ended September 30, 2020 or 2019. Including the development revenue, revenues from our five largest customers were 31% and 25%

of total revenue for the three months ended September 30, 2020 and 2019, respectively. Revenues from our five largest customers were 23% and 20% of total revenue for the nine months ended September 30, 2020 and 2019, respectively. There was no single customer that represented more than 10% of total accounts receivable at September 30, 2020, or December 31, 2019.

Our products include components that are currently procured from a single source or a limited number of sources. We believe that other vendors would be able to provide similar components; however, the qualification of such vendors may require start-up time. In order to mitigate any adverse impacts from a disruption of supply, we attempt to maintain an adequate supply of critical limited-source components.

Leases

We determine if an arrangement is a lease, or contains a lease, at inception. Operating leases are included in operating lease right-of-use (ROU) assets and current and non-current operating lease liabilities in our condensed consolidated balance sheets. ROU assets represent our right-to-use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. As most of our leases do not provide an implicit rate, we generally use our incremental borrowing rate based on the estimated rate of interest for collateralized borrowing over a similar term of the lease payments at commencement date. Significant judgment is required in determining the incremental collateralized borrowing rate. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

We elected the short-term lease recognition exemption for all leases that qualify. For those leases that qualify, we will not recognize ROU assets or lease liabilities for leases with an initial lease term of one year or less. We also elected not to separate lease and nonlease components for our building leases. The nonlease components are generally variable in nature and are expected to represent most of our variable lease costs. Variable costs are expensed as incurred. We have taken a portfolio approach for our vehicle leases by country.

Goodwill, Intangible Assets and Other Long-Lived Assets

Goodwill, which has an indefinite useful life, represents the excess of cost over fair value of net assets acquired. Our intangible assets include developed technology, patents and licenses. The cost of identifiable intangible assets with finite lives is generally amortized on a straight-line basis over the assets' respective estimated useful lives.

Goodwill and intangible assets with indefinite lives are not subject to amortization but are tested for impairment on an annual basis during the fourth quarter or whenever events or changes in circumstances indicate the carrying amount of these assets may not be recoverable. Events or changes in circumstances that could affect the likelihood that we will be required to recognize an impairment charge include, but are not limited to, declines in our stock price or market capitalization, economic downturns and other macroeconomic events, including the current COVID-19 pandemic, declines in our market share or revenues, and an increase in our losses, rapid changes in technology, failure to achieve the benefits of capacity increases and utilization, significant litigation arising out of an acquisition, or other matters. Any impairment charges could have a material adverse effect on our operating results and net asset value in the quarter in which we recognize the impairment charge.

In evaluating our goodwill and intangible assets with indefinite lives for indications of impairment, we first conduct an assessment of qualitative factors to determine whether it is more likely than not that the fair value of our reporting unit is less than its carrying amount. If we determine that it is more likely than not that the fair value of our reporting unit is less than its carrying amount, we compare the fair value of our reporting unit to its carrying value. If the fair value of our reporting unit exceeds its carrying value, goodwill is not considered impaired and no further analysis is required. If the carrying value of the reporting unit exceeds its fair value, then an impairment loss equal to the difference would be recorded to goodwill. We did not recognize any impairment of goodwill for any of the periods presented herein.

We evaluate our long-lived assets, including finite-lived intangibles, for indicators of possible impairment when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. If any indicator of impairment exists, we assess the recoverability of the affected long-lived assets by determining whether the carrying value of the asset can be recovered through undiscounted future operating cash flows. If impairment is indicated, we estimate the asset's fair value using future discounted cash flows associated with the use of the asset and adjust the carrying value of the asset accordingly. We did not recognize any impairment of intangibles for any of the periods presented herein.

Deferred Grant Income

In September 2020, we executed a definitive contract with the National Institutes of Health (NIH) for a project under the NIH Rapid Acceleration of Diagnostics (RADx) program. The definitive contract, which amended the letter contract we entered

into with the NIH in July 2020 (collectively, the NIH Contract), has a total value of up to \$34.0 million upon the achievement of certain conditional milestones. Proceeds from the NIH Contract will be used primarily to expand production capacity and product throughput capabilities.

Accounting for the NIH Contract does not fall under ASC 606, Revenue from Contracts with Customers, as the NIH will not benefit directly from our expansion or product development. As there is no authoritative guidance under U.S. GAAP on accounting for government assistance to for-profit business entities, we applied International Accounting Standards (IAS) 20, Accounting for Government Grants and Disclosure of Government Assistance, by analogy when accounting for the NIH Contract payments to Fluidigm.

The NIH Contract proceeds meet the definition of grants related to assets as the primary condition for the payments is to fund the purchase and construction of longer-term assets to scale up production capacity. Under IAS 20, government grants related to assets are presented in the statement of financial position either by setting up the grant as deferred income or by deducting the grant in arriving at the carrying amount of the asset. Either of these two methods of presentation of grants related to assets in financial statements are regarded as acceptable alternatives under IAS 20. We have elected to record the grants received as deferred income using the first method.

Under IAS 20, grant proceeds are recognized when there is reasonable assurance the conditions of the grant will be met and the grant will be received. With the NIH Contract, this occurs when either each milestone has been accepted by NIH or management concludes the conditions of the grant have been substantially met. We record the NIH Contract proceeds as deferred income. Proceeds used for capital expenditures will be amortized over the period of depreciation for the assets as a reduction of depreciation expense. Any portion of the proceeds used to reimburse research and development expense are recorded as a reduction of those expenses incurred to date.

Convertible Notes

In February 2014, we closed an underwritten public offering of \$201.3 million aggregate principal amount of our 2.75% Senior Convertible Notes due 2034 (2014 Notes). In March 2018, we entered into separate privately negotiated transactions with certain holders of our 2014 Notes to exchange \$150.0 million in aggregate principal amount of the 2014 Notes for our 2.75% Exchange Convertible Senior Notes due 2034 (2018 Notes). As the 2018 Notes were convertible, at our election, into cash, shares of our common stock, or a combination of cash and shares of our common stock, we accounted for the 2018 Notes under the cash conversion guidance in ASC 470, whereby the embedded conversion option in the 2018 Notes was separated and accounted for in equity. In the first quarter of 2019, the 2018 Notes were converted into 19.5 million shares of our common stock and the 2018 Notes were retired. We recorded a loss of \$9.0 million on the retirement of the 2018 Notes. We determined the fair value of the 2018 Notes using valuation techniques that required us to make assumptions related to the implied discount rate.

In November 2019, we closed a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of \$55.0 million aggregate principal amount of our 5.25% Senior Convertible Notes due 2024 (2019 Notes). Most of the issuance proceeds were used to retire approximately \$50.2 million of aggregate principal amount of our 2014 Notes, leaving approximately \$1.1 million of aggregate principal amount of our 2014 Notes outstanding.

As the 2019 Notes do not provide for a cash conversion feature, the 2019 Notes are recorded as debt in their entirety in accordance with ASC 470. For the 2014, 2018 and 2019 Notes, offering-related costs, including underwriting costs, were capitalized as debt issuance costs, recorded as an offset to the carrying value of the related Notes, and are amortized over the expected term of the related Notes using the effective interest method.

See Note 8 for a detailed discussion of the accounting treatment of the transactions and additional information.

Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) consists of unrealized gains and losses on our investments and foreign currency translation adjustments. Total comprehensive loss for all periods presented has been disclosed in the condensed consolidated statements of comprehensive loss.

The components of accumulated other comprehensive loss, net of tax, for the three and nine months ended September 30, 2020 are as follows (in thousands):

	Foreign Currency Translation Adjustment	Unrealized Gain (Loss) on Investments	Accumulated Other Comprehensive Income (Loss)
Ending balance at December 31, 2019	\$ (618)	\$ 36	\$ (582)
Other comprehensive income (loss)	(303)	—	(303)
Ending balance at March 31, 2020	\$ (921)	\$ 36	\$ (885)
Other comprehensive income (loss)	109	(33)	76
Ending balance at June 30, 2020	\$ (812)	\$ 3	\$ (809)
Other comprehensive income (loss)	523	(3)	520
Ending balance at September 30, 2020	\$ (289)	\$ —	\$ (289)

Immaterial amounts of unrealized gains and losses have been reclassified into the condensed consolidated statement of operations for the three and nine months ended September 30, 2020 and 2019.

Net Loss per Share

Our basic and diluted net loss per share is calculated by dividing net loss by the weighted-average number of shares of common stock outstanding for the period. Restricted stock units, performance share units, and stock options to purchase our common stock are considered to be potentially dilutive common shares but have been excluded from the calculation of diluted net loss per share as their effect is anti-dilutive for all periods presented.

The following potentially dilutive common shares were excluded from the computations of diluted net loss per share for the periods presented because including them would have been anti-dilutive (in thousands):

	Nine Months Ended September 30,	
	2020	2019
Stock options, restricted stock units and performance awards	7,652	5,342
2019 Convertible Notes	18,966	—
2019 Convertible Notes potential make-whole shares	826	—
2014 Convertible Notes	19	916
Total	27,463	6,258

Recent Accounting Changes and Accounting Pronouncements

Adoption of New Accounting Guidance

In August 2018, the U.S.-based Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2018-15-Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40), which establishes new guidance on the accounting for costs incurred to implement a cloud computing arrangement that is considered a service arrangement. The new guidance requires the capitalization of such costs, aligning it with the accounting for costs associated with developing or obtaining internal-use software. The new guidance is effective for fiscal years beginning after December 15, 2019. The adoption of the new guidance did not have a significant impact on our financial results.

In January 2017, the FASB issued ASU 2017-04, Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. The ASU eliminates the requirement for an entity to calculate the implied fair value of goodwill to measure a goodwill impairment charge. Instead, an entity performs its annual, or interim, goodwill impairment testing by comparing the fair value of a reporting unit with its carrying amount and recording an impairment charge for the amount by which the carrying amount exceeds the fair value. The ASU is effective for annual and interim goodwill impairment testing performed for our fiscal year beginning January 1, 2020. The adoption of the new guidance did not have a significant impact on our financial results.

The FASB issued two ASUs related to financial instruments – credit losses. The ASUs issued were: (1) in June 2016, ASU 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, and (2) in November 2018, ASU 2018-19-Codification Improvements to Topic 326, Financial Instruments-Credit Losses. ASU 2016-13 is intended to improve financial reporting by requiring more timely recording of credit losses on loans and other financial

instruments held by financial institutions and other organizations. ASU 2018-19 clarifies that receivables arising from operating leases are not within the scope of the credit losses standard, but rather, should be accounted for in accordance with the lease standard. These ASUs are effective for fiscal years beginning after December 15, 2019, and interim periods within those years, with early adoption permitted. The modified retrospective method is required upon adoption. The adoption of the new guidance resulted in an adjustment of approximately \$0.1 million to reduce the accumulated deficit component of stockholders' equity and decrease current assets by the same amount in our condensed consolidated balance sheet.

Recent Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06 Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. The amendment to this ASU reduces the number of accounting models for convertible instruments and allows more contracts to qualify for equity classification, which is expected to result in more convertible instruments being accounted for as a single unit, rather than being bifurcated between debt and equity. The new guidance is effective for fiscal years beginning after December 15, 2021. We are currently evaluating the impact of adoption on our condensed consolidated financial statements.

In November 2019, the FASB issued ASU 2019-12-Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. The amendments in this update improve consistent application of and simplify U.S. GAAP for Topic 740 by clarifying and amending existing guidance for, among other items, intra-period allocation, reporting tax law changes and losses in interim periods, state and local taxes not fully based on income and recognition of deferred tax liability related to certain transactions. There is also new guidance related to consolidated group reporting and tax impacts resulting from business combinations. The new guidance is effective for fiscal years beginning after December 15, 2020. We are currently evaluating the impact of adoption on our condensed consolidated financial statements.

3. Business Combination

On January 17, 2020, we completed the acquisition of all of the outstanding shares of InstruNor AS, a privately held Norwegian company (InstruNor).

InstruNor is a provider of the only fully integrated sample preparation system for flow and mass cytometry. The acquisition of InstruNor supports our entry into the sample preparation market for cytometry analysis and expands our capabilities to include fully automated sample preparation for flow and mass cytometry. The value of this technology is reflected in the intangible asset for developed technology. The developed technology was valued using a discounted cash flow model for which the most sensitive assumption was revenue growth rate.

The purchase price of \$7.2 million included approximately \$5.2 million in cash and 485,451 shares of our common stock valued at the closing price on the effective date of \$4.22.

A summary of the net cash flows is summarized below (in thousands):

	January 17, 2020
Cash consideration paid to former equity holders	\$ 5,165
Less: cash and cash equivalents acquired	(11)
Acquisition of InstruNor, net of cash acquired	<u>\$ 5,154</u>

The acquisition was accounted for in accordance with ASC 805, Business Combinations. The assets acquired and liabilities assumed were recorded at their estimated fair values at the InstruNor acquisition date. Goodwill of \$2.2 million was calculated as the purchase price less the fair value of the net assets acquired as follows (in thousands):

	January 17, 2020
Purchase price:	
Cash consideration paid on closing to former equity holders	\$ 5,165
Non-cash consideration common shares	2,049
Total purchase price	\$ 7,214
Assets acquired:	
Cash and cash equivalents	\$ 11
Accounts receivable	32
Other receivables	13
Inventories, net	153
Developed technology	5,380
Liabilities assumed:	
Accounts payable	14
Other current liabilities	15
Deferred tax liability, net	566
Fair value of identifiable net assets acquired	\$ 4,994
Goodwill acquired on acquisition	\$ 2,220

4. RADx Program

In July 2020, we entered into a letter contract with the National Institutes of Health (NIH) for a project under the NIH Rapid Acceleration of Diagnostics (RADx) program. The RADx program provides grants to support a range of new lab-based and point-of-care tests that could significantly increase the number, type and availability of COVID-19 tests. On September 28, 2020, we executed a definitive contract with the NIH as an amendment to the letter contract (collectively, the NIH Contract). The NIH Contract has a total value of up to \$34.0 million upon the achievement of certain conditional milestones. Proceeds from the NIH Contract will be used primarily to expand production capacity and product throughput capabilities for COVID-19 testing with Fluidigm microfluidics technology. We expect to complete the NIH Contract by the end of 2021.

The NIH has the right to terminate the NIH Contract for convenience. In the event of termination for convenience, Fluidigm will be paid a percentage of the NIH Contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges. In the event of termination for cause due to our default, NIH is not liable for supplies or services not accepted.

If we fail to deliver within the time specified in the NIH Contract and the delay is due to Fluidigm's fault or negligence, we are required to pay liquidated damages in the amount of 33% of the amount(s) already disbursed to date under the NIH Contract within six months from the date of termination.

The following table summarizes the activity under the NIH Contract through September 30, 2020 (in thousands):

Total value of milestones reasonably assured	\$ 18,607
Amounts applied against research and development expenses	383
Deferred grant income	\$ 18,224
Total value of milestones reasonably assured	\$ 18,607
Funding received	11,151
Grant receivable from RADx	\$ 7,456

5. Revenue

Disaggregation of Revenue

The following table presents our revenue for the three and nine months ended September 30, 2020 and 2019, respectively, based on geographic area and by source (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Geographic Markets:				
Americas	\$ 23,653	\$ 11,112	\$ 52,437	\$ 35,203
EMEA	8,837	9,092	23,490	28,465
Asia-Pacific	7,371	6,292	17,609	21,135
Total revenue	<u>\$ 39,861</u>	<u>\$ 26,496</u>	<u>\$ 93,536</u>	<u>\$ 84,803</u>
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Source:				
Instruments	\$ 12,624	\$ 9,159	\$ 30,672	\$ 34,200
Consumables	16,586	11,507	34,924	34,528
Product revenue	29,210	20,666	65,596	68,728
Service revenue	6,131	5,630	16,457	15,875
Development revenue	3,180	—	6,180	—
Other revenue				
License and royalty revenue	—	—	3,163	—
Grant revenue	1,340	200	2,140	200
Total other revenue	1,340	200	5,303	200
Total revenue	<u>\$ 39,861</u>	<u>\$ 26,496</u>	<u>\$ 93,536</u>	<u>\$ 84,803</u>

Performance Obligations

We reported \$20.0 million of deferred revenue in our December 31, 2019 consolidated balance sheet. During the nine months ended September 30, 2020, \$8.8 million of the opening balance was recognized as revenue and \$9.9 million of net additional advance payments were received from customers, primarily associated with instrument service contracts. At September 30, 2020, we reported \$21.1 million of deferred revenue.

The following table summarizes the expected timing of revenue recognition for unfulfilled performance obligations associated with instrument service contracts that were partially completed at September 30, 2020 (in thousands):

Fiscal Year	Expected Revenue ⁽¹⁾
2020 (remainder of the year)	\$ 3,873
2021	10,385
2022	5,775
Thereafter	4,079
Total	<u>\$ 24,112</u>

(1) Expected revenue includes both billed amounts included in deferred revenue and unbilled amounts that are not reflected in our condensed consolidated financial statements and are subject to change if our customers decide to cancel or modify their contracts. Purchase orders for instrument service contracts can generally be canceled before the service period begins without penalty.

We apply the practical expedient that permits us not to disclose information about unsatisfied performance obligations for service contracts with an expected term of one year or less.

6. Goodwill and Intangible Assets, net

In connection with our acquisition of DVS Sciences, Inc. in February 2014, we recognized goodwill of \$104.1 million and \$112.0 million of developed technology. In the first quarter of 2020, we recognized \$2.2 million (Euro 2.0 million) of goodwill from the InstruNor acquisition and \$5.4 million (Euro 4.9 million) of developed technology (see Note 3). As the goodwill and developed technology from the InstruNor acquisition are recorded in the functional currency of our European operations, which is the Euro, these balances are revalued each period and the U.S. dollar value of these assets will fluctuate as foreign exchange rates change. We are amortizing InstruNor developed technology over 8.0 years.

Goodwill and intangible assets with indefinite lives are not subject to amortization but are tested for impairment on an annual basis during the fourth quarter or whenever events or changes in circumstances indicate the carrying amount of these assets may not be recoverable. Qualitative assessment includes assessing significant events and circumstances such as our current results, assumptions regarding future performance, strategic initiatives and overall economic factors, including the ongoing global COVID-19 pandemic and macroeconomic developments to determine the existence of potential indicators of impairment and assess if it is more likely than not that the fair value of our reporting unit or intangible assets is less than their carrying value. If indicators of impairment are identified, a quantitative impairment test is performed.

During the first quarter of fiscal 2020, the Company assessed whether the current and potential future impact of the COVID-19 pandemic represented an event which necessitated an impairment review. This assessment included an update of the qualitative and quantitative factors affecting our business. As a result of this assessment, we determined that a triggering event had occurred and a quantitative impairment test was performed. As a result of this quantitative analysis, we determined that the fair values of our goodwill and developed technology intangibles were not less than their carrying values and no impairment was recognized.

Intangible assets also include other patents and licenses, which are included in other non-current assets. Intangible assets, net, were as follows (in thousands):

September 30, 2020				
	Gross Amount	Accumulated Amortization and Translation	Net	Weighted-Average Amortization Period
Developed technology	\$ 117,380	\$ (74,425)	\$ 42,955	9.9 years
Patents and licenses	\$ 11,274	\$ (9,030)	\$ 2,244	7.8 years

December 31, 2019				
	Gross Amount	Accumulated Amortization and Translation	Net	Weighted-Average Amortization Period
Developed technology	\$ 112,000	\$ (65,800)	\$ 46,200	10.0 years
Patents and licenses	\$ 11,274	\$ (8,342)	\$ 2,932	7.8 years

Total amortization expense for the three months ended September 30, 2020 and 2019 was \$3.2 million and \$3.0 million, respectively. Amortization of intangibles was \$9.6 million and \$9.2 million for the nine months ended September 30, 2020 and 2019, respectively.

Based on the carrying value of intangible assets, net, as of September 30, 2020, the amortization expense is expected to be as follows (in thousands):

Fiscal Year	Developed Technology Amortization Expense	Patents and Licenses Amortization Expense	Total
2020 (remainder of the year)	\$ 2,978	\$ 229	\$ 3,207
2021	11,911	760	12,671
2022	11,911	677	12,588
2023	11,911	571	12,482
2024	2,111	7	2,118
Thereafter	2,133	—	2,133
Total	\$ 42,955	\$ 2,244	\$ 45,199

7. Balance Sheet Details

Cash, Cash Equivalents and Restricted Cash

Cash, cash equivalents and restricted cash consisted of the following as of September 30, 2020 and December 31, 2019 (in thousands):

	September 30, 2020	December 31, 2019
Cash and cash equivalents	\$ 72,345	\$ 21,661
Restricted cash	1,015	2,075
Total cash, cash equivalents and restricted cash	\$ 73,360	\$ 23,736

Short-term restricted cash of approximately \$15 thousand is included in prepaid expenses and other current assets and \$1.0 million of non-current restricted cash is included in other non-current assets in the condensed consolidated balance sheet as of September 30, 2020.

Inventories

Inventories consisted of the following as of September 30, 2020 and December 31, 2019 (in thousands):

	September 30, 2020	December 31, 2019
Raw materials	\$ 8,768	\$ 6,133
Work-in-process	920	659
Finished goods	9,872	7,092
Total inventories	\$ 19,560	\$ 13,884

Property and Equipment, net

Property and equipment consisted of the following as of September 30, 2020 and December 31, 2019 (in thousands):

	September 30, 2020	December 31, 2019
Computer equipment and software	\$ 4,363	\$ 3,997
Laboratory and manufacturing equipment	18,988	19,325
Leasehold improvements	8,118	7,788
Office furniture and fixtures	2,211	1,824
Property and equipment, gross	33,680	32,934
Less accumulated depreciation and amortization	(26,262)	(24,954)
Construction-in-progress	113	76
Property and equipment, net	\$ 7,531	\$ 8,056

Warranties

Activity for our warranty accrual for the nine months ended September 30, 2020 and 2019, which is included in other accrued liabilities, is summarized below (in thousands):

	Nine Months Ended September 30,	
	2020	2019
Beginning balance	\$ 1,390	\$ 863
Accrual for current period warranties	677	912
Warranty costs incurred	(387)	(668)
Ending balance	\$ 1,680	\$ 1,107

8. Convertible Notes and Credit Facility

2014 Senior Convertible Notes (2014 Notes)

In February 2014, we closed an underwritten public offering of \$201.3 million aggregate principal amount of our 2014 Notes. We received \$195.2 million, net of underwriting discounts, from the issuance of the 2014 Notes and incurred approximately \$1.1 million in offering-related expenses. The underwriting discount and offering-related expenses are being amortized to interest expense using the effective-interest rate method. The effective interest rate on the 2014 Notes, reflecting the impact of debt discounts and issuance costs, is 3.0%. The 2014 Notes will mature on February 1, 2034, unless earlier converted, redeemed, or repurchased in accordance with the terms of the 2014 Notes. We have retired the majority of the 2014 Notes through the issuance of the 2018 Notes and 2019 Notes, as discussed below. As of September 30, 2020, there is \$1.1 million aggregate principal of the 2014 Notes outstanding.

2018 Senior Convertible Notes (2018 Notes)

In March 2018, we entered into separate privately negotiated transactions with certain holders of our 2014 Notes to exchange \$150.0 million in aggregate principal amount of the 2014 Notes for 2018 Notes, leaving \$51.3 million of the aggregate principal amount of the 2014 Notes outstanding. As of the closing of the 2018 Notes on March 12, 2018, the estimated fair value was \$145.5 million. The difference between the \$150.0 million aggregate principal amount of the 2018 Notes and its fair value was being amortized over the expected term of the 2018 Notes using the effective interest method through the first note holder put date of February 6, 2023.

The 2018 Notes accrued interest at a rate of 2.75% payable semi-annually in arrears on February 1 and August 1 of each year. The 2018 Notes were set to mature on February 1, 2034, unless earlier converted, redeemed, or repurchased in accordance with the terms of the indenture governing the 2018 Notes. The initial conversion rate of the 2018 Notes was 126.9438 shares of our common stock, par value \$0.001 per share, per \$1,000 principal amount of the 2018 Notes (which is equivalent to an initial conversion price of approximately \$7.88 per share). The conversion rate was subject to adjustment upon the occurrence of certain specified events. Those certain specified events included holders who converted their 2018 Notes voluntarily prior to our exercise of the issuer's conversion option described below or in connection with a make-whole fundamental change prior to February 6, 2023, entitling the holders, under certain circumstances, to a make-whole premium in the form of an increase in the conversion rate determined by reference to a make-whole table set forth in the indenture governing the 2018 Notes. Any time

prior to the maturity of the 2018 Notes, we could convert the 2018 Notes, in whole but not in part, into cash, shares of our common stock, or combination thereof, if the closing price of our common stock equaled or exceeded 110% of the conversion price then in effect for a specified number of days.

Offering-related costs for the 2018 Notes were approximately \$2.8 million. Offering-related costs of \$2.2 million were capitalized as debt issuance costs, recorded as an offset to the carrying value of the 2018 Notes, and were being amortized over the expected term of the 2018 Notes using the effective interest method through the first note holder put date of February 6, 2023. The effective interest rate on the 2018 Notes was 12.3%. Offering-related costs of \$0.6 million were accounted for as equity issuance costs, recorded as an offset to additional paid-in capital, and were not subject to amortization. Offering-related costs were allocated between debt and equity in the same proportion as the allocation of the 2018 Notes between debt and equity.

In the first quarter of 2019, we received notices from holders of the 2018 Notes electing to voluntarily convert approximately \$138.1 million in aggregate principal amount of the 2018 Notes. In February 2019, we notified the trustee, U.S. Bank National Association, of our intention to exercise our issuer's conversion option with respect to the remaining approximately \$11.9 million in aggregate principal amount of the 2018 Notes. In total, \$150.0 million of the 2018 Notes were converted into 19.5 million shares of our common stock and the bonds were retired. We recognized a loss of \$9.0 million on the retirement of the 2018 Notes, which represented the difference between the fair value of the bonds retired and their carrying costs. The net impact on equity was \$133.3 million and represented the fair value of the bonds retired.

2019 Senior Convertible Notes (2019 Notes)

In November 2019, we issued \$55.0 million aggregate principal amount of 2019 Notes. Net proceeds of the offering of the 2019 Notes issuance were \$52.7 million, after deductions for commissions and other debt issuance costs of approximately \$2.3 million. \$51.8 million of the proceeds of the 2019 Notes were used to retire \$50.2 million aggregate principal amount of our 2014 Notes, leaving \$1.1 million of aggregate principal value of 2014 Notes outstanding. We accounted for the transaction as an extinguishment of debt due to the significance of the change in value of the embedded conversion option, resulting in a \$3.0 million loss in the fourth quarter of 2019. The loss on extinguishment of debt was calculated as the difference between the reacquisition price (i.e., the fair value of the principal amount of 2019 Notes) and the net carrying value of the 2014 Notes exchanged.

The 2019 Notes bear interest at 5.25% per annum, payable semiannually in arrears on June 1 and December 1 of each year, beginning on June 1, 2020. The Notes will mature on December 1, 2024, unless earlier repurchased or converted pursuant to their terms. The 2019 Notes will be convertible at the option of the holder at any point prior to the close of business on the second scheduled trading day preceding the maturity date. The initial conversion rate of the Notes is 344.8276 shares of the Company's common stock per \$1,000 principal amount of 2019 Notes (which is equivalent to an initial conversion price of approximately \$2.90 per share). The conversion rate is subject to adjustment upon the occurrence of certain specified events. Those certain specified events include voluntary conversion of the 2019 Notes prior to our exercise of the Issuer's Conversion Option or in connection with a make-whole fundamental change, entitling the holders, under certain circumstances, to a make-whole premium in the form of an increase in the conversion rate determined by reference to a make-whole table set forth in the indenture governing the 2019 Notes. The conversion rate will not be adjusted for any accrued and unpaid interest.

The 2019 Notes will also be convertible at our option upon certain conditions in accordance with the terms of the indenture governing the 2019 Notes. On or after December 1, 2021 to December 1, 2022, if the price of the Company's common stock has equaled or exceeded 150% of the conversion price then in effect for a specified number of days (Issuer's Conversion Option), we may, at our option, elect to convert the 2019 Notes in whole but not in part into shares of the Company, determined in accordance with the terms of the indenture. On or after December 1, 2022, if the price of the Company's common stock has equaled or exceeded 130% of the conversion price then in effect for a specified number of days, we may, at our option, elect to convert the 2019 Notes in whole but not in part into shares of the Company, determined in accordance with the terms of the indenture.

Offering-related costs for the 2019 Notes were capitalized as debt issuance costs and are recorded as an offset to the carrying value of the 2019 Notes. The debt issuance costs are being amortized over the expected term of the 2019 Notes using the effective interest method through the maturity date of December 1, 2024. The effective interest rate on the 2019 Notes is 6.2%.

The carrying values of the components of the 2014 Notes and the 2019 Notes are as follows (in thousands):

	September 30, 2020	December 31, 2019
2.75% 2014 Notes due 2034		
Principal amount	\$ 1,079	\$ 1,079
Unamortized debt discount	(17)	(18)
Unamortized debt issuance cost	(4)	(4)
	<u>\$ 1,058</u>	<u>\$ 1,057</u>
5.25% 2019 Notes due 2024		
Principal amount	\$ 55,000	\$ 55,000
Unamortized debt issuance cost	(1,937)	(2,236)
	<u>\$ 53,063</u>	<u>\$ 52,764</u>
Net carrying value of all Notes	<u>\$ 54,121</u>	<u>\$ 53,821</u>

2018 Revolving Credit Facility

In August 2018, we entered into a revolving credit facility with Silicon Valley Bank (as amended, the Revolving Credit Facility) in an aggregate principal amount of up to the lesser of (i) \$15.0 million (Maximum Amount) or (ii) the sum of (a) 85% of our eligible receivables and (b) 50% of our eligible inventory, in each case, subject to certain limitations (Borrowing Base), provided that the amount of eligible inventory that may be counted towards the Borrowing Base shall be subject to a cap as set forth in the Revolving Credit Facility. Subject to the level of this Borrowing Base, we may make and repay borrowings from time to time until the maturity of the Revolving Credit Facility. The Borrowing Base as of September 30, 2020 under the Revolving Credit Facility was \$15.0 million. There were no borrowings outstanding under the Revolving Credit Facility at September 30, 2020.

The Revolving Credit Facility is collateralized by substantially all our property, other than intellectual property. Until an amendment in April 2020, the Revolving Credit Facility was set to mature on August 2, 2020. The interest rate on outstanding loans under the Revolving Credit Facility was the greater of (i) prime rate plus 0.50% or (ii) 5.50%. Interest on any outstanding loans is due and payable monthly and the principal balance is due at maturity, though loans can be prepaid at any time without penalty. Effective April 21, 2020, the Revolving Credit Facility was amended to extend the maturity date to August 2, 2022. In addition, the interest rate on outstanding loans under the Revolving Credit Facility was reduced by 0.25%. The quarterly unused line fee, which was previously based on the Maximum Amount, will now be based on the Borrowing Base. The annual commitment fee of \$112,500 is unchanged.

The Revolving Credit Facility contains customary affirmative and negative covenants that, unless waived by the bank, limit our ability to, among other things, incur additional indebtedness, grant liens, make investments, repurchase stock, pay dividends, transfer assets, enter into affiliate transactions, undergo a change of control, or engage in merger and acquisition activity, including merging or consolidating with a third party. The Revolving Credit Facility also contains customary events of default, subject to customary cure periods for certain defaults, that include, among other things, non-payment defaults, covenant defaults, material judgment defaults, bankruptcy and insolvency defaults, cross-defaults to certain other material indebtedness, and defaults due to inaccuracy of representation and warranties. Upon an event of default, the lender may declare all or a portion of the outstanding obligations payable by us to be immediately due and payable and exercise other rights and remedies provided for under the Revolving Credit Facility. During the existence of an event of default, interest on the obligations under the Revolving Credit Facility could be increased to 5.0% above the otherwise applicable rate of interest. We were in compliance with all the terms and conditions of the Revolving Credit Facility at September 30, 2020.

9. Leases

We have operating leases for buildings, equipment and vehicles. Existing leases have remaining terms of less than one year to ten years. Some leases contain options to extend the lease, usually for up to five years, and termination options.

Supplemental balance sheet information related to leases was as follows as of September 30, 2020 and December 31, 2019 (in thousands, except for discount rate and lease term):

	September 30, 2020	December 31, 2019
Operating lease right-of-use buildings	\$ 40,723	\$ 6,234
Operating lease right-of-use equipment	86	69
Operating lease right-of-use vehicles	583	355
Total operating lease right-of-use assets, gross	41,392	6,658
Accumulated amortization	(2,923)	(1,798)
Total operating lease right-of-use assets, net	<u>\$ 38,469</u>	<u>\$ 4,860</u>
Operating lease liabilities, current	\$ 2,697	\$ 1,833
Operating lease liabilities, non-current	38,607	4,323
Total operating lease liabilities	<u>\$ 41,304</u>	<u>\$ 6,156</u>
Weighted average remaining lease term (in years)	8.9	4.7
Weighted average discount rate per annum	11.9 %	5.0 %

A new operating lease for our corporate headquarters in South San Francisco, California commenced in March 2020. We recorded a ROU asset of \$35.7 million at the inception of the lease and an operating lease liability of \$35.3 million. The lease term is approximately ten years. Future minimum lease payments over the life of the lease were discounted at a rate of 12.6%, which was our estimated incremental collateralized borrowing rate for the term of the lease at the inception of the lease.

The following table presents the components of lease expense for the three and nine months ended September 30, 2020 and 2019, respectively (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating lease cost (including variable costs)	\$ 2,501	\$ 1,604	\$ 7,012	\$ 4,660
Variable costs including non-lease component	\$ 407	\$ 748	\$ 1,576	\$ 2,051

Supplemental Cash Flow Information:

Cash paid for amounts included in the measurement of operating lease liabilities (included in net cash used in operating activities in thousands):

	Nine Months Ended September 30,	
	2020	2019
Operating cash flows from operating leases	<u>\$ 3,443</u>	<u>\$ 3,068</u>

Future minimum lease payments under commenced non-cancelable operating leases, which are as of September 30, 2020 as follows (in thousands):

Fiscal Year	Minimum Lease Payments for Operating Leases
2020 (remainder of year)	\$ 1,802
2021	7,362
2022	7,040
2023	6,950
2024	7,152
Thereafter	39,254
Total future minimum payments	\$ 69,560
Less: imputed interest	(28,256)
Total	\$ 41,304

10. Fair Value of Financial Instruments

The following tables summarize our cash and available-for-sale securities that were measured at fair value by significant investment category within the fair value hierarchy (in thousands):

	September 30, 2020						
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value	Cash and Cash Equivalents	Short-Term Marketable Securities	Cash-Restricted
Assets:							
Cash-unrestricted	\$ 49,144	\$ —	\$ —	\$ 49,144	\$ 49,144	\$ —	\$ —
Cash-restricted	1,015	—	—	1,015	—	—	1,015
Total cash	\$ 50,159	\$ —	\$ —	\$ 50,159	\$ 49,144	\$ —	\$ 1,015
Available-for-sale:							
Level I:							
Money market funds	\$ 23,201	\$ —	\$ —	\$ 23,201	\$ 23,201	\$ —	\$ —
Total	\$ 73,360	\$ —	\$ —	\$ 73,360	\$ 72,345	\$ —	\$ 1,015
	December 31, 2019						
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value	Cash and Cash Equivalents	Short-Term Marketable Securities	Cash-Restricted
Assets:							
Cash-unrestricted	\$ 16,614	\$ —	\$ —	\$ 16,614	\$ 16,614	\$ —	\$ —
Cash-restricted	2,075	—	—	2,075	—	—	2,075
Total cash	\$ 18,689	\$ —	\$ —	\$ 18,689	\$ 16,614	\$ —	\$ 2,075
Available-for-sale:							
Level I:							
Money market funds	\$ 5,047	\$ —	\$ —	\$ 5,047	\$ 5,047	\$ —	\$ —
US treasury securities	36,942	36	—	36,978	—	36,978	—
Subtotal	\$ 41,989	\$ 36	\$ —	\$ 42,025	\$ 5,047	\$ 36,978	\$ —
Total	\$ 60,678	\$ 36	\$ —	\$ 60,714	\$ 21,661	\$ 36,978	\$ 2,075

There were no transfers between Level I and Level II measurements, and no changes in the valuation techniques used, during the nine months ended September 30, 2020.

Based on an evaluation of securities that were in a loss position, we did not recognize any other-than-temporary impairment charges for the nine months ended September 30, 2020 and 2019. None of our investments have been in a continuous loss position for more than 12 months. We concluded that the declines in market value of our available-for-sale securities investment portfolio were temporary in nature and did not consider any of our investments to be other-than-temporarily impaired.

Convertible Notes

In 2019, we significantly reduced the amount of our outstanding debt. As a result, our convertible notes are not regularly traded and it is difficult to estimate a reliable and accurate market price for these securities. The estimated fair values for these securities represent Level III valuations since a fair value for these securities cannot be determined by using readily observable inputs or measures, such as market prices. Fair values were estimated using pricing models and risk-adjusted value ranges.

The following table summarizes the par value, carrying value and the estimated fair value of the 2014 and 2019 Notes at September 30, 2020 and December 31, 2019, respectively (in thousands):

	September 30, 2020			December 31, 2019		
	Par Value	Carrying Value	Fair Value	Par Value	Carrying Value	Fair Value
2014 Notes	\$ 1,079	\$ 1,058	\$ 1,122	\$ 1,079	\$ 1,057	\$ 1,122
2019 Notes	55,000	53,063	143,039	55,000	52,764	73,975
Total	\$ 56,079	\$ 54,121	\$ 144,161	\$ 56,079	\$ 53,821	\$ 75,097

11. Shareholders' Equity

2020 At-the-Market Offering

In March 2020, we entered into an Open Market Sale Agreement (Sale Agreement) with Jefferies LLC (Jefferies) to sell shares of our common stock having aggregate sales proceeds of up to \$50,000,000, from time to time, through an "at-the-market" equity offering program under which Jefferies acts as sales agent. During the third quarter of 2020, we sold 2.5 million shares of our common stock pursuant to the Sale Agreement, for aggregate gross proceeds of \$20.9 million. Our net proceeds from the sale of such shares of common stock were approximately \$20.1 million, after deducting related expenses, including commissions of approximately \$0.6 million and issuance costs of approximately \$0.2 million.

InstruNor Acquisition

In January 2020, we completed the acquisition of all of the outstanding shares of InstruNor (see Note 3). The purchase price was approximately \$7.2 million, consisting of \$5.2 million in cash and 485,451 shares of our common stock.

Conversion of 2018 Notes

In the first quarter of 2019, we issued 19,460,260 shares of our common stock in connection with the conversion of our 2018 Notes (see Note 8). As a result of this issuance of our common stock, we recorded a total of \$133.3 million of equity, which was equivalent to the fair value of the bonds retired.

At September 30, 2020, we had reserved shares of common stock for future issuance under equity compensation plans as follows:

(in 000's)	Securities To Be Issued Upon Exercise Of Options	Securities To Be Issued Upon Release Of Restricted Stock and Performance Share Units	Number Of Remaining Securities Available For Future Issuance
2009 Equity Incentive Plan	19	—	—
2011 Equity Incentive Plan	1,387	5,810	3,057
DVS Sciences Inc. 2010 Equity Incentive Plan	13	—	—
2017 Inducement Award Plan	207	216	—
2017 Employee Stock Purchase Plan	—	—	3,100
	1,626	6,026	6,157

12. Stock-Based Plans

Our board of directors sets the terms, conditions, and restrictions related to our 2017 Employee Stock Purchase Plan (ESPP) and the grant of stock options, restricted stock units (RSUs) and performance-based awards under our equity incentive plans. Our board of directors determines the number of awards to grant and also sets vesting criteria.

In general, RSUs vest on a quarterly basis over a period of four years from the date of grant at a rate of either 25% on the first anniversary of the grant date and ratably each quarter over the remaining 12 quarters, or ratably each quarter over 16 quarters, subject to the employees' continued employment. In May 2020, we granted 1.8 million retention RSUs that vest over three years, with 50% of the RSUs vesting after one year and 25% of the RSUs vesting each year thereafter.

Incentive stock options and non-statutory stock options granted under our 2011 Equity Incentive Plan (2011 Plan) have a term of no more than ten years from the date of grant and an exercise price of at least 100% of the fair market value of the underlying common stock on the date of grant. If a participant owns stock representing more than 10% of the voting power of all classes of our stock on the grant date, an incentive stock option awarded to the participant will have a term of no more than five years from the date of grant and an exercise price of at least 110% of the fair market value of the underlying common stock on the date of grant. Generally, options vest at a rate of either 25% on the first anniversary of the option grant date and ratably each month over the remaining period of 36 months, or ratably each month over 48 months. We may grant options with different vesting terms from time to time.

For performance-based share awards, our board of directors sets the performance objectives and other vesting provisions in determining the number of shares or value of performance units and performance shares that will be paid out. Such payout will be a function of the extent to which performance objectives or other vesting provisions have been achieved.

2011 Equity Incentive Plan

In January 2011, our board of directors adopted the 2011 Plan under which incentive stock options, non-statutory stock options, RSUs, stock appreciation rights, performance stock units (PSUs), and performance shares may be granted to our employees, directors, and consultants. In April 2019, our board of directors authorized, and in June 2019, our stockholders approved an amendment and restatement of the 2011 Plan to make various changes, including increasing the number of shares reserved for issuance by approximately 5.0 million shares and extending the term of the 2011 Plan until April 2029. In May 2020, our board of directors authorized, and in June 2020, our stockholders approved an increase in the number of shares reserved for issuance under the 2011 Plan of 1.4 million shares.

2009 Equity Incentive Plan and 2017 Inducement Award Plan

Our 2009 Equity Incentive Plan (the 2009 Plan) terminated on the date the 2011 Plan was adopted. Options granted, or shares issued under the 2009 Plan that were outstanding on the date the 2011 Plan became effective, remained subject to the terms of the 2009 Plan.

In January 2017, we adopted the Fluidigm Corporation 2017 Inducement Award Plan (Inducement Plan) and reserved 2 million shares of our common stock for issuance pursuant to equity awards granted under the Inducement Plan. The Inducement Plan provided for the grant of equity-based awards on terms substantially similar to the 2011 Plan. In accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules, awards under the Inducement Plan were only be made to individuals not previously our

employees or non-employee members of our board of directors (or following such individual's bona fide period of non-employment), as an inducement material to the individual's entry into employment with us or in connection with a merger or acquisition, to the extent permitted by Rule 5635(c)(3) of the Nasdaq Listing Rules. In June 2019, concurrently with the increase in shares available for grant under the 2011 Plan, the Inducement Plan was terminated such that no further grants could be made thereunder. Options granted and shares issued under the Inducement Plan that were outstanding when the Inducement Plan was terminated remain outstanding subject to their terms and the terms of the Inducement Plan.

Valuation and Expense Information

We use the Black-Scholes option-pricing model to estimate the fair value of stock options granted under our equity incentive plans. We grant stock options at exercise prices not less than the fair value of our common stock at the date of grant. The fair value of RSUs granted to employees was estimated on the date of grant by multiplying the number of shares granted by the fair market value of our common stock on the grant date.

Activity under the various plans was as follows:

Restricted Stock Units:

	Number of Units (in 000s)	Weighted-Average Grant Date Fair Value per Unit
Balance at December 31, 2019	2,551	\$ 7.43
RSU granted	3,642	\$ 3.95
RSU released	(872)	\$ 7.30
RSU forfeited	(305)	\$ 6.39
Balance as of September 30, 2020	<u>5,016</u>	<u>\$ 4.99</u>

As of September 30, 2020, the unrecognized compensation costs related to outstanding unvested RSUs under our equity incentive plans were \$22.0 million. We expect to recognize those costs over a weighted average period of 2.8 years.

Stock Options:

	Number of Options (000s)	Weighted-Average Exercise Price per Option	Weighted-Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value ⁽¹⁾ in (000s)
Balance at December 31, 2019	2,027	\$ 7.78	6.8	\$ 81
Options granted	105	\$ 3.74		
Options exercised	(98)	\$ 4.90		\$ 352
Options forfeited	(408)	\$ 9.20		
Balance as of September 30, 2020	<u>1,626</u>	<u>\$ 7.34</u>	<u>6.4</u>	<u>\$ 2,514</u>
Vested at September 30, 2020	<u>1,259</u>	<u>\$ 7.86</u>	<u>6.0</u>	<u>\$ 1,799</u>
Awards expected to vest at September 30, 2020	<u>367</u>	<u>\$ 5.56</u>	<u>7.9</u>	<u>\$ 715</u>

(1) Aggregate intrinsic value as of September 30, 2020 was calculated as the difference between the closing price per share of our common stock on the last trading day of September 30, 2020, which was \$7.43, and the exercise price of the options, multiplied by the number of in-the-money options.

As of September 30, 2020, the unrecognized compensation costs related to outstanding unvested options under our equity incentive plans were \$1.1 million. We expect to recognize those costs over a weighted average period of 1.4 years.

Performance-based Awards

Performance Stock Units with Market Conditions

We have granted PSU awards to certain executive officers and senior level employees. The number of PSUs ultimately earned under these awards is calculated based on the Total Shareholder Return (TSR) of our common stock as compared to the TSR of a defined group of peer companies during the applicable three-year performance period. The percentage of PSUs that vest will depend on our relative position at the end of the performance period and can range from 0% to 200% of the number of units granted. Under FASB ASC Topic 718, the provisions of the PSU awards related to TSR are considered a market

condition, and the effects of that market condition are reflected in the grant date fair value of the awards. We used a Monte Carlo simulation pricing model to incorporate the market condition effects at our grant date.

Activity under the TSR-based PSUs is as follows:

	Number of Units (in 000s)	Weighted-Average Grant Date Fair Value per Unit
Balance at December 31, 2019	547	\$ 15.09
PSU granted	509	\$ 4.82
PSU released	—	\$ —
PSU forfeited	(94)	\$ 14.26
Balance at September 30, 2020	<u>962</u>	<u>\$ 9.74</u>

As of September 30, 2020, the unrecognized compensation costs related to these awards were \$4.6 million. We expect to recognize those costs over a weighted average period of 1.7 years.

Performance Stock Units with Performance Conditions

During 2019, we also granted a PSU award under which the number of PSUs that ultimately vest is dependent on achieving certain discrete operational milestones between September 30, 2019 and December 31, 2020. Activity to date under this PSU award is as follows:

	Number of Units (in 000s)	Weighted-Average Grant Date Fair Value per Unit
Balance at December 31, 2019	64	\$ 7.05
PSU granted	—	\$ —
PSU released	(4)	\$ 7.05
PSU forfeited	(12)	\$ 7.05
Balance at September 30, 2020	<u>48</u>	<u>\$ 7.05</u>

2017 Employee Stock Purchase Plan

In August 2017, our stockholders approved our ESPP at the annual meeting of stockholders. Our ESPP offers U.S. and some non-U.S. employees the right to purchase shares of our common stock. Our first ESPP offering period began on October 1, 2017 with a shorter offering period ending on November 30, 2017.

Prior to June 2019, our ESPP program had a six-month offering period, with a new period commencing on the first trading day on or after May 31 and November 30 of each year. Employees were eligible to participate through payroll deductions of up to 10% of their compensation. The purchase price at which shares were sold under the ESPP was 85% of the lower of the fair market value of a share of our common stock on the first day of the offering period or the last day of the offering period.

Effective in June 2019, our ESPP program was amended to offer a twelve-month offering period with two six-month purchase periods beginning on each of May 31 and November 30. Employees were eligible under the amended program to participate through payroll deductions of up to 15% of their compensation. Employees may not purchase more than \$25 thousand of stock for any calendar year.

Under the updated ESPP program, the purchase price at which shares are sold for the first purchase period is 85% of the lower of the fair market value of a share of our common stock on the first day of the offering period or the last day of the first purchase period. For the second purchase period, the purchase price at which shares are sold is 85% of the lower of the fair market value of the common stock on the first day of the offering period and the last day of the offering period. In the event the fair market value of the common stock at the beginning of the second purchase period is less than the fair market value on the beginning of the offering period, the purchase price for the second offering period is reset to 85% of the lower of the fair value of the common stock at the beginning of the second purchase period and the last day of the offering period.

The offering period of June 1, 2019 to May 31, 2020 had two purchase periods, with one period ending November 30, 2019 and the other period ending May 31, 2020. As the fair market value of the common stock at November 30, 2019 was lower than the fair value of the common stock at the beginning of the offering period, the purchase price for the second purchase period was reset based on the lower of the November 30, 2019 price and the May 31, 2020 price. The resetting of the purchase price is considered to be a modification of the original terms of the award. Under ASC 718, the incremental fair value based on the

difference between the fair value of the modified award and the fair value of the original award immediately before it was modified was approximately \$0.3 million. This amount was amortized over the remaining offering period which ended May 31, 2020.

In April 2020, our board of directors authorized, and in June 2020, our stockholders approved, an amendment and restatement of the ESPP that increased the number of shares reserved for issuance by an additional 3.0 million shares and made various other changes. Effective June 2020, our ESPP program was amended to offer a six-month offering period, with a new offering and purchase period commencing on the first trading day on or after May 31 and November 30 of each year. Employees are eligible under the amended program to participate through payroll deductions of up to 10% of their compensation. Employees may not purchase more than \$25 thousand of stock for any calendar year. The purchase price of the shares sold under the ESPP is 85% of the lower of fair market value of a share of our common stock on the first day of the offering period or the last day of the offering period.

Total stock-based compensation expense recognized was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Restricted stock units, stock options and performance share units	\$ 4,114	\$ 2,738	\$ 9,558	\$ 7,731
Employee stock purchase plan	243	291	800	561
Total stock-based compensation	\$ 4,357	\$ 3,029	\$ 10,358	\$ 8,292

13. Income Taxes

Our quarterly provision for income taxes is based on an estimated effective annual income tax rate. Our quarterly provision for income taxes also includes the tax impact of certain unusual or infrequently occurring items, if any, including changes in judgment about valuation allowances and effects of changes in tax laws or rates, in the interim period in which they occur.

We recorded a tax benefit of \$0.2 million and \$2.1 million for the three and nine months ended September 30, 2020, respectively. We recorded a tax benefit of \$1.2 million and \$2.3 million for the three and nine months ended September 30, 2019, respectively. The benefits for all periods were primarily attributable to the tax benefit from the amortization of our acquisition-related deferred tax liabilities partially offset by tax provisions for our foreign operations and state minimum income taxes.

Our tax benefit for income taxes for the periods presented differ from the 21% U.S. Federal statutory rate for the nine months ended September 30, 2020 and 2019, respectively, primarily due to maintaining a valuation allowance for most of our deferred tax assets, which primarily consist of net operating loss carryforwards.

Our tax positions are subject to audits by multiple tax jurisdictions. We believe that we have provided adequate reserves for uncertain tax positions for all tax years still open for assessment. For the three and nine months ended September 30, 2020, and 2019, respectively, we did not recognize any material interest or penalties related to uncertain tax positions.

Recording deferred tax assets is appropriate when realization of these assets is more likely than not. Assessing the realizability of deferred tax assets is dependent upon several factors including historical financial results and future expected financial results. The deferred tax assets have been offset by valuation allowances. In the future we may release valuation allowances and recognize deferred tax assets in certain of our foreign subsidiaries depending on the achievement of future profitability in the relevant jurisdictions. Any release of valuation allowances could have the effect of decreasing the income tax provision in the period the valuation allowance is released. We continue to monitor the likelihood that we will be able to recover our deferred tax assets, including those for which a valuation allowance is recorded. There can be no assurance that we will generate profits in the future periods enabling us to fully realize our deferred tax assets. The timing of recording a valuation allowance or the reversal of such valuation allowance is subject to objective and subjective factors that cannot be readily predicted in advance.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security (CARES) Act was signed into law. The CARES Act includes provisions relating to refundable payroll tax credits, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to the tax depreciation methods for qualified improvement property. We are currently analyzing the impact of these changes and therefore, an estimate of the impact on income taxes, if any, is not yet available.

14. Information About Geographic Areas

We operate in one reporting segment that develops, manufactures and commercializes tools for life sciences research. Our chief executive officer manages our operations and evaluates our financial performance on a consolidated basis. For purposes of allocating resources and evaluating regional financial performance, our chief executive officer reviews separate sales information for the different regions of the world. Our general and administrative expenses and our research and development expenses are not allocated to any specific region. Most of our principal operations, other than manufacturing, and our decision-making functions are located at our corporate headquarters in the United States.

A summary table of our total revenue by geographic areas of our customers and by product and services for the three and nine months ended September 30, 2020 and 2019 is included in Note 5 to the condensed consolidated financial statements.

Sales to customers in the United States represented \$23.3 million, or 58% of total revenues, and \$50.7 million, or 54% of total revenues, for the three and nine months ended September 30, 2020, respectively. Sales to customers in the United States represented \$10.5 million, or 40% of total revenues, and \$32.9 million, or 39% of total revenues, for the three and nine months ended September 30, 2019, respectively.

No foreign country or jurisdiction had sales in excess of 10% of total revenues for the three months ended September 30, 2020 and 2019, except for China, which had total revenues of \$3.9 million, or 15% of total revenues for the three months ended September 30, 2019. There was no foreign country or jurisdiction with sales in excess of 10% of our total revenues for the nine months ended September 30, 2020 or 2019, except for China, which had sales of \$11.4 million, or 13% of total revenues, for the nine months ended September 30, 2019.

15. Development Agreement

Effective March 31, 2020, we signed an OEM Supply and Development Agreement (Development Agreement) with a customer. Under the Development Agreement, Fluidigm will develop products based on our microfluidics technology. The Development Agreement provides up-front and periodic milestone payments of up to \$11.7 million during the development stage. The development stage is expected to last approximately one year from the date of the agreement. We recognized \$3.2 million and \$6.2 million of development revenue from this agreement in the three and nine months ended September 30, 2020, respectively.

16. Commitments and Contingencies

Indemnification

From time to time, we have entered into indemnification provisions under certain of our agreements in the ordinary course of business, typically with business partners, customers, and suppliers. Pursuant to these agreements, we may indemnify, hold harmless, and agree to reimburse the indemnified parties on a case-by-case basis for losses suffered or incurred by the indemnified parties in connection with any patent or other intellectual property infringement claim by any third party with respect to our products. The term of these indemnification provisions is generally perpetual from the time of the execution of the agreement. The maximum potential amount of future payments we could be required to make under these indemnification provisions is typically not limited to a specific amount. In addition, we have entered into indemnification agreements with our officers, directors, and certain other employees. With certain exceptions, these agreements provide for indemnification for related expenses including, among others, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding.

Contingencies

In September 2020, a putative class action complaint alleging violations of the federal securities laws was filed against the Company (also naming our Chief Executive Officer and Chief Financial Officer as defendants) in the U.S. District Court for the Northern District of California. The complaint seeks unspecified damages on behalf of a purported class of persons and entities who acquired our common stock between February 7, 2019 and November 5, 2019. The litigation is in its early stages and the lead plaintiff has not yet been determined. We believe the claims alleged in the complaint lack merit and we intend to defend ourselves vigorously.

From time to time, we may be subject to various legal proceedings and claims arising in the ordinary course of business. These include disputes and lawsuits related to intellectual property, mergers and acquisitions, licensing, contract law, tax, regulatory, distribution arrangements, employee relations and other matters. Periodically, we review the status of each matter and assess its potential financial exposure. If the potential loss from any claim or legal proceeding is considered probable and a range of possible losses can be estimated, we accrue a liability for the estimated loss. Legal proceedings are subject to uncertainties, and the outcomes are difficult to predict. Because of such uncertainties, accruals are based only on the best information available at the time. As additional information becomes available, we continue to reassess the potential liability related to pending claims and litigation and may revise estimates.

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

The following discussion and analysis should be read together with our condensed consolidated financial statements and the notes to those statements included elsewhere in this Form 10-Q. This Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act, that are based on our management’s beliefs and assumptions and on information currently available to our management. The forward-looking statements are contained principally in the section entitled “Risk Factors” and this Management’s Discussion and Analysis of Financial Condition and Results of Operations. Forward-looking statements include information concerning our possible or assumed future cash flow, revenue, sources of revenue and results of operations, cost of product revenue and product margin, operating and other expenses, unit sales and the selling prices of our products, business strategies, financing plans, expansion of our business, competitive position, industry environment, potential growth opportunities, market growth expectations, and the effects of competition and public health crises (including the COVID-19 pandemic) on our business. Forward-looking statements include statements that are not historical facts and can be identified by terms such as “anticipates,” “believes,” “could,” “seeks,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would,” or similar expressions and the negatives of those terms.

Forward-looking statements involve known and unknown risks, uncertainties, and other 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. We discuss these risks in greater detail in Part II, Item 1A, “Risk Factors,” elsewhere in this quarterly report on Form 10-Q, and in our annual report on Form 10-K filed with the Securities and Exchange Commission (SEC). Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management’s beliefs and assumptions only as of the date of this Form 10-Q.

Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. You should read this Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect.

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Unless the context requires otherwise, references in this Form 10-Q to “Fluidigm,” the “Company,” “we,” “us,” and “our” refer to Fluidigm Corporation and its subsidiaries.

Overview

Fluidigm is a global company that improves life through comprehensive health insight. Our innovative technologies and multi-omic tools are used by researchers to reveal meaningful insights into health and disease, identify biomarkers to inform decisions, and accelerate the development of more effective therapies. We create, manufacture, and market a range of products and services, including instruments, reagents and software that are used by researchers and clinical labs worldwide.

Our focus is on the most pressing needs in translational and clinical research, including infectious disease, cancer, immunology and immunotherapy. We use proprietary CyTOF® and microfluidics technologies to develop innovative end-to-end solutions that have the flexibility required to meet the needs of translational research and the robustness to support high-impact clinical research studies.

We sell our products to leading academic, government, pharmaceutical, biotechnology, clinical, and plant and animal research laboratories worldwide. We distribute our systems through our direct sales force and support organizations located in North America, Europe, and Asia-Pacific, and through distributors or sales agents in several European, Latin American, Middle Eastern, and Asia-Pacific countries.

Our manufacturing operations are located in Singapore and Canada. Our facility in Singapore manufactures our genomics instruments, which are assembled by our contract manufacturer located within our Singapore facility. All of our microfluidics IFCs are fabricated at our Singapore facility. Our mass cytometry instruments, assays and reagents are manufactured at our facility in Canada. We also use U.S.-based third-party contract manufacturers for reagent manufacturing.

Our total revenue for the nine months ended September 30, 2020 was \$93.5 million compared to \$84.8 million for the nine months ended September 30, 2019. Our total revenue was \$117.2 million in 2019 and \$113.0 million in 2018. We have incurred significant net losses since our inception in 1999 and, as of September 30, 2020, our accumulated deficit was \$658.7 million.

Recent Developments

We have been responding to the COVID-19 pandemic by taking steps to protect our employees, support our customers, and manage our liquidity. As Fluidigm is a designated essential business, our employees have been working from home offices or our laboratories and offices, and in some cases, at customer sites. We have implemented health and safety practices in accordance with evolving government and public health agency guidelines in all of our facilities around the world, including maintaining social distancing and enhanced cleaning protocols, facilities modifications, temperature checks in some locations, and usage of face masks and other personal protective equipment where appropriate. Other operational adjustments made in response to COVID-19 include increased raw material stocking and proactive supplier management.

We have activated our business continuity plans as a result of this pandemic, which include steps taken not only to help keep our workforce healthy and safe, but also to ensure a strong data security and internal control environment. Our controls around financial reporting have been modified slightly as needed to reflect the impact of working remotely. To date we have not needed to take advantage of extended SEC filing deadlines.

While Fluidigm is a designated essential business, widespread global adoption of work-from-home and shelter-in-place orders have resulted in a significant slowdown in customer activities for much of the year. In the first half of 2020, we saw near-term COVID-19-related priorities temporarily displacing longer term projects and research activities. As customers return to work, we have seen some customer ordering recover, but the timing of complete recovery remains uncertain, given additional waves of infection and timing of a vaccine. We estimate that about 10% of our customers are either closed or working at reduced capacity as of the end of September 2020 because of the COVID-19 pandemic, compared to 30-40% in June 2020. We believe the impact of COVID-19 on our customers has resulted in expected sales of our mass cytometry instrument systems to be delayed to future periods. The development of COVID-19-related applications has positively impacted sales of our microfluidics instruments, consumables, and mass cytometry reagents.

Since the beginning of the COVID-19 pandemic, Fluidigm has been working with a growing body of researchers around the world who are aggressively responding to the pandemic. In June 2020, we submitted an emergency use authorization (EUA) application with the U.S. Food and Drug Administration (FDA) for our saliva-based Advanta Dx SARS-CoV-2 Assay, and the FDA granted the EUA in August 2020. In addition, Fluidigm is actively supporting customers who are developing lab-developed tests, as well as customers who are providing COVID-19 diagnostic tests outside of the U.S. Fluidigm's mass cytometry technology and workflows are also being used by our customers in the U.S. and Europe for multi-site COVID-19 patient immune profiling studies.

We believe our microfluidics and mass cytometry capabilities can play a significant role in virus detection as well as in immune profiling of patients and populations. Furthermore, we believe our technologies and solutions will be important to the durable response from government and medical institutions to be prepared for future outbreaks. Despite these opportunities, there is still uncertainty regarding the impact of COVID-19 on the global economy, our customers, and our business over the near term. Also, though we are now able to sell our Advanta Dx SARS-CoV-2 Assay for diagnostic use and certain clinical laboratory customers are developing lab developed tests using our technology, our experience selling into diagnostic markets is limited and we face significant competition. Many of our target customers in these markets do not have significant prior experience using Fluidigm instruments and consumables, and require validation steps and assistance in establishing, integrating and scaling up testing programs using our technology and products. Also, many such laboratories have experience working with certain of our competitors for diagnostic testing, and we have faced, and expect to continue to face, complex sales processes and competition in the COVID-19 testing market. We expect to seek collaborations with third parties and invest in customer support infrastructure and personnel to meet the challenges associated with penetrating these markets.

We have actively sought government funding to support our investment to expand our diagnostics capabilities for microfluidics. In July 2020, we entered into a letter contract with the National Institutes of Health (NIH) for a project under the NIH Rapid Acceleration of Diagnostics (RADx) program. The RADx program provides grants to support a range of new lab-based and point-of-care tests that could significantly increase the number, type and availability of COVID-19 tests. On September 28, 2020, we executed a definitive contract with the NIH as an amendment to the letter contract (collectively, the NIH Contract). The NIH Contract has a total value of up to \$34.0 million upon the achievement of certain milestones. Through September 30, 2020, we have achieved milestones with a total value of \$18.6 million and have received cash of \$11.2 million. Proceeds from the NIH Contract will be used primarily to expand production capacity and product throughput capabilities for COVID-19 testing with Fluidigm microfluidics technology. We expect to spend approximately \$30.0 million for capital expenditures over the next two quarters for the expansion of our Singapore facility as a result of the NIH Contract.

The NIH has the right to terminate the NIH Contract for convenience. In the event of termination for convenience, Fluidigm will be paid a percentage of the NIH Contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges. In the event of termination for cause due to our default, NIH is not liable for supplies or services not accepted. If we fail to deliver within the time specified in the NIH Contract and the delay is due to Fluidigm's fault or negligence, we are required to pay liquidated damages in the amount of 33% of the amount(s) already disbursed to date under the NIH Contract within six months from the date of termination.

In March 2020, we entered into an Open Market Sale Agreement (Sale Agreement) with Jefferies LLC (Jefferies) to sell shares of our common stock having aggregate sales proceeds of up to \$50,000,000, from time to time, through an "at the market" (ATM) equity offering program under which Jefferies acts as sales agent. During the third quarter of 2020, we sold 2.5 million shares of our common stock, \$0.001 par value per share, pursuant to the Sale Agreement, for aggregate gross proceeds of \$20.9 million. Our net proceeds were approximately \$20.1 million, after deducting related expenses, including commissions of approximately \$0.6 million and issuance costs of approximately \$0.2 million.

In this period of uncertainty, we are actively managing our operating expenses and cash flows in response to the evolving market conditions. In addition, we implemented reductions in our operating expense structure including temporary salary reductions which began in the second quarter and ended in the third quarter of this year and constrained hiring until our business returns to more normal volumes. We have also taken advantage of various government programs available to us. For example, we have applied for or received wage subsidies in certain countries. In the U.S., the Coronavirus Aid, Relief and Economic Security (CARES) Act includes provisions relating to refundable payroll tax credits, deferment of the employer portion of certain payroll taxes, and other tax-related provisions. As a result, we have been preserving cash by deferring payment of U.S. payroll taxes and are currently evaluating the applicability of other provisions in the CARES Act.

We are continuing to assess the potential impact of the COVID-19 pandemic on our business and operations. For additional information on the various risks posed by the pandemic, refer to Part II, Item 1A. Risk Factors of this Form 10-Q.

Critical Accounting Policies, Significant Judgments and Estimates

Our condensed consolidated financial statements and the related notes included elsewhere in this Form 10-Q are prepared in accordance with accounting principles generally accepted in the United States. The preparation of these condensed financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, costs and expenses and related disclosures. We base our estimates on historical experience and on various other assumptions believed to be reasonable, which together form the basis for making judgments about the carrying values of assets and liabilities. The full extent to which the COVID-19 pandemic impacts our business, results of operations and financial condition will depend on numerous evolving factors including, but not limited to, the magnitude and duration of the pandemic, the extent to which it will impact worldwide macroeconomic conditions, including the speed of recovery, and governmental and business reactions to the pandemic. We evaluate our estimates and assumptions on an ongoing basis. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial condition, results of operations, and cash flows will be affected.

We have expanded disclosure of our critical accounting policies and estimates in the preparation of our condensed consolidated financial statements during the nine months ended September 30, 2020 compared to those disclosed in our annual report on Form 10-K for the year ended December 31, 2019, as filed with the SEC on February 27, 2020, to reflect the impact of the NIH Contract under the RADx program (see Note 4) and a new development agreement (see Note 15).

Recent Accounting Changes and Accounting Pronouncements

Adoption of New Accounting Guidance

In August 2018, the FASB issued ASU 2018-15-Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40) which establishes new guidance on the accounting for costs incurred to implement a cloud computing arrangement that is considered a service arrangement. The new guidance requires the capitalization of such costs, aligning it with the accounting for costs associated with developing or obtaining internal-use software. The new guidance is effective for fiscal years beginning after December 15, 2019. The adoption of the new guidance did not have a significant impact on our financial results.

In January 2017, the FASB issued ASU 2017-04, Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. The ASU eliminates the requirement for an entity to calculate the implied fair value of goodwill to measure a goodwill impairment charge. Instead, an entity performs its annual, or interim, goodwill impairment testing by comparing the fair value of a reporting unit with its carrying amount and recording an impairment charge for the amount by which the carrying amount exceeds the fair value. The ASU is effective for annual and interim goodwill impairment testing

performed for our fiscal year beginning January 1, 2020, with early adoption permitted, which we did not exercise. The adoption of the new guidance did not have a significant impact on our financial results.

The FASB issued two ASUs related to financial instruments – credit losses. The ASUs issued were: (i) in June 2016, ASU 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, and (ii) in November 2018, ASU 2018-19-Codification Improvements to Topic 326, Financial Instruments-Credit Losses. ASU 2016-13 is intended to improve financial reporting by requiring more timely recording of credit losses on loans and other financial instruments held by financial institutions and other organizations. ASU 2018-19 clarifies that receivables arising from operating leases are not within the scope of the credit losses standard, but rather, should be accounted for in accordance with the leasing standard. These ASUs are effective for fiscal years beginning after December 15, 2019, and interim periods within those years, with early adoption permitted. The modified retrospective method is required upon adoption. The adoption of the new guidance resulted in an adjustment of \$0.1 million to reduce the accumulated deficit component of stockholders' equity and decrease current assets by the same amount in the condensed consolidated balance sheet.

Recent Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06 Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. The amendment to this ASU reduces the number of accounting models for convertible instruments and allows more contracts to qualify for equity classification, which is expected to result in more convertible instruments being accounted for as a single unit, rather than being bifurcated between debt and equity. The new guidance is effective for fiscal years beginning after December 15, 2021. We are currently evaluating the impact of adoption on our condensed consolidated financial statements.

In November 2019, the FASB issued ASU 2019-12 Income Taxes (Topic 740)-Simplifying the Accounting for Income Taxes. The amendments in this update improve consistent application of and simplify GAAP for Topic 740 by clarifying and amending existing guidance for, among other items, intra-period allocation, reporting tax law changes and losses in interim periods, state and local taxes not fully based on income and recognition of deferred tax liability related to certain transactions. There is also new guidance related to consolidated group reporting and tax impacts resulting from business combinations. The new guidance is effective for fiscal years beginning after December 15, 2020. We are currently evaluating the impact of adoption on our condensed consolidated financial statements.

Results of Operations

The following table presents our historical consolidated statements of operations data for the three and nine months ended September 30, 2020 and 2019, and as a percentage of total revenue for the respective periods (in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2020		2019		2020		2019	
Revenue:								
Total revenue	\$ 39,861	100 %	\$ 26,496	100 %	\$ 93,536	100 %	\$ 84,803	100 %
Costs and expenses:								
Cost of product revenue	12,773	32	10,520	40	31,896	34	33,009	39
Cost of service revenue	1,769	4	1,938	7	4,531	5	5,403	6
Research and development	8,128	21	7,125	27	25,275	27	23,362	28
Selling, general and administrative	22,655	57	20,729	78	65,966	70	65,687	77
Total costs and expenses	45,325	114	40,312	152	127,668	136	127,461	150
Loss from operations	(5,464)	(14)	(13,816)	(52)	(34,132)	(36)	(42,658)	(50)
Interest expense	(885)	(2)	(444)	(1)	(2,682)	(3)	(3,636)	(4)
Loss from extinguishment of debt	—	—	—	—	—	—	(9,000)	(11)
Other income (expense), net	107	—	205	1	(248)	—	920	1
Loss before income taxes	(6,242)	(16)	(14,055)	(52)	(37,062)	(40)	(54,374)	(64)
Income tax benefit	243	1	1,168	4	2,068	3	2,269	3
Net loss	\$ (5,999)	(15)%	\$ (12,887)	(48)%	\$ (34,994)	(37)	\$ (52,105)	(61)%

Revenue

We generate revenue primarily from sales of our products and services, and from development agreements, license and royalty agreements, and grants. Our product revenue consists of sales of instruments and consumables. Consumable revenues are largely driven by the size of our installed base of instruments and the annual level of pull-through per instrument. Service revenue is linked to our sales of instruments as our service revenue consists of post-warranty service contracts, preventive maintenance plans, instrument parts, installation and training. We sell our products to leading academic, government, pharmaceutical, biotechnology, clinical, plant and animal research laboratories worldwide.

One customer from which we derived development revenue exceeded 10% of revenue for the three and nine months ended September 30, 2020. No other customer represented more than 10% of total revenue for the three and nine months ended September 30, 2020 or 2019. Revenues from our five largest customers were 31% and 25% of total revenue for the three months ended September 30, 2020 and 2019, respectively. Revenues from our five largest customers were 23% and 20% of total revenue for the nine months ended September 30, 2020 and 2019, respectively.

The following table presents our revenue by source for the three and nine months ended September 30, 2020 and 2019, and as a percentage of total revenue for the respective period (in thousands):

	Three Months Ended September 30,				Year-over-Year Change	Nine Months Ended September 30,				Year-over-Year Change
	2020		2019			2020		2019		
Revenue:										
Instruments	\$ 12,624	32 %	\$ 9,159	35 %	38 %	\$ 30,672	33 %	\$ 34,200	40 %	(10)%
Consumables	16,586	42	11,507	43	44 %	34,924	37	34,528	41	1 %
Product revenue	29,210	74	20,666	78	41 %	65,596	70	68,728	81	(5)%
Service revenue	6,131	15	5,630	21	9 %	16,457	18	15,875	19	4 %
Product and service revenue	35,341	89	26,296	99	34 %	82,053	88	84,603	100	(3)%
Development revenue	3,180	7	—	—	NA	6,180	7	—	—	NA
Grant revenue	1,340	4	200	1	570 %	2,140	2	200	—	970 %
License revenue	—	—	—	—	NA	3,163	3	—	—	NA
Total revenue	\$ 39,861	100 %	\$ 26,496	100 %	50 %	\$ 93,536	100 %	\$ 84,803	100 %	10 %

The following table presents our total revenue by geographic area of our customers and as a percentage of total revenue for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,				Year-over-Year Change	Nine Months Ended September 30,				Year-over-Year Change
	2020		2019			2020		2019		
Americas	\$ 23,653	60 %	\$ 11,112	42 %	113 %	\$ 52,437	56 %	\$ 35,203	41 %	49 %
EMEA	8,837	22	9,092	34	(3)%	23,490	25	28,465	34	(17)%
Asia-Pacific	7,371	18	6,292	24	17 %	17,609	19	21,135	25	(17)%
Total revenue	\$ 39,861	100 %	\$ 26,496	100 %	50 %	\$ 93,536	100 %	\$ 84,803	100 %	10 %

The Americas revenue includes revenue generated in the United States of \$23.3 million and \$50.7 million for the three and nine months ended September 30, 2020, respectively. Sales to customers in the United States represented \$10.5 million and \$32.9 million for the three and nine months ended September 30, 2019, respectively.

No foreign country or jurisdiction had sales in excess of 10% of total revenues for the three months ended September 30, 2020 and 2019, except for China, which had revenues of \$3.9 million, or 15% of total revenues for the three months ended September 30, 2019. There was no foreign country or jurisdiction with sales in excess of 10% of our total revenues for the nine months ended September 30, 2020 or 2019, except for China, which had revenues of \$11.4 million, or 13% of total revenues, for the nine months ended September 30, 2019.

Total Revenue

Three Months ended September 30, 2020

Total revenue increased by \$13.4 million or 50%, for the three months ended September 30, 2020 compared to the three months ended September 30, 2019, driven primarily by higher product and service revenue, development revenue, and higher grant revenue. Product revenue increased primarily due to COVID-19-related applications which resulted in higher sales of our microfluidic instruments and consumables and our mass cytometry consumable products.

Americas revenues increased by \$12.5 million, or 113%, which includes \$8.2 million of higher product and service revenue driven by COVID-19-related opportunities along with \$1.1 million of higher grant revenue and \$3.2 million of development revenue for the three months ended September 30, 2020 compared to the three months ended September 30, 2019. EMEA revenues fell \$0.3 million or 3%. Lower microfluidic consumables and mass cytometry instrument sales were partially offset by increases in microfluidics instrument revenue and service revenue. Favorable foreign exchange rates impacted EMEA revenue by 3%. The \$1.1 million, or 17%, increase in Asia-Pacific revenues was driven primarily by higher instrument sales. On a company-wide basis, stronger foreign exchange rates impacted revenues by less than 1% for the three months ended September 30, 2020 compared to the same period in 2019.

Nine Months ended September 30, 2020

Total revenue increased by \$8.7 million or 10%, for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019 due to higher development revenue, license revenue, and grant revenue, partially offset by lower product revenue. Lower mass cytometry instrument revenue was partially offset by higher service revenue and microfluidics instrument and consumables sales, driven primarily by COVID-19-related opportunities.

Americas revenues increased by \$17.2 million, or 49%, driven by higher development revenue of \$6.2 million, higher product and service revenue of \$5.9 million, license revenue of \$3.1 million, and a \$2.1 million increase in grant revenue for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. Higher microfluidics revenue was partially offset by decreases in mass cytometry instruments and consumables revenue for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. EMEA revenues fell \$5.0 million or 17%, for the same period, driven by lower mass cytometry instrument and microfluidics consumables revenue partially offset by higher microfluidics instrument and mass cytometry consumables revenues. A stronger Euro compared to the U.S. dollar favorably impacted EMEA revenues by approximately 1%. The \$3.5 million, or 17%, decrease in Asia-Pacific revenues was driven by declines in mass cytometry instrument and microfluidics consumable revenues, partially offset by higher service revenues. On a company-wide basis, foreign exchange rates had a negligible impact for the nine months ended September 30, 2020 compared to the same period in 2019.

Product Revenue

Product revenue increased by \$8.5 million, or 41%, for the three months ended September 30, 2020 compared to the three months ended September 30, 2019. Increases in microfluidic instrument and mass cytometry and microfluidic consumable revenues were partially offset by lower mass cytometry instrument revenue. Higher microfluidics revenue was largely driven by higher unit sales of Biomark and Juno instruments and related consumables, reflecting several COVID-19-related opportunities.

Product revenue decreased by \$3.1 million, or 5%, for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019, primarily due to lower sales volumes and lower average selling prices of mass cytometry instruments, partially offset by higher revenue from Biomark and Juno instruments and related consumables.

We expect the average selling prices of our products to fluctuate over time based on market conditions, product mix, and currency fluctuations.

Service Revenue

Service revenue increased by \$0.5 million, or 9%, for the three months ended September 30, 2020 compared to the three months ended September 30, 2019. Service plan revenues, which are recognized over the life of the service agreement and are not activity-dependent, drove the majority of the increase in service revenues. As customers have begun to reopen their facilities, we are also seeing increases in training and repair-related revenues.

Service revenue increased by \$0.6 million, or 4%, for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. Service plan revenues drove the majority of the increase, partially offset by lower revenues from training and product maintenance activities. Training and product maintenance revenues declined due primarily to closed customer facilities.

Development Revenue

Effective March 31, 2020, we signed an OEM Supply and Development Agreement (Development Agreement) with a customer. Under the Development Agreement, Fluidigm will develop products based on our microfluidics technology. The Development Agreement provides up-front and periodic milestone payments of up to \$11.7 million during the development stage. The development stage is expected to last approximately one year from the date of the Development Agreement. We recognized \$3.2 million and \$6.2 million of development revenue from this agreement in the three and nine months ended September 30, 2020, respectively.

We recognize revenue under the Development Agreement using an input method based on our costs incurred relative to the total expected cost which determines the extent of our progress toward satisfaction of our obligations under the agreement. Costs associated with the Development Agreement are recorded in research and development expense.

Grant Revenue

We receive grants to perform research and development activities over contractually defined periods. Grant revenue in the current quarter is attributable to a grant agreement entered into in the second half of 2019 and which is expected to end in the first half of 2021. Costs associated with grant agreements are recorded in research and development expense.

License and Royalty Revenue

In March 2020, we entered into an agreement to settle intellectual property infringement claims, in which we received a \$3.5 million payment in exchange for a perpetual license under certain of our intellectual property. The settlement is considered a multiple-element arrangement with each element accounted for individually. Accordingly, \$3.1 million of the proceeds was recognized as license revenue and \$0.4 million was offset against legal costs.

Product and Service Cost, Product and Service Gross Profit, and Product and Service Margin

Cost of product revenue includes manufacturing costs incurred in the production process, including component materials, labor and overhead, installation, packaging, and delivery costs. In addition, cost of product revenue includes amortization of developed technology and intangibles, royalty costs for licensed technologies included in our products, warranty, provisions for slow-moving and obsolete inventory, and stock-based compensation expense. Our cost of product revenue and related product margin may fluctuate depending on the capacity utilization of our manufacturing facilities in response to market conditions and the demand for our products.

Cost of service revenue includes direct labor hours, overhead, and instrument parts. Our cost of service revenue and related service margin may fluctuate depending on the variability in material and labor costs of servicing instruments.

The following table presents our product and service cost, product and service gross profit and product and service margin for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Year-over-Year Change	2020	2019	Year-over-Year Change
Cost of product revenue	\$ 12,773	\$ 10,520	21 %	\$ 31,896	\$ 33,009	(3)%
Cost of service revenue	1,769	1,938	(9)%	4,531	5,403	(16)%
Cost of product and service revenue	\$ 14,542	\$ 12,458	17 %	\$ 36,427	\$ 38,412	(5)%
Product and service gross profit	\$ 20,799	\$ 13,838	50 %	\$ 45,626	\$ 46,191	(1)%
Product and service margin	58.9 %	52.6 %	6.3 ppts	55.6 %	54.6 %	1.0 ppts

Product and service margin increased by 6.3 percentage points for the three months ended September 30, 2020 compared to the three months ended September 30, 2019. Fixed depreciation and amortization costs on a higher revenue base positively impacted margins by 3.2 percentage points. Margins were also favorably impacted by COVID-19-related consumable products and lower charges for inventory reserves. This favorability was partially offset by lower average selling prices, lower production volumes of mass cytometry instruments and product mix, which included lower margin microfluidics instruments.

Product and service margin increased by 1.0 percentage points for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. Fixed depreciation and amortization costs on a higher revenue base contributed 0.2 percentage points to the improvement in the product and service margins. Lower service costs, COVID-19-related consumables products, cost reductions for mass cytometry reagents, and lower charges for inventory reserves also favorably impacted product and service gross margins. This favorability was partially offset by lower average selling prices and production volumes of mass cytometry instruments and product mix, which included lower margin microfluidics instruments.

Operating Expenses

The following table presents our operating expenses for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,		Year-over-Year Change	Nine Months Ended September 30,		Year-over-Year Change
	2020	2019		2020	2019	
Research and development	\$ 8,128	\$ 7,125	14 %	\$ 25,275	\$ 23,362	8 %
Selling, general and administrative	22,655	20,729	9 %	65,966	65,687	—
Total	\$ 30,783	\$ 27,854	11 %	\$ 91,241	\$ 89,049	2 %

Research and Development

Research and development expense consists primarily of compensation-related costs, product development and material expenses, and other allocated facilities and information technology expenses. Our research and development efforts have focused primarily on enhancing our technologies and supporting development and commercialization of new and existing products and services. Research and development expense also includes costs incurred in conjunction with research grants and development arrangements. We have made substantial investments in research and development since our inception and expect to continue to do so.

Research and development expense increased by \$1.0 million, or 14%, for the three months ended September 30, 2020 compared to the three months ended September 30, 2019. Increases were primarily attributable to higher laboratory supplies and outside service costs related to development and grant projects, partially offset by lower compensation costs. The lower compensation costs reflect temporary salary reductions implemented during the second quarter of 2020, Singapore and Canadian government subsidy programs, and funding from the NIH Contract. The temporary salary reduction program ended during the third quarter of 2020.

Research and development expense increased by \$1.9 million, or 8%, for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. Increases were primarily attributable to higher laboratory supplies and outside service costs related to development and grants projects, partially offset by reduced compensation costs.

We believe our continued investment in research and development is essential to our long-term competitive position and these expenses may increase in future periods.

Selling, General and Administrative

Selling, general and administrative expense consists primarily of personnel costs for our sales and marketing, business development, finance, legal, human resources, information technology, and general management, as well as professional services, such as legal and accounting services.

Selling, general and administrative expense increased by \$1.9 million, or 9%, for the three months ended September 30, 2020 compared to the three months ended September 30, 2019. Facilities cost increased approximately \$1.3 million for the three months ended September 30, 2020 compared to the three months ended September 30, 2019, reflecting higher lease costs associated with our new corporate headquarters. Higher legal expenses and an \$0.8 million increase in stock-based compensation costs were partially offset by lower travel costs. Travel expense declined \$1.4 million in the three months ended September 30, 2020 compared to the three months ended September 30, 2019 due to the COVID-19 pandemic. The remaining increase in selling, general and administrative expense was due to a variety of smaller items.

Selling, general and administrative expense increased by \$0.3 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. Compensation costs fell compared to the prior year period due to the impact of temporary salary reductions implemented in the second quarter of 2020, which salaries were restored to earlier levels in the third quarter of 2020. Travel costs fell \$3.0 million compared to the prior period, while costs related to trade shows and

other events fell \$1.3 million due to the cancellation of these events in light of the COVID-19 pandemic. Offsetting these declines was \$3.4 million of higher facilities costs for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019, reflecting higher moving and lease costs associated with our new corporate headquarters. In addition, stock-based compensation costs increased by \$1.4 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. The remaining change in selling, general and administrative expense was due to a variety of smaller items.

Interest Expense, Loss on Extinguishment of Debt and Other Income (Expense), Net

The following table presents these items for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,		Year-over-Year Change	Nine Months Ended September 30,		Year-over-Year Change
	2020	2019		2020	2019	
Interest expense	\$ (885)	\$ (444)	99 %	\$ (2,682)	\$ (3,636)	(26)%
Loss from extinguishment of debt	—	—	NA	—	(9,000)	NA
Other income (expense), net	107	205	(48)%	(248)	920	(127)%
Total	\$ (778)	\$ (239)	226 %	\$ (2,930)	\$ (11,716)	(75)%

In November 2019, we issued \$55.0 million aggregate principal amount of our 5.25% Senior Convertible Notes due 2024 (2019 Notes). Net proceeds of the 2019 Notes issuance were used primarily to retire \$50.2 million aggregate principal amount of our Senior Convertible Notes due 2034 (2014 Notes). The 2019 Notes have an effective interest rate of 6.2% compared to the 2014 Notes, which have an effective interest rate 3.0%. The increase in interest expense for the three months ended September 30, 2020 compared to the prior year period reflects the impact of the higher effective interest rate on the 2019 Notes compared to the 2014 Notes.

In February 2014, we closed an underwritten public offering of \$201.3 million aggregate principal amount of our 2014 Notes. In March 2018, we entered into separate privately negotiated transactions with certain holders of our 2014 Notes to exchange \$150.0 million in aggregate principal amount of the 2014 Notes for our 2.75% Exchange Senior Convertible Notes due 2034 (2018 Notes). The 2018 Notes had an effective interest rate of 12.3%. In the first quarter of 2019, the 2018 Notes were converted into 19.5 million shares of our common stock and the 2018 Notes were retired. We recognized a loss of \$9.0 million on the conversion of 2018 Notes, which was included in loss on extinguishment of debt. This amount represents the difference between the fair value of the bonds converted and the carrying value of the bonds at the time of conversion.

Interest expense of \$2.7 million for the nine months ended September 30, 2020 consists primarily of interest on \$55.0 million of 2019 Notes, while interest expense of \$3.6 million for the nine months ended September 30, 2019 includes both the interest on \$51.3 million of 2014 Notes and a partial quarter of interest expense on \$150.0 million of 2018 Notes, which accrued at an effective rate of 12.3%. The higher interest expense for the nine months ended September 30, 2019 compared to the current year-to-date period reflects the impact of higher debt balances and higher interest rates for the first nine months of 2019 compared to the first nine months of 2020.

Other income of \$0.1 million for the three months ended September 30, 2020 is primarily attributable to \$0.1 million of foreign exchange gains. Other income of \$0.2 million for the three months ended September 30, 2019 includes \$0.3 million of interest income, partially offset by \$0.1 million of foreign exchange losses. The lower interest income in the current year period is attributable to lower market interest rates.

Other expense of \$0.2 million for the nine months ended September 30, 2020 is primarily attributable to \$0.5 million of foreign exchange losses, reflecting the impact of a stronger U.S. dollar, partially offset by \$0.3 million of interest and other income. Other income of \$0.9 million for the nine months ended September 30, 2019 consists primarily of \$1.1 million of interest income, offset by \$0.2 million of foreign exchange losses.

Income Tax Benefit

Our tax provision is generally driven by three components: (i) tax provision from our foreign operations, (ii) tax benefits from the amortization of acquisition-related intangible assets, and (iii) discrete items, such as changes in valuation allowances or adjustments upon finalization of tax returns. Depending on the relative value of these components, we can have either a tax benefit or expense for any given period.

We recorded a tax benefit of \$0.2 million, for an effective tax rate of 3.9%, for the three months ended September 30, 2020. For the three months ended September 30, 2019, we recorded a tax benefit of \$1.2 million for an effective tax rate of

8.3%. For the nine months ended September 30, 2020, we recorded an income tax benefit of \$2.1 million for an effective rate of 5.6%. For the nine months ended September 30, 2019, we recorded a tax benefit of \$2.3 million, for an effective tax rate of 4.2%. The benefit for all periods was primarily attributable to the tax benefit from the amortization of our acquisition-related deferred tax liabilities partially offset by a provision from our foreign operation and state minimum income taxes.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2020, our principal sources of liquidity consisted of \$72.3 million of cash and cash equivalents, as well as \$1.0 million of restricted cash and \$15.0 million of availability under our \$15.0 million revolving senior credit facility (Revolving Credit Facility).

The following table presents our cash flow summary for the nine months ended September 30, 2020 and 2019 (in thousands):

	Nine Months Ended September 30,	
	2020	2019
Cash flow summary:		
Net cash used in operating activities	\$ (11,684)	\$ (29,691)
Net cash provided by (used in) investing activities	40,797	(38,750)
Net cash provided by financing activities	20,425	1,006
Effect of foreign exchange rate fluctuations on cash and cash equivalents	86	(5)
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ 49,624</u>	<u>\$ (67,440)</u>

Net Cash Used in Operating Activities

We derive cash flows from operations primarily from cash collected from the sale of our products and services, and license agreements and grants. Our cash flows from operating activities are also significantly influenced by our use of cash for operating expenses and working capital to support our business. We have historically experienced negative cash flows from operating activities as we have expanded our business and built our infrastructure domestically and internationally.

Net cash used in operating activities in the nine months ended September 30, 2020 was \$11.7 million and consisted of net loss of \$35.0 million, adjusted for non-cash items of \$25.4 million, partially offset by a net increase in assets and liabilities of \$2.1 million. Non-cash items included amortization of developed technology of \$8.9 million, stock-based compensation expense of \$10.4 million, depreciation and amortization of \$3.0 million, lease amortization of \$1.9 million, a provision for excess and obsolete inventory of \$0.7 million and a variety of smaller items. The net change in assets and liabilities was primarily due to an increase in inventories of \$6.8 million caused by increases in mass cytometry instruments, chips, and reagents, an increase in prepaid expenses and other assets of \$2.4 million, primarily comprised of payments to vendors for our Singapore capacity expansion under the NIH Contract and prepaid insurance and a decrease in other liabilities of \$0.2 million, partially offset by a decrease in accounts receivable of \$1.0 million, an increase in accounts payable of \$5.0 million, and an increase in deferred revenue of \$1.3 million.

Net cash used in operating activities for the nine months ended September 30, 2019 was \$29.7 million and consisted of net loss of \$52.1 million, adjusted for non-cash items of \$32.5 million, and an increase in the assets and liabilities of \$10.1 million. Non-cash items primarily included a \$9.0 million loss on extinguishment of debt, amortization of developed technology of \$8.4 million, stock-based compensation expense of \$8.3 million, amortization of debt discounts, premiums, and issuance costs of \$2.1 million, depreciation and amortization of \$3.5 million, and a provision for excess and obsolete inventory of \$1.4 million. The net change in assets and liabilities included a decrease in other liabilities of \$10.5 million, an increase in inventories of \$3.7 million, and an increase in prepaid and other assets of \$1.3 million, partially offset by a decrease in accounts receivable of \$3.2 million, an increase in accounts payable of \$0.6 million, and an increase in deferred revenue of \$1.6 million.

Net Cash Provided by (Used in) Investing Activities

Our primary investing activities consist of purchases, sales, and maturities of our short-term investments and to a much lesser extent, capital expenditures for manufacturing, laboratory, computer equipment and software to support our infrastructure and work force. We expect to continue to incur costs for capital expenditures to expand capacity under the NIH Contract, improve manufacturing efficiencies and strengthen information technology and network security, as well as capital expenditures incurred in moving our corporate headquarters in 2020. However, we may choose to decrease or defer certain capital expenditures and development activities, while further optimizing our organization.

Net cash provided by investing activities in the nine months ended September 30, 2020 was \$40.8 million, which was mainly due to proceeds from the NIH Contract of \$11.2 million, proceeds from maturities of investments of \$31.8 million and proceeds from the sale of investments of \$5.0 million, partially offset by the acquisition of InstruNor AS, net of cash acquired, of \$5.2 million, and capital expenditures of \$2.0 million to support our commercial and manufacturing operations. We expect to spend approximately \$30.0 million for capital expenditures over the next two quarters for the expansion of our Singapore facility as a result of the NIH Contract, which will be offset by the proceeds of the NIH Contract.

Net cash used in investing activities in the nine months ended September 30, 2019 was \$38.8 million, which consisted of purchases of investments of \$52.7 million and capital expenditures of \$2.0 million to support our commercial and manufacturing operations, partially offset by \$16.0 million of proceeds from maturities of investments.

Net Cash Provided by Financing Activities

We generated cash from financing activities of \$20.4 million during the nine months ended September 30, 2020, which was primarily due to proceeds from our ATM equity offering of \$20.2 million, net of commissions, proceeds from stock issuance from the ESPP of \$0.6 million, and proceeds from the exercise of stock options of \$0.5 million, partially offset by payment of debt and equity issuance costs of \$0.5 million, which includes costs from the 2019 Notes offering and the ATM equity offering, and payments for income tax withholding related to net share settlement of equity awards of \$0.4 million.

We generated cash from financing activities of \$1.0 million during the nine months ended September 30, 2019, which included \$1.0 million from the exercise of stock options and \$0.6 million of ESPP proceeds, partially offset by \$0.6 million for income tax withholding related to net share settlement of equity awards, and payment of debt and equity issuance costs of \$0.1 million.

Capital Resources

At September 30, 2020 and December 31, 2019, our working capital, excluding deferred revenues and restricted cash, was \$93.3 million and \$74.0 million, respectively, including cash and cash equivalents of \$72.3 million and \$21.7 million, respectively, and short-term investments of \$37.0 million at December 31, 2019. We had no investments outstanding as of September 30, 2020.

In February 2014, we closed an underwritten public offering of \$201.3 million in aggregate principal amount of our 2014 Notes. In March 2018, we entered into privately negotiated transactions with certain holders of our 2014 Notes to exchange \$150.0 million in aggregate principal amount of the 2014 Notes for \$150.0 million in aggregate principal amount of 2018 Notes.

In the first quarter of 2019, we received notices from holders of the 2018 Notes electing to voluntarily convert \$138.1 million in aggregate principal amount of the 2018 Notes. In February 2019, we notified trustee U.S. Bank National Association of our intention to exercise our issuer's conversion option with respect to the remaining \$11.9 million in aggregate principal amount of 2018 Notes. In total, \$150.0 million of the 2018 Notes were converted into 19.5 million shares of our common stock and the 2018 Notes were retired.

In November 2019, we closed a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of \$55.0 million aggregate principal amount of our 2019 Notes. Net proceeds of the 2019 Notes issuance were \$52.7 million, after deductions for commissions and other debt issuance costs. \$51.8 million of the proceeds was used to retire \$50.2 million aggregate principal amount of our 2014 Notes, leaving \$1.1 million of aggregate principal amount of our 2014 Notes outstanding. Pursuant to the Indenture governing the 2014 Notes, holders of the 2014 Notes have the right, subject to certain conditions specified in such indenture, to require the Company to purchase their 2014 Notes beginning in February 2021. The private placement of the 2019 Notes, and concurrent repurchase of a portion of the 2014 Notes, had the effect of refinancing a portion of the Company's outstanding debt under the 2014 Notes to December 2024.

The 2019 Notes bear interest at 5.25% per annum, payable semiannually on June 1 and December 1 of each year, beginning on June 1, 2020. The Notes will mature on December 1, 2024, unless earlier repurchased or converted pursuant to their terms. The 2019 Notes will be convertible at the option of the holder at any point prior to close of business on the second scheduled trading day preceding the maturity date. The initial conversion rate of the Notes is 344.8276 shares of the Company's common stock per \$1,000 principal amount of 2019 Notes (which is equivalent to an initial conversion price of \$2.90 per share). The conversion rate will be subject to adjustment upon the occurrence of certain specified events but will not be adjusted for any accrued and unpaid interest.

The 2019 Notes will also be convertible at our option upon certain conditions in accordance with the terms of the indenture governing the 2019 Notes. On or after December 1, 2021 to December 1, 2022, if the price of the Company's common stock has equaled or exceeded 150% of the Conversion Price (as defined in the indenture, currently \$2.90, subject to adjustment) for a

specified number of days (Issuer's Conversion Option), we may, at our option, elect to convert the 2019 Notes in whole but not in part into shares of the Company, determined in accordance with the terms of the indenture. On or after December 1, 2022, if the price of the Company's common stock has equaled or exceeded 130% of the Conversion Price then in effect for a specified number of days, we may, at our option, elect to convert the 2019 Notes in whole but not in part into shares of the Company, determined in accordance with the terms of the indenture.

The foregoing summaries of the 2014 Notes, the 2018 Notes, the 2019 Notes and the exchange transactions completed in March 2018 and November 2019 are not complete and are qualified in their entirety by the applicable indentures, forms of global notes, and other agreements and documents filed with the SEC.

In March 2020, we entered into the Sale Agreement with Jefferies to sell shares of our common stock having aggregate sales proceeds of up to \$50,000,000, from time to time, through the ATM equity offering program under which Jefferies acts as sales agent. During the third quarter of 2020, we sold 2.5 million shares of our common stock, pursuant to the Sale Agreement, for aggregate gross proceeds of \$20.9 million. Our net proceeds were approximately \$20.1 million, after deducting related expenses, including commissions of approximately \$0.6 million and issuance costs of approximately \$0.2 million.

On August 2, 2018, we entered into our Revolving Credit Facility with Silicon Valley Bank (SVB), with a maturity date of August 2, 2020. The Revolving Credit Facility is collateralized by substantially all our property, other than intellectual property. Outstanding loans under the Revolving Credit Facility bear interest, at the greater of (i) prime rate plus 0.50% or (ii) 5.50%. Amounts drawn under the Revolving Credit Facility will be used for working capital and general corporate purposes.

On April 21, 2020, we entered into the Third Amendment to Loan and Security Agreement with SVB (the Amendment), which amends the Loan and Security Agreement dated as of August 2, 2018, between the Company and SVB (as amended by the Default Waiver and First Amendment to Loan and Security Agreement dated September 7, 2018, and the Second Amendment to Loan and Security Agreement dated November 20, 2019, the Revolving Credit Agreement). The Amendment extends the maturity date by two years, to August 2, 2022. We also amended the interest rate to be the greater of (i) prime rate (as customarily defined), plus 0.50%, floating, and (ii) 5.25%. Interest on any outstanding loans continues to be due and payable monthly and the principal balance is due at maturity though loans can be prepaid at any time without penalty. Annual administration fees are unchanged. The Amendment also includes various administrative changes.

As of September 30, 2020, total availability under the Revolving Credit Facility was \$15.0 million. We currently have no outstanding debt under the Revolving Credit Facility, and we are in compliance with all the terms and conditions of the Revolving Credit Agreement governing the Revolving Credit Facility. See Note 8 to our consolidated financial statements for more information about the Revolving Credit Facility.

We believe our existing cash, cash equivalents, and investments will be sufficient to meet our working capital and capital expenditure needs for at least the next 18 months. However, we may experience lower than expected cash generated from operating activities or greater than expected capital expenditures, cost of revenue, or operating expenses, and we may need to raise additional capital to fund our operations, further our research and development activities, or acquire or invest in a business. Our future funding requirements will depend on many factors, including market acceptance of our products, the cost of our research and development activities, the cost of filing and prosecuting patent applications, the cost associated with litigation or disputes relating to intellectual property rights or otherwise, the cost and timing of regulatory clearances or approvals, if any, the cost and timing of establishing additional sales, marketing, and distribution capabilities, the cost and timing of establishing additional technical support capabilities, and the effect of competing technological and market developments. In the future, we may acquire businesses or technologies from third parties, and we may decide to raise additional capital through debt or equity financing to the extent we believe this is necessary to successfully complete these acquisitions.

If we require additional funds in the future, we may not be able to obtain such funds on acceptable terms, or at all, and our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the COVID-19 pandemic. If we raise additional funds by issuing equity securities, our stockholders could experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any additional debt or equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support, research and development, or other resources devoted to our products.

Contractual Obligations and Commitments

Our operating lease obligations relate to leases for our current corporate headquarters and leases for manufacturing and office space for our foreign subsidiaries. Please see Note 9 to our condensed consolidated financial statements for a discussion of our lease obligations.

Other than as disclosed above, there have been no material changes during the nine months ended September 30, 2020 to our contractual obligations disclosed in our “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our annual report on Form 10-K for the year ended December 31, 2019.

Off-Balance Sheet Arrangements

Since our inception, we have not had any off-balance sheet arrangements as defined in Item 303(a)(4) of the SEC’s Regulation S-K.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in foreign currency exchange rates and interest rates. We do not hold or issue financial instruments for trading purposes.

Foreign Currency Exchange Risk

As we expand internationally our results of operations and cash flows will become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Our revenue is generally denominated in the local currency of the contracting party. Historically, the majority of our revenue has been denominated in U.S. dollars. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States, with a portion of expenses incurred in Singapore and Canada where our manufacturing facilities are located. Our results of operations and cash flows are, therefore, subject to fluctuations due to changes in foreign currency exchange rates. The volatility of exchange rates depends on many factors that we cannot forecast with reliable accuracy. We have experienced and will continue to experience fluctuations in our net income or loss as a result of transaction gains or losses related to revaluing certain current asset and current liability balances that are denominated in currencies other than the functional currency of the entities in which they are recorded. For the nine months ended September 30, 2020, we had a foreign currency loss of \$0.5 million compared to a foreign currency loss of \$0.2 million in the prior year for the same period. To date, we have not entered into any foreign currency hedging contracts although we may do so in the future. As our international operations grow, we will continue to reassess our approach to manage our risk relating to fluctuations in currency rates. If foreign currency exchange rates had changed by 10% during the periods presented, it would not have had a material impact on our financial position or results of operations.

Interest Rate Sensitivity

We had cash and cash equivalents of \$72.3 million as of September 30, 2020. These amounts were held primarily in cash on deposit with banks and money market funds which are short-term. We held no investments in treasury securities at September 30, 2020. Cash, cash equivalents and investments are held for working capital purposes. We believe that we do not have any material exposure to changes in the fair value of our money market portfolio as a result of changes in interest rates. Declines in interest rates, however, will reduce future investment income. If overall interest rates had decreased by 10% during the periods presented, our interest income would not have been materially affected.

Fair Value of Financial Instruments

We do not have material exposure to market risk with respect to investments. We do not use derivative financial instruments for speculative or trading purposes. We may adopt specific hedging strategies in the future.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2020. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the

SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2020, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Control systems, no matter how well conceived and operated, are designed to provide a reasonable, but not an absolute, level of assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Because of the inherent limitations in any control system, misstatements due to error or fraud may occur and not be detected.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

In September 2020, a putative class action complaint alleging violations of the federal securities laws was filed against the Company (also naming our Chief Executive Officer and Chief Financial Officer as defendants) in the U.S. District Court for the Northern District of California. The complaint seeks unspecified damages on behalf of a purported class of persons and entities who acquired our common stock between February 7, 2019 and November 5, 2019. The litigation is in its early stages and the lead plaintiff has not yet been determined. We believe the claims alleged in the complaint lack merit and we intend to defend ourselves vigorously.

In the normal course of business, we are from time to time involved in legal proceedings or potential legal proceedings, including matters involving employment, intellectual property, or others. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of any currently pending matters would not have a material adverse effect on our business, operating results, financial condition, or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 1A. Risk Factors

We operate in a rapidly changing environment that involves numerous uncertainties and risks. The following risks and uncertainties may have a material and adverse effect on our business, financial condition, or results of operations. You should consider these risks and uncertainties carefully, together with all of the other information included or incorporated by reference in this Form 10-Q. The risks described below are not the only ones we face. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions, global sociopolitical events, and international operations. Further, additional risks not currently known to us or that we currently believe are immaterial may in the future materially and adversely affect our business, operations, liquidity and stock price. If any of these risks occur, our business, results of operations, or financial condition could suffer, the trading price of our securities could decline, and you may lose all or part of your investment.

Risks Related to Fluidigm's Business and Strategy

The global COVID-19 pandemic has significantly affected our business operations and could adversely impact our financial position and cash flows to an extent that is unknown and difficult to predict.

The pandemic and international public health emergency caused by SARS-CoV-2, the novel strain of coronavirus that causes the disease commonly known as COVID-19, has spread throughout all the countries in which we and our customers, suppliers, and other business partners operate, causing significant disruption and volatility in global financial markets and raising the prospect of an extended global recession. Public health problems resulting from COVID-19 and precautionary measures instituted by governments and businesses to mitigate its spread, including travel restrictions and quarantines, could continue to contribute to a general slowdown in the global economy, cause increasingly adverse impacts on our customers, suppliers, and other business partners, and further disrupt our operations. Changes in our operations as a result of the COVID-19 pandemic have resulted in inefficiencies and delays, including in sales and product development efforts, and additional costs related to business continuity initiatives that cannot be fully mitigated through succession planning, employees working remotely, or teleconferencing technologies.

The COVID-19 pandemic and related governmental reactions have had, and may continue to have, a negative impact on our business, liquidity, results of operations, and stock price due to the occurrence of some or all of the following events or circumstances among others:

- reduced demand for some of our products and services due to the impact of COVID-19 on our customers, particularly in the global academic research community;
- diminished business productivity due to inefficiencies in employees working from home or increasing physical distancing and other pandemic response protocols in our production facilities;
- increased susceptibility to the risk of information technology security breaches and other disruptions due to increased volumes of remote access to our information systems from our employees working at home;
- the negative impact of travel restrictions and social distancing policies on our sales operations, marketing efforts, and customer field support;
- impaired ability to hire and effectively train new personnel due to travel restrictions and physical distancing protocols;

- increased operating costs if one of our facilities were to experience a COVID-19 outbreak;
- disruption of the operations of our contract manufacturers, suppliers, and other business partners; and
- increased volatility in our stock price due to financial market instability.

The extent to which the COVID-19 pandemic will continue to adversely impact our business and financial results will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the continued spread of the disease, the duration of the public health emergency, and actions taken in the United States and elsewhere to contain the virus and prevent new outbreaks, such as social distancing and quarantines, business closures or business disruptions.

Because the severity, magnitude, and duration of the COVID-19 pandemic and its economic consequences are uncertain and rapidly changing, we are unable to predict the impact of COVID-19 on our operations, our financial performance, and our ability to successfully execute our business strategies and initiatives. The ultimate impact of the COVID-19 pandemic on our operations and financial performance depends on many factors that are not within our control, including, but not limited to: governmental, business, and individual actions that have been and continue to be taken in response to the pandemic (including restrictions on travel, transport and workforce pressures); the impact of the pandemic and actions taken in response on global and regional economies, travel, and economic activity; the availability of federal, state, local or non-U.S. funding programs; general economic uncertainty in key global markets and financial market volatility; global economic conditions and levels of economic growth; and the pace of recovery when the COVID-19 pandemic subsides.

As the COVID-19 crisis continues to adversely affect our operating and financial results, it may also have the effect of heightening many of the other risks described in our other risk factors below. COVID-19 may also affect our operating and financial results in a manner that is not presently known to us or that we currently do not expect to present significant risks to our operations or financial results, particularly if the pandemic and its associated impacts reoccur in the coming months.

Our financial results and revenue growth rates have varied significantly from quarter-to-quarter and year-to-year due to a number of factors, and a significant variance in our operating results or rates of growth, if any, could lead to substantial volatility in our stock price.

Our revenue, results of operations, and revenue growth rates have varied in the past and may continue to vary significantly from quarter-to-quarter or year-to-year. We may experience substantial variability in our product mix from period-to-period as revenue from sales of our instruments relative to sales of our consumables may fluctuate or deviate significantly from expectations. For example, our revenue declined year-over-year in 2017 compared to 2016, but increased year-over-year in 2018 compared to 2017. Our revenue continued to increase year-over-year in 2019 compared to 2018, but we may not be able to achieve similar revenue growth in future periods. We are also increasingly dependent on our mass cytometry business, which is very capital intensive. Variability in our quarterly or annual results of operations, mix of product revenue, including any decline in our mass cytometry revenue, or variability in rates of revenue growth, if any, may lead to volatility in our stock price as research analysts and investors respond to these fluctuations. These fluctuations are due to numerous factors that are difficult to forecast, including: fluctuations in demand for our products; changes in customer budget cycles and capital spending; seasonal variations in customer operations; tendencies among some customers to defer purchase decisions to the end of the quarter; the large unit value of our systems, particularly our proteomics systems; changes in our pricing and sales policies or the pricing and sales policies of our competitors; our ability to design, manufacture, market, sell, and deliver products to our customers in a timely and cost-effective manner; fluctuations or reductions in revenue from sales of legacy instruments that may have contributed significant revenue in prior periods; quality control or yield problems in our manufacturing operations; our ability to timely obtain adequate quantities of the materials or components used in our products, which in certain cases are purchased through sole and single source suppliers; new product introductions and enhancements by us and our competitors; unanticipated increases in costs or expenses; our complex, variable and, at times, lengthy sales cycle; global economic conditions; and fluctuations in foreign currency exchange rates. Additionally, we have certain customers who have historically placed large orders in multiple quarters during a calendar year. A significant reduction in orders from one or more of these customers could adversely affect our revenue and operating results, and if these customers defer or cancel purchases or otherwise alter their purchasing patterns, our financial results and actual results of operations could be significantly impacted. Other unknown or unpredictable factors also could harm our results.

The foregoing factors, as well as other factors, could materially and adversely affect our quarterly and annual results of operations and rates of revenue growth, if any. We have experienced significant revenue growth in the past but we may not achieve similar growth rates in future periods. You should not rely on our operating results for any prior quarterly or annual period as an indication of our future operating performance. If we are unable to achieve adequate revenue growth, our operating results could suffer and our stock price could decline. In addition, a significant amount of our operating expenses are relatively fixed due to our manufacturing, research and development, and sales and general administrative efforts. Any failure to adjust

spending quickly enough to compensate for a shortfall relative to our anticipated revenue could magnify the adverse impact of such shortfalls on our results of operations. We expect that our sales will continue to fluctuate on an annual and quarterly basis and that our financial results for some periods may be below those projected by securities analysts, which could significantly decrease the price of our common stock.

We have incurred losses since inception, and we may continue to incur substantial losses for the foreseeable future.

We have incurred significant losses in each fiscal year since our inception, including net losses of \$64.8 million, \$59.0 million, and \$60.5 million during the years 2019, 2018, and 2017, respectively. As of September 30, 2020, we had an accumulated deficit of \$658.7 million. These losses have resulted principally from costs incurred in our research and development programs, and from our manufacturing costs and selling, general, and administrative expenses. To date, we have funded our operations primarily through equity offerings, the issuance of debt instruments, and from sales of our products.

Until we are able to generate additional revenue to support our level of operating expenses, we will continue to incur operating and net losses and negative cash flow from operations. We believe that our continued investment in research and development, sales, and marketing is essential to our long-term competitive position and future revenue growth and, as a result, we may incur operating losses for the foreseeable future and may never achieve profitability.

The life science markets are highly competitive and subject to rapid technological change, and we may not be able to successfully compete.

The markets for our products are characterized by rapidly changing technology, evolving industry standards, changes in customer needs, emerging competition, new product introductions, and strong price competition. We compete with both established and development stage life science research companies that design, manufacture, and market instruments and consumables for gene expression analysis, single-cell targeted gene expression and protein expression analysis, SNP genotyping, quantitative polymerase chain reaction (qPCR), digital PCR, flow cytometry, cell imaging, and additional applications using well established laboratory techniques, as well as newer technologies such as bead encoded arrays, microfluidics, next generation DNA sequencing, microdroplets, spatial protein expression, and photolithographic arrays. Most of our current competitors have significantly greater name recognition, greater financial and human resources, broader product lines and product packages, larger sales forces, larger existing installed bases, larger intellectual property portfolios, and greater experience and scale in research and development, manufacturing, and marketing than we do.

We consider Agilent Technologies, Inc., Thermo Fisher Scientific Inc. (Thermo), Bio-Rad Laboratories, Inc., NanoString Technologies, Inc. (NanoString), and Agena Bioscience, Inc. to be our principal competitors in the microfluidics space. We believe that Cytek Biosciences, Inc. and Becton, Dickinson and Company are currently our principal competitors for our mass cytometry market share, and that IonPath Inc., Akoya Biosciences, Inc., and NanoString are our principal competitors for our Imaging Mass Cytometry™ market share. While the aforementioned principal competitors are the largest and most prevalent in their representative technology areas, the combined markets in which we compete have an additional 10 to 20 smaller competitors with competing approaches and technologies that we routinely face in selling situations.

Competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards, or customer requirements. In light of these advantages, even if our technology is more effective than the product or service offerings of our competitors, current or potential customers might accept competitive products and services in lieu of purchasing our technology. We anticipate that we will continue to face increased competition in the future as existing companies and competitors develop new or improved products and as new companies enter the market with new technologies. Increased competition is likely to result in pricing pressures, which could reduce our profit margins and increase our sales and marketing expenses. In addition, mergers, consolidations, or other strategic transactions between two or more of our competitors, or between our competitor and one of our key customers, could change the competitive landscape and weaken our competitive position, adversely affecting our business.

Market opportunities may not develop as quickly as we expect, limiting our ability to successfully sell our products, or our product development and strategic plans may change and our entry into certain markets may be delayed, if it occurs at all.

The application of our technologies to high-throughput genomics, single-cell genomics and, particularly, mass cytometry applications are in many cases emerging market opportunities. We believe these opportunities will take several years to develop or mature and we cannot be certain that these market opportunities will develop as we expect. The future growth of our markets and the success of our products depend on many factors beyond our control, including recognition and acceptance by the scientific community, and the growth, prevalence, and costs of competing methods of genetic and protein analysis. Additionally, our success depends on the ability of our sales organization to successfully sell our products into these new markets. If we are not able to successfully market and sell our products, or to achieve the revenue or margins we expect, our

operating results may be harmed and we may not recover our product development and marketing expenditures. In addition, our product development and strategic plans may change, which could delay or impede our entry into these markets.

If our products fail to achieve and sustain sufficient market acceptance, our revenue will be adversely affected.

Our success depends on our ability to develop and market products that are recognized and accepted as reliable, enabling and cost-effective. Most of our potential customers already use expensive research systems in their laboratories and may be reluctant to replace those systems. Market acceptance of our systems will depend on many factors, including our ability to convince potential customers that our systems are an attractive alternative to existing technologies. Compared to some competing technologies, our technology is relatively new, and most potential customers have limited knowledge of, or experience with, our products. Prior to adopting our systems, some potential customers may need to devote time and effort to testing and validating our systems. Any failure of our systems to meet these customer benchmarks could result in customers choosing to retain their existing systems or to purchase systems other than ours, and revenue from the sale of legacy instruments that may have contributed significant revenue in prior periods may decrease.

In addition, it is important that our systems be perceived as accurate and reliable by the scientific and medical research community as a whole. Historically, a significant part of our sales and marketing efforts has been directed at convincing industry leaders of the advantages of our systems and encouraging such leaders to publish or present the results of their evaluation of our system. If we are unable to continue to induce leading researchers to use our systems, or if such researchers are unable to achieve and publish or present significant experimental results using our systems, acceptance and adoption of our systems will be slowed and our ability to increase our revenue would be adversely affected.

We may experience development or manufacturing problems or delays that could limit the potential growth of our revenue or increase our losses.

We may encounter unforeseen situations in the manufacturing and assembly of our products that would result in delays or shortfalls in our production. For example, our production processes and assembly methods may have to change to accommodate any significant future expansion of our manufacturing capacity, which may increase our manufacturing costs, delay production of our products, reduce our product margin, and adversely impact our business. Conversely, if demand for our products shifts such that a manufacturing facility is operated below its capacity for an extended period, we may adjust our manufacturing operations to reduce fixed costs, which could lead to uncertainty and delays in manufacturing times and quality during any transition period.

Additionally, all of our integrated fluidic circuits (IFCs) for commercial sale are manufactured at our facility in Singapore. Production of the elastomeric block that is at the core of our IFCs is a complex process requiring advanced clean rooms, sophisticated equipment, and strict adherence to procedures. Any contamination of the clean room, equipment malfunction, or failure to strictly follow procedures can significantly reduce our yield in one or more batches. We have in the past experienced variations in yields due to such factors. A drop in yield can increase our cost to manufacture our IFCs or, in more severe cases, require us to halt the manufacture of our IFCs until the problem is resolved. Identifying and resolving the cause of a drop in yield can require substantial time and resources.

Furthermore, developing an IFC for a new application may require developing a specific production process for that type of IFC. While all of our IFCs are produced using the same basic processes, significant variations may be required to ensure adequate yield of any particular type of IFC. Developing such a process can be very time consuming, and any unexpected difficulty in doing so can delay the introduction of a product.

If our manufacturing activities are adversely impacted, or if we are otherwise unable to keep up with demand for our products by successfully manufacturing, assembling, testing, and shipping our products in a timely manner, our revenue could be impaired, market acceptance for our products could be adversely affected and our customers might instead purchase our competitors' products.

If our research and product development efforts do not result in commercially viable products within anticipated timelines, if at all, our business and results of operations will be adversely affected.

Our business is dependent on the improvement of our existing products, our development of new products to serve existing markets, and our development of new products to create new markets and applications that were previously not practical with existing systems. We intend to devote significant personnel and financial resources to research and development activities designed to advance the capabilities of our technology. We have developed design rules for the implementation of our technology that are frequently revised to reflect new insights we have gained about the technology. In addition, we have discovered that biological or chemical reactions sometimes behave differently when implemented on our systems rather than in a standard laboratory environment. Furthermore, many such reactions take place within the confines of single cells, which have

also demonstrated unexpected behavior when grown and manipulated within microfluidic environments. As a result, research and development efforts may be required to transfer certain reactions and cell handling techniques to our systems. In the past, product development projects have been significantly delayed when we encountered unanticipated difficulties in implementing a process on our systems. We may have similar delays in the future, and we may not obtain any benefits from our research and development activities. Any delay or failure by us to develop and release new products or product enhancements would have a substantial adverse effect on our business and results of operations.

Our products could have defects or errors, which may give rise to claims against us, adversely affect market adoption of our systems, and adversely affect our business, financial condition, and results of operations.

Our systems utilize novel and complex technology and such systems may develop or contain undetected defects or errors. We cannot assure you that material performance problems, defects, or errors will not arise, and as we increase the density and integration of our systems, these risks may increase. We generally provide warranties that our systems will meet performance expectations and will be free from defects. The costs incurred in correcting any defects or errors may be substantial and could adversely affect our operating margins. For example, we have experienced a performance issue with respect to certain IFCs used in our C1 systems due to the presence of more than one cell in an IFC chamber. Although we have redesigned such C1 IFCs, we may experience additional unexpected product defects or errors that could affect our ability to adequately address these performance issues.

In manufacturing our products, including our systems, IFCs, and assays, we depend upon third parties for the supply of various components, many of which require a significant degree of technical expertise to produce. In addition, we purchase certain products from third-party suppliers for resale. If our suppliers fail to produce components to specification or provide defective products to us for resale and our quality control tests and procedures fail to detect such errors or defects, or if we or our suppliers use defective materials or workmanship in the manufacturing process, the reliability and performance of our products will be compromised.

If our products contain defects, we may experience:

- a failure to achieve market acceptance or expansion of our product sales;
- loss of customer orders and delay in order fulfillment;
- damage to our brand reputation;
- increased cost of our warranty program due to product repair or replacement;
- product recalls or replacements;
- inability to attract new customers;
- diversion of resources from our manufacturing and research and development departments into our service department; and
- legal claims against us, including product liability claims, which could be costly and time consuming to defend and result in substantial damages.

In addition, certain of our products are marketed for use with products sold by third parties. For example, certain of our systems are marketed as compatible with major next-generation DNA sequencing instruments. If such third-party products are not produced to specification, are produced in accordance with modified specifications, or are defective, they may not be compatible with our products. In such case, the reliability and performance of our products may be compromised.

The occurrence of any one or more of the foregoing could negatively affect our business, financial condition, and results of operations.

Our business depends on research and development spending levels of our customers, a reduction in which could limit our ability to sell our products and adversely affect our business.

We expect that our revenue in the foreseeable future will continue to be derived primarily from sales of our systems, IFCs, assays, and reagents to academic research institutions, translational research and medicine centers, cancer centers, clinical research laboratories biopharmaceutical, biotechnology, and plant and animal research companies, and contract research organizations worldwide. Our success will depend upon their demand for and use of our products. Accordingly, the spending policies and practices of these customers—which have been impacted by the COVID-19 pandemic and may additionally be impacted by other factors—could have a significant effect on the demand for our technology. These policies may be based on a wide variety of factors, including concerns regarding any future federal government budget sequestrations, the availability of

resources to make purchases, the spending priorities among various types of equipment, policies regarding spending during recessionary periods, and changes in the political climate. In addition, academic, governmental, and other research institutions that fund research and development activities may be subject to stringent budgetary constraints that could result in spending reductions, reduced allocations, or budget cutbacks, which could jeopardize the ability of these customers to purchase our products. Our operating results may fluctuate substantially due to reductions and delays in research and development expenditures by our customers. For example, reductions in operating expenditures by global academic research facilities because of the COVID-19 pandemic have resulted in lower than expected sales of our mass cytometry instruments. Similar reductions and delays in customer spending may result from other factors that are not within our control, such as:

- changes in economic conditions;
- natural disasters or public health crises;
- changes in government programs that provide funding to research institutions and companies;
- changes in the regulatory environment affecting life science and plant and animal research companies engaged in research and commercial activities;
- differences in budget cycles across various geographies and industries;
- market-driven pressures on companies to consolidate operations and reduce costs;
- mergers and acquisitions in the life science and plant and animal research industries; and
- other factors affecting research and development spending.

Any decrease in our customers' budgets or expenditures, or in the size, scope, or frequency of capital or operating expenditures, could materially and adversely affect our operations or financial condition.

If one or more of our manufacturing facilities become unavailable or inoperable, we will be unable to continue manufacturing our instruments, IFCs, assays and/or reagents and, as a result, our business will be harmed until we are able to secure a new facility.

We manufacture our genomics analytical and preparatory instruments and IFCs for commercial sale at our facility in Singapore and our mass cytometry instruments, assays, and reagents for commercial sale at our facility in Canada. No other manufacturing facilities are currently available to us, particularly facilities of the size and scope of our Singapore and Canada operations. Our facilities and the equipment we use to manufacture our instruments, IFCs, assays, and reagents would be costly to replace and could require substantial lead times to repair or replace. Our facilities may be harmed or rendered inoperable by natural or man-made disasters, which may render it difficult or impossible for us to manufacture our products for some period of time. If any of our facilities become unavailable to us, we cannot provide assurances that we will be able to secure a new manufacturing facility on acceptable terms, if at all. The inability to manufacture our products, combined with our limited inventory of manufactured supplies, may result in the loss of customers or harm our reputation, and we may be unable to reestablish relationships with those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. If our manufacturing capabilities are impaired, we may not be able to manufacture and ship our products in a timely manner, which would adversely impact our business.

Disruption of our manufacturing facilities or other operations, or in the operations of our customers or business partners, due to earthquake, flood, other natural catastrophic events, public health crises, or terrorism could result in cancellation of orders, delays in deliveries or other business activities, or loss of customers and could seriously harm our business.

We have significant manufacturing operations in Singapore and Canada and operations in the United States. In addition, our business is international in nature, with our sales, service and administrative personnel and our customers located in numerous countries throughout the world. Operations at our manufacturing facilities and our subcontractors, as well as our other operations and those of our customers, are subject to disruption for a variety of reasons, including work stoppages, acts of war, terrorism, public health crises (including the ongoing COVID-19 pandemic), fire, earthquake, volcanic eruptions, energy shortages, flooding, or other natural disasters. Such disruption could cause delays in, among other things, shipments of products to our customers, our ability to perform services requested by our customers, or the installation of our products at customer sites.

We cannot provide any assurance that alternate means of conducting our operations (whether through alternate production capacity or service providers or otherwise) would be available if a major disruption were to occur or that, if such alternate means were available, they could be obtained on favorable terms.

We generate a substantial portion of our revenue internationally and our international business exposes us to business, regulatory, political, operational, financial, and economic risks associated with doing business outside of the United States.

During the years 2019, 2018, and 2017, approximately 63%, 57%, and 55%, respectively, of our product and service revenue was generated from sales to customers located outside of the United States. We believe that a significant percentage of our future revenue will continue to come from international sources as we expand our international operations and develop opportunities in other countries. Engaging in international business inherently involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign regulatory requirements and laws that are or may be applicable to our business in the future, such as the European Union's General Data Protection Regulation and other data privacy requirements, labor and employment regulations, anticompetition regulations, the U.K. Bribery Act of 2010 and other anticorruption laws, and the RoHS and WEEE directives, which regulate the use of certain hazardous substances in, and require the collection, reuse, and recycling of waste from, products we manufacture;
- required compliance with U.S. laws such as the Foreign Corrupt Practices Act, and other U.S. federal laws and regulations established by the office of Foreign Asset Control;
- export requirements and import or trade restrictions;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- changes in social, economic, and political conditions or in laws, regulations and policies governing foreign trade, manufacturing, development, and investment both domestically as well as in the other countries and jurisdictions in which we operate and into which we sell our products, including as a result of the separation of the United Kingdom from the European Union (Brexit);
- business interruptions resulting from global sociopolitical events, including war and terrorism, public health crises such as the COVID-19 pandemic, and natural disasters including earthquakes, typhoons, floods and fires;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements, and other trade barriers;
- difficulties and costs of staffing and managing foreign operations; and
- difficulties protecting or procuring intellectual property rights.

If one or more of these risks occurs, it could require us to dedicate significant resources to remedy, and if we are unsuccessful in finding a solution, our financial results will suffer.

We are subject to fluctuations in the exchange rate of the U.S. dollar and foreign currencies.

A majority of our product sales are currently denominated in U.S. dollars and fluctuations in the value of the U.S. dollar relative to foreign currencies could decrease demand for our products and adversely impact our financial performance. For example, if the value of the U.S. dollar increases relative to foreign currencies, our products could become more costly to the international consumer and therefore less competitive in international markets, or if the value of the U.S. dollar decreases relative to the Singapore dollar or the Canadian dollar, it would become more costly in U.S. dollars for us to manufacture our products in Singapore and/or in Canada. Additionally, our expenses are generally denominated in the currencies of the countries in which our operations are located, which is primarily in the United States, with a portion of expenses incurred in Singapore and Canada where a significant portion of our manufacturing operations are located. Our results of operations and cash flows are, therefore, subject to fluctuations due to changes in foreign currency exchange rates. The volatility of exchange rates depends on many factors that we cannot forecast with reliable accuracy. We have experienced and will continue to experience fluctuations in our net income or loss as a result of transaction gains or losses related to revaluing certain current asset and current liability balances that are denominated in currencies other than the functional currency of the entities in which they are recorded. Fluctuations in currency exchange rates could have an adverse impact on our financial results in the future.

Any disruption or delay in the shipping or off-loading of our products, whether domestically or internationally, may have an adverse effect on our financial condition and results of operations.

We rely on shipping providers to deliver products to our customers globally. Labor, tariff, or World Trade Organization-related disputes, piracy, physical damage to shipping facilities or equipment caused by severe weather or terrorist incidents, congestion at shipping facilities, complications related to public health crises, inadequate equipment to load, dock, and offload

our products, energy-related tie-ups, or other factors could disrupt or delay shipping or off-loading of our products domestically and internationally. Such disruptions or delays may have an adverse effect on our financial condition and results of operations.

We are dependent on single and sole source suppliers for some of the components and materials used in our products, and the loss of any of these suppliers could harm our business.

We rely on single and sole source suppliers for certain components and materials used in our products. Additionally, several of our instruments are assembled at the facilities of contract manufacturers in Singapore. We do not have long term contracts with our suppliers of these components and materials or our assembly service providers. The loss of a single or sole source supplier of any of the following components and/or materials would require significant time and effort to locate and qualify an alternative source of supply, if at all:

- The IFCs used in our microfluidic systems are fabricated using a specialized polymer, and other specialized materials, that are available from a limited number of sources. In the past, we have encountered quality issues that have reduced our manufacturing yield or required the use of additional manufacturing processes.
- The electron multiplier detector included in the Hyperion/Helios systems and certain metal isotopes used with the Hyperion/Helios systems are purchased from sole source suppliers.
- The raw materials for our Delta Gene and SNP Type assays and Access Array target-specific primers are available from a limited number of sources.

Our reliance on single and sole source suppliers and assembly service providers also subjects us to other risks that could harm our business, including the following:

- we may be subject to increased component or assembly costs and
- we may not be able to obtain adequate supply or services in a timely manner or on commercially reasonable terms.

We have in the past experienced quality control and supply problems with some of our suppliers, such as manufacturing errors, and may again experience problems in the future. We may not be able to quickly establish additional or replacement suppliers, particularly for our single source components, or assembly service providers. Any interruption or delay in the supply of components or materials or assembly of our instruments, or our inability to obtain components, materials, or assembly services from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products.

Our future success is dependent upon our ability to expand our customer base and introduce new applications.

Our customer base is primarily composed of academic research institutions, translational research and medicine centers, cancer centers, clinical research laboratories, biopharmaceutical, biotechnology, and plant and animal research companies, and contract research organizations that perform analyses for research and commercial purposes. Our success will depend, in part, upon our ability to increase our market share among these customers, attract additional customers outside of these markets, and market new applications to existing and new customers as we develop such applications. Attracting new customers and introducing new applications require substantial time and expense. For example, it may be difficult to identify, engage, and market to customers who are unfamiliar with the current applications of our systems. Any failure to expand our existing customer base or launch new applications would adversely affect our ability to increase our revenue.

We may not be able to develop new products or enhance the capabilities of our existing systems to keep pace with rapidly changing technology and customer requirements, which could have a material adverse effect on our business, revenue, financial condition, and operating results.

Our success depends on our ability to develop new products and applications for our technology in existing and new markets, while improving the performance and cost-effectiveness of our systems. New technologies, techniques, or products could emerge that might offer better combinations of price and performance than our current or future product lines and systems. Existing markets for our products, including high-throughput genomics, single-cell genomics and mass cytometry, as well as potential markets for our products such as high-throughput DNA sequencing and molecular applications, are characterized by rapid technological change and innovation. It is critical to our success for us to anticipate changes in technology and customer requirements and to successfully introduce new, enhanced, and competitive technology to meet our customers' and prospective customers' needs on a timely and cost-effective basis. Developing and implementing new technologies will require us to incur substantial development costs and we may not have adequate resources available to be able to successfully introduce new applications of, or enhancements to, our systems. We cannot guarantee that we will be able to maintain technological advantages over emerging technologies in the future. While we typically plan improvements to our

systems, we may not be able to successfully implement these improvements. If we fail to keep pace with emerging technologies, demand for our systems will not grow and may decline, and our business, revenue, financial condition, and operating results could suffer materially. In addition, if we introduce enhanced systems but fail to manage product transitions effectively, customers may delay or forgo purchases of our systems and our operating results may be adversely affected by product obsolescence and excess inventory. Even if we successfully implement some or all of these planned improvements, we cannot guarantee that our current and potential customers will find our enhanced systems to be an attractive alternative to existing technologies, including our current products.

Our business operations depend upon the continuing efforts of our management team and other skilled and experienced personnel, and if we are unable to retain them or to recruit and train new key executives, scientists, and technical support personnel, we may be unable to achieve our goals.

Our success depends largely on the skills, experience, and performance of our management team and scientific and technical support personnel. The loss of the services of any key member of our management team or our scientific or technical support staff might significantly delay or prevent the development of our products or achievement of other business objectives by diverting management's attention to transition matters and identification of suitable replacements, if any, and could have a material adverse effect on our business. Our research and product development efforts could also be delayed or curtailed if we are unable to attract, train, and retain highly skilled employees, particularly, senior scientists and engineers. For example, as part of our cost reduction program to manage the impact of the COVID-19 pandemic, we implemented temporary enterprise-wide salary reductions and delayed implementation of 2020 merit-based salary increases. Although all salaries have been restored as of the date of this filing, any reinstatement of salary reductions or any other failure to maintain competitive levels of compensation may negatively impact our ability to retain the personnel necessary to achieve our goals. We do not maintain fixed term employment contracts or significant key person life insurance with any of our employees.

Additionally, to expand our research and product development efforts, we need to retain and recruit scientists skilled in areas such as molecular and cellular biology, assay development, and manufacturing. We also need highly trained technical support personnel with the necessary scientific background and ability to understand our systems at a technical level to effectively support potential new customers and the expanding needs of current customers. Competition for these people is intense and we may face challenges in retaining and recruiting such individuals if, for example, our stock price declines, reducing the retention value of equity awards, or our business or technology is no longer perceived as leading in our field. Because of the complex and technical nature of our systems and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize our technology.

Our business growth strategy involves the potential for significant acquisitions, and our operating results and prospects could be harmed if we are unable to integrate future acquisitions successfully.

We may acquire other businesses to improve our product offerings or expand into new markets. Our future acquisition strategy will depend on our ability to identify, negotiate, complete, and integrate acquisitions and, if necessary, to obtain satisfactory debt or equity financing to fund those acquisitions. Mergers and acquisitions are inherently risky, and any transaction we complete may not be successful. Any merger or acquisition we may pursue would involve numerous risks, including but not limited to the following:

- difficulties in integrating and managing the operations, technologies, and products of the companies we acquire;
- diversion of our management's attention from normal daily operation of our business;
- our inability to maintain the key business relationships and the reputations of the businesses we acquire;
- our inability to retain key personnel of the acquired company;
- uncertainty of entry into markets in which we have limited or no prior experience and in which competitors have stronger market positions;
- our dependence on unfamiliar affiliates and customers of the companies we acquire;
- insufficient revenue to offset our increased expenses associated with acquisitions;
- our responsibility for the liabilities of the businesses we acquire, including those which we may not anticipate; and
- our inability to maintain internal standards, controls, procedures, and policies.

We may be unable to secure the equity or debt funding necessary to finance future acquisitions on terms that are acceptable to us. If we finance acquisitions by issuing equity or convertible debt securities, our existing stockholders will likely experience

dilution, and if we finance future acquisitions with debt funding, we will incur interest expense and may have to comply with financial covenants and secure that debt obligation with our assets.

Security breaches, loss of data, cyberattacks, and other information technology failures could disrupt our operations, damage our reputation, and adversely affect our business, operations, and financial results.

We are dependent upon our data and information technology systems for the effective operation of our business and for the secure maintenance and storage of confidential data relating to our business and third-party businesses. Our information technology systems may be damaged, disrupted or shut down due to attacks by experienced programmers or hackers who may be able to penetrate our security controls and deploy computer viruses, cyberattacks, phishing schemes, or other malicious software programs, or due to employee error or malfeasance, power outages, hardware failures, telecommunication or utility failures, catastrophes or other unforeseen events, and our system redundancy and other disaster recovery planning may be ineffective or inadequate in preventing or responding to any of these circumstances. Any such compromise of our information technology systems could result in the unauthorized publication of our confidential business or proprietary information and unauthorized release of customer, supplier or employee data, any of which could expose us to a risk of legal claims or proceedings, liability under privacy or other laws, disruption of our operations and damage to our reputation, which could divert our management's attention from the operation of our business and materially and adversely affect our business, revenues and competitive position. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related breaches. The cost and operational consequences of implementing further data protection measures, either as a response to specific breaches or as a result of evolving risks, could be significant. In addition, our inability to use or access our information systems at critical points in time could adversely affect the timely and efficient operation of our business. Any delayed sales, significant costs or lost customers resulting from these technology failures could adversely affect our business, operations, and financial results.

We have implemented security controls to protect our information technology infrastructure but, despite our efforts, we are not fully insulated from technology disruptions that could adversely impact us. For example, in March 2019, we experienced a ransomware attack that infiltrated and encrypted certain of our information technology systems, including systems containing critical business data. Immediately following the attack, actions were taken to recover the compromised systems and we believe we were able to restore their operation without significant loss of business data. Based on the nature of the attack and its impact on our systems, we do not believe confidential data was lost or disclosed. If, however, confidential data is later determined to have been released in the course of this or any future event, it is possible that we could be the subject of actions by governmental authorities or claims from persons alleging they suffered damages from such a release. Although we believe we have contained the disruption from the March 2019 attack, we anticipate additional work and expense in the future as we continue to enhance our security processes and initiatives in response to ever-evolving information security threats.

In addition to risks affecting our own systems, we could also be negatively impacted by a data breach or cyber incident happening to a third party's network and affecting us. Third parties with which we conduct business have access to certain portions of our sensitive data, including information pertaining to our customers and employees. In the event that these third parties do not adequately safeguard our data, security breaches could result and negatively impact our business, operations, and financial results.

Due to the COVID-19 pandemic, we have an increased number of employees working remotely. As a result, we may have increased cyber security and data security risks, due to increased use of home wi-fi networks and virtual private networks, as well as increased disbursement of physical machines. While we have implemented security controls to reduce the risk of cyberattacks and security breaches, there is no guarantee that these measures will be adequate to safeguard all systems with the increased number of employees working remotely.

Our efficiency and cost-savings initiatives could be disruptive to our operations and adversely affect our results of operations and financial condition, and we may not realize some or all of the anticipated benefits of these initiatives in the time frame anticipated or at all.

Since 2017, we have implemented efficiency and cost-savings initiatives intended to stabilize our business operations and return to growth. These efficiency initiatives have included targeted workforce reductions, optimizing our facilities, and reducing excess space. In response to the COVID-19 pandemic, we initiated a range of additional actions aimed at temporarily reducing our operating expenses and preserving liquidity. These actions included implementing temporary enterprise-wide salary reductions of 20% for employees at or above the 'director' level and 10% for all others, temporarily reducing our board members' cash retainers by 20%, and constraining hiring. Further actions such as these may be required on an ongoing basis to preserve liquidity and optimize our organization. For example, we may need to decrease or defer capital expenditures and development activities or implement further operating expense reduction measures. The implementation of these further efficiency and cost-savings initiatives could impair our ability to invest in developing, marketing and selling new and existing products, be disruptive to our operations, make it difficult to attract or retain employees, result in higher than anticipated

charges, divert the attention of management, result in a loss of accumulated knowledge, impact our customer and supplier relationships, and otherwise adversely affect our results of operations and financial condition. In addition, our ability to complete our efficiency and cost-savings initiatives and achieve the anticipated benefits within the expected time frame is subject to estimates and assumptions and may vary materially from our expectations, including as a result of factors that are beyond our control. Furthermore, our efforts to grow our business and become profitable may not be successful.

To use our products, our Biomark, EP1, Helios/CyTOF 2, and Hyperion systems in particular, customers typically need to purchase specialized reagents. Any interruption in the availability of these reagents for use in our products could limit our ability to market our products.

Our products, our Biomark, EP1, Helios, and Hyperion systems in particular, must be used in conjunction with one or more reagents designed to produce or facilitate the particular biological or chemical reaction desired by the user. Many of these reagents are highly specialized and available to the user only from a single supplier or a limited number of suppliers. Although we sell reagents for use with certain of our products, our customers may purchase these reagents directly from third-party suppliers, and we have no control over the supply of those materials. In addition, our products are designed to work with these reagents as they are currently formulated. We have no control over the formulation of reagents sold by third-party suppliers, and the performance of our products might be adversely affected if the formulation of these reagents is changed. If one or more of these reagents were to become unavailable or were reformulated, our ability to market and sell our products could be materially and adversely affected.

In addition, the use of a reagent for a particular process may be covered by one or more patents relating to the reagent itself, the use of the reagent for the particular process, the performance of that process, or the equipment required to perform the process. Typically, reagent suppliers, who are either the patent holders or their authorized licensees, sell the reagents along with a license or covenant not to sue with respect to such patents. The license accompanying the sale of a reagent often purports to restrict the purposes for which the reagent may be used. If a patent holder or authorized licensee were to assert against us or our customers that the license or covenant relating to a reagent precluded its use with our systems, our ability to sell and market our products could be materially and adversely affected. For example, our Biomark system involves real-time quantitative polymerase chain reaction (qPCR) technology. Leading suppliers of reagents for real-time qPCR reactions include Life Technologies Corporation (now part of Thermo) and Roche Diagnostics Corporation, who are our direct competitors, and their licensees. These real-time qPCR reagents are typically sold pursuant to limited licenses or covenants not to sue with respect to patents held by these companies. We do not have any contractual supply agreements for these real-time qPCR reagents, and we cannot assure you that these reagents will continue to be available to our customers for use with our systems, or that these patent holders will not seek to enforce their patents against us, our customers, or suppliers.

Although the FDA granted Emergency Use Authorization (EUA) for our Advanta Dx SARS-CoV-2 RT-PCR Assay in August 2020, this approval is only valid during the COVID-19 pandemic, and when the federally declared public health emergency ends, we will be required to stop commercial distribution of our test immediately unless we can obtain FDA clearance or approval for our test under a traditional regulatory pathway for in vitro diagnostics, which is lengthy and expensive.

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA has authority to allow certain unapproved medical products or unapproved uses of approved medical products to be used during a public health emergency. In issuing an EUA, the FDA will consider the totality of scientific evidence available to the FDA regarding safety, efficacy and known and potential risks of such products and availability of alternatives to the emergency use products, among others. EUAs issued by the FDA will specify the scope of authorization and conditions of authorization, including limitations on distribution and conditions related to product advertising and promotion. Once granted, an EUA is effective until the declaration that circumstances exist justifying the authorization of the emergency use is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act, after which the product must be cleared or approved by the FDA under a traditional pathway in order to remain on the market or to continue commercialization of the product.

In August 2020, the FDA granted EUA for our Advanta Dx SARS-CoV-2 RT-PCR Assay for qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens from individuals suspected by their healthcare providers of having COVID-19. As set forth in the EUA, we are required to comply with the conditions of authorization, including certain requirements pertaining to FDA notification, distribution, printed materials, advertising and promotion. If we, our distributors, or authorized laboratories do not comply with the EUA requirements, our business, financial condition and results of operations may be adversely impacted, and we may be subject to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, penalties, or fines, among other adverse actions.

If the FDA's policies and guidance change unexpectedly and/or materially or if we misinterpret them, potential sales of Advanta Dx SARS-CoV-2 RT-PCR could be adversely impacted. In addition, the FDA will revoke an EUA where it is

determined that the underlying public health emergency no longer exists or warrants such authorization, or if new evidence becomes available that indicates the test does not meet the conditions of authorization or perform as provided in the EUA application. We cannot predict how long this EUA will remain effective. The termination or revocation of the EUA and changing policies and regulatory requirements could adversely impact our business, financial condition and results of operations. Given the uncertain nature of the COVID-19 pandemic and future legislation and regulation in this space, we can provide no assurance with respect to our ability to achieve or sustain profitability on a quarterly or annual basis.

Our contract with the National Institutes of Health (NIH) could expose us to unique risks and costs as an entity contracting with the federal government.

The NIH launched the Rapid Acceleration of Diagnostics (RADx) program to expedite development, commercialization, and implementation of technologies for COVID-19 testing to help increase testing in the United States. In July 2020, we entered into a letter contract with the NIH for a project under the RADx program. The letter contract provided access to approximately \$12.2 million of the total proposed funding for the project prior to execution of a further definitive contract for the project. In September 2020, we executed a definitive contract with the NIH as an amendment to the letter contract (collectively, the NIH Contract) to expand production capacity and throughput capabilities for COVID-19 testing with our microfluidics technology. Pursuant to the terms of the NIH Contract, the funding for the project was increased by approximately \$22.0 million, for a total contract value of up to approximately \$34.0 million. Release of funding under the NIH Contract is based on the achievement of milestones, including expansion of our manufacturing facilities, addition of production lines, and achieving full production capacity.

There is significant competition among RADx projects, which are evaluated by experts on a rolling basis. Projects with the most potential for success are advanced to the next stage. There is no certainty that we can meet all the milestones in our NIH Contract on a timely basis, if at all. If we do not meet all the milestones, we will not be able access all \$34.0 million in funding under the NIH Contract. We cannot guarantee that we will be able to access all the available funding under the NIH Contract in a timely manner, or at all. We must prioritize among many different opportunities, and we may expend our limited resources on programs that do not yield a successful or profitable product candidate and may forego other more profitable opportunities. Further, the Bayh-Dole Act applies to all NIH research and development funding granted to for-profit organizations, which requires the government to be provided a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.

Factors that could materially adversely affect our revenue stemming from the NIH Contract include:

- budgetary constraints affecting U.S. government spending generally, or NIH in particular;
- changes in U.S. government or NIH fiscal policies or available funding, including due to changes in Congressional appropriations;
- changes in U.S. government or NIH programs, requirements or priorities;
- adoption of new laws or regulations;
- technological developments;
- U.S. government shutdowns, threatened shutdowns or budget delays;
- competition and consolidation in our industry; and
- general economic conditions.

These or other factors could cause NIH to reduce its funding or future activities under the NIH Contract, or to exercise its right to terminate the NIH Contract for convenience, either of which could have a material adverse effect on the revenue generated by the NIH Contract.

The NIH Contract includes certain provisions from the Federal Acquisition Regulations (FAR), some of which are customary or legally required, that give the U.S. government substantial rights and remedies, many of which are not typically found in commercial contracts. For example, the NIH Contract contains provisions permitting unilateral termination or modification, in whole or in part, at the convenience of the U.S. government. Under general principles of government contracting law, if the U.S. government terminates a contract for convenience, the government contractor may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination. If the U.S. government terminates a contract for default, the government contractor is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. In addition, government contracts normally contain additional requirements that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions. These requirements

include, for example, mandatory internal control systems and policies, mandatory socioeconomic compliance requirements, including labor standards, non-discrimination and affirmative action programs and environmental compliance requirements and public disclosures of certain contract information, which may enable competitors to gain insights into our research program. If we fail to maintain compliance with these requirements, we may be subject to potential contract or False Claims Act liability and to termination of our NIH Contract:

Other examples of rights and remedies under the NIH Contract include provisions that allow NIH to:

- terminate the NIH Contract, in whole or in part, for any reason or no reason;
- unilaterally reduce or modify the government's obligations under the NIH Contract, without our consent, including by imposing price adjustments;
- claim rights, including intellectual property rights, in or to (i) products, (ii) data, and (iii) facilities, in each case developed under the NIH Contract;
- under certain circumstances involving public health and safety, license inventions made under such agreements to third parties;
- suspend us from receiving new contracts pending resolution of alleged violations of procurement laws or regulations;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under the NIH Contract;
- suspend or debar us from doing future business with the government;
- change the course of a development program in a manner that differs from the NIH Contract's original terms or from our desired development plan, including decisions regarding our partners in the program;
- pursue civil or criminal remedies under the False Claims Act and False Statements Act; and
- control or prohibit the export of products.

Furthermore, we may be required to enter into agreements and subcontracts with third parties, including suppliers, consultants and other third-party contractors in order to satisfy our contractual obligations pursuant to our agreements with the United States government. Negotiating and entering into such arrangements can be time-consuming and we may not be able to reach agreement with such third parties. Any such agreement must also be compliant with the terms of the NIH Contract. Any delay or inability to enter into such arrangements or entering into such arrangements in a manner that is non-compliant with the terms of our contract, may result in violations of our contract.

U.S. government agencies routinely audit and investigate government contractors and recipients of federal grants and contracts. These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards. The audit may also include review of the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's accounting, purchasing, property, estimating, compensation and management information systems. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions. In addition, we could suffer serious reputational harm if allegations of impropriety were made against us, which could cause our stock price to decrease.

If we elect to label and promote any of our non-EUA products as medical devices, we would be required to obtain prior approval or clearance by the FDA, which would take significant time and expense and could fail to result in FDA clearance or approval for the intended uses we believe are commercially attractive.

Except for the Advanta Dx SARS-CoV-2 Assay authorized by the FDA under an EUA granted in August 2020, our other products are currently labeled, promoted and sold to academic research institutions, translational research and medicine centers, cancer centers, clinical research laboratories, contract research organizations, and biopharmaceutical, biotechnology, and plant and animal research companies as "research use only" (RUO), and are not designed, or intended to be used, for clinical diagnostic tests or as medical devices as currently marketed. If we elect to label and market our products for use as, or in the performance of, clinical diagnostics in the United States, thereby subjecting them to FDA regulation as medical devices, we would be required to obtain premarket 510(k) clearance or premarket approval from the FDA, unless an exception applies.

We are currently registered with the FDA as a medical device manufacturer, with the reagents for the Advanta Dx SARS-CoV-2 Assay listed as our sole medical device product. As noted in the issued EUA for the Advanta Dx SARS-CoV-2 Assay, the FDA has waived certain quality system requirements under 21 CFR Part 820 for the duration of the EUA. We may in the future list some of our other products with the FDA pursuant to an FDA Class I listing for general purpose laboratory equipment if we pursue clinical applications for such equipment. While this regulatory classification is generally exempt from

certain FDA requirements, such as the need to submit a premarket notification commonly known as a 510(k), and some of the requirements of the FDA's Quality System Regulations (QSRs), we would be subject to ongoing FDA "general controls," which include compliance with FDA regulations for labeling, inspections by the FDA, complaint evaluation, corrections and removals reporting, promotional restrictions, reporting adverse events or malfunctions for our products, and general prohibitions against misbranding and adulteration. If we do not comply with all the requirements of the EUA or the normal regulatory requirements for any of our medical device products, including additional regulatory requirements that would apply to the Advanta Dx SARS-CoV-2 Assay after the expiration or termination of the EUA, we may be subject to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, penalties, or fines, among other adverse actions, any of which may adversely impact our business, financial condition and results of operations. Compliance with additional or changing regulatory requirements can be time-consuming and costly.

In addition, we may in the future submit 510(k) premarket notifications to the FDA to obtain FDA clearance of certain of our products on a selected basis. It is possible, in the event we elect to submit 510(k) applications for certain of our products, that the FDA would take the position that a more burdensome premarket application, such as a premarket approval application or a de novo application is required for some of our products. If such applications were required, greater time and investment would be required to obtain FDA approval. Even if the FDA agreed that a 510(k) was appropriate, FDA clearance can be expensive and time consuming. It generally takes a significant amount of time to prepare a 510(k), including conducting appropriate testing on our products, and several months to years for the FDA to review a submission. Notwithstanding the effort and expense, FDA clearance or approval could be denied for some or all of our products. Even if we were to seek and obtain regulatory approval or clearance, it may not be for the intended uses we believe are important or commercially attractive.

If we sought and received regulatory clearance or approval for certain of our products, we would be subject to ongoing FDA obligations and continued regulatory oversight and review, including the general controls listed above and the FDA's QSRs for our development and manufacturing operations. In addition, we would be required to obtain a new 510(k) clearance before we could introduce subsequent modifications or improvements to such products. We could also be subject to additional FDA post-marketing obligations for such products, any or all of which would increase our costs and divert resources away from other projects. If we sought and received regulatory clearance or approval and are not able to maintain regulatory compliance with applicable laws, we could be prohibited from marketing our products for use as, or in the performance of, clinical diagnostics and/or could be subject to enforcement actions, including warning letters and adverse publicity, fines, injunctions, and civil penalties; recall or seizure of products; operating restrictions; and criminal prosecution.

In addition, we could decide to seek regulatory clearance or approval for certain of our products in countries outside of the United States. Sales of such products outside the United States will likely be subject to foreign regulatory requirements, which can vary greatly from country to country. As a result, the time required to obtain clearances or approvals outside the United States may differ from that required to obtain FDA clearance or approval and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. In Europe, we need to comply with the In Vitro Diagnostic Directive 98/79/EC and transition to the In Vitro Diagnostic Regulation 2017/746, which became effective May 26, 2017, with an application date of May 26, 2022. This will increase the difficulty of regulatory approvals in Europe in the future. In addition, the FDA regulates exports of medical devices. Failure to comply with these regulatory requirements or obtain and maintain required approvals, clearances and certifications could impair our ability to commercialize our products for diagnostic use outside of the United States.

Our products could become subject to regulation as medical devices by the FDA or other regulatory agencies even if we do not elect to seek regulatory clearance or approval to market our products for diagnostic purposes, which would adversely impact our ability to market and sell our products and harm our business.

As products that are currently labeled, promoted and intended as RUO, our products are not currently subject to regulation as medical devices by the FDA or comparable agencies of other countries. However, the FDA or comparable agencies of other countries could disagree with our conclusion that our products are currently intended for research use only or deem our current sales, marketing and promotional efforts as being inconsistent with research use only products. For example, our customers may independently elect to use our research use only labeled products in their own laboratory developed tests (LDTs) for clinical diagnostic use. The FDA has historically exercised enforcement discretion in not enforcing the medical device regulations against laboratories offering LDTs. However, on October 3, 2014, the FDA issued two draft guidance documents that set forth the FDA's proposed risk-based framework for regulating LDTs, which are designed, manufactured, and used within a single laboratory. The draft guidance documents provide the anticipated details through which the FDA would propose to establish an LDT oversight framework, including premarket review for higher-risk LDTs, such as those that have the same intended use as FDA-approved or cleared companion diagnostic tests currently on the market. In January 2017, the FDA announced that it would not issue final guidance on the oversight of LDTs and manufacturers of products used for LDTs, but would seek further public discussion on an appropriate oversight approach, and give Congress an opportunity to develop a legislative solution. More recently, the FDA has issued warning letters to certain genomics labs for illegally marketing genetic

tests that claim to predict patients' responses to specific medications, noting that the FDA has not created a legal "carve-out" for LDTs and retains discretion to take action when appropriate, such as when certain genomic tests raise significant public health concerns. As manufacturers develop more complex genetic tests and diagnostic software, the FDA may increase its regulation of LDTs. Any future legislative or administrative rule making or oversight of LDTs, if and when finalized, may impact the sales of our products and how customers use our products, and may require us to change our business model in order to maintain compliance with these laws. We cannot predict how these various efforts will be resolved, how Congress or the FDA will regulate LDTs in the future, or how that regulatory system will impact our business.

Additionally, on November 25, 2013, the FDA issued Final Guidance "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only." The guidance emphasizes that the FDA will review the totality of the circumstances when it comes to evaluating whether equipment and testing components are properly labeled as RUO. The final guidance states that merely including a labeling statement that the product is for research purposes only will not necessarily render the device exempt from the FDA's clearance, approval, and other regulatory requirements if the circumstances surrounding the distribution, marketing and promotional practices indicate that the manufacturer knows its products are, or intends for its products to be, used for clinical diagnostic purposes. These circumstances may include written or verbal sales and marketing claims or links to articles regarding a product's performance in clinical applications and a manufacturer's provision of technical support for clinical applications.

Recently, as part of the Trump Administration's efforts to combat COVID-19 and consistent with the President's direction in Executive Orders 13771 and 13924, the Department of Health and Human Services (HHS) announced rescission of guidances and other informal issuances of the FDA regarding premarket review of LDTs absent notice-and-comment rulemaking, stating that, absent notice-and-comment rulemaking, those seeking approval or clearance of, or an emergency use authorization, for an LDT may nonetheless voluntarily submit a premarket approval application, premarket notification or an EUA request, respectively, but are not required to do so. However, laboratories opting to use LDTs without FDA premarket review or authorization would not be eligible for liability protection under the Public Readiness and Emergency Preparedness Act, or the PREP Act. Following this HHS announcement, the FDA announced in October 2020 that it will no longer review EUA requests for COVID-19 LDTs at this time and will continue to prioritize review of EUA requests for point-of-care tests, home collection tests, at-home tests, tests that reduce reliance on test supplies, and high-throughput tests that are widely distributed. While these actions by HHS and the FDA are expected to reduce the regulatory burden on clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) that develop LDTs, it is unclear how this action as well as future legislation by federal and state governments and FDA regulation will impact the industry, including our business and that of our customers. Such measures may compel the FDA to formalize earlier enforcement discretionary policies and informal guidances through notice-and-comment rulemaking. HHS's rescission policy and the FDA's position with respect to EUAs in the short-term or LDTs in general in the long-term may also change over time. Congress could also enact legislation restricting LDTs. Any restrictions on LDTs by the FDA, HHS, Congress, or state regulatory authorities may decrease the demand for our products. The adoption of new restrictions on RUOs, whether by the FDA or Congress, could adversely affect demand for our specialized reagents and instruments. Further, we could be required to obtain premarket clearance or approval from the FDA before we can sell our products to certain customers.

If the FDA determines our products or related applications should be subject to additional regulation as in vitro diagnostic devices based upon customers' use of our products for clinical diagnostic or therapeutic purposes, our ability to market and sell our products could be impeded and our business, prospects, results of operations and financial condition may be adversely affected. In addition, the FDA could consider our products to be misbranded or adulterated under the Federal Food, Drug, and Cosmetic Act and subject to recall and/or other enforcement action.

Compliance or the failure to comply with current and future regulations affecting our products and business operations worldwide, such as environmental regulations enacted in the European Union, could cause us significant expense and adversely impact our business.

We are subject to many federal, state, local, and foreign regulations relating to various aspects of our business operations. Governmental entities at all levels are continuously enacting new regulations, and it is difficult to identify all applicable regulations and anticipate how such regulations will be implemented and enforced. We continue to evaluate the necessary steps for compliance with applicable regulations. To comply with applicable regulations, we have and will continue to incur significant expense and allocate valuable internal resources to manage compliance-related issues. In addition, such regulations could restrict our ability to expand or equip our facilities, or could require us to acquire costly equipment or to incur other significant expenses to comply with the regulations. For example, the Restriction on the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Directive (RoHS) and the Waste Electrical and Electronic Equipment Directive (WEEE), both enacted in the European Union, regulate the use of certain hazardous substances in, and require the collection, reuse, and recycling of waste from, products we manufacture. Certain of our products sold in these countries are subject to WEEE and RoHS. These and similar regulations that have been or are in the process of being enacted in other countries may

require us to redesign our products, use different types of materials in certain components, or source alternative components to ensure compliance with applicable standards, and may reduce the availability of parts and components used in our products by negatively impacting our suppliers' ability to source parts and components in a timely and cost-effective manner.

The Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation (EC) No. 1907/2006 is the European Union's regulation on chemicals and their safe use. The list of chemicals has been updated and some of the updates affect chemicals used in our products. We will request a research exception, but if not granted, we will need to reduce the concentration of some of the chemicals in our products, which will require significant research and development and operations efforts.

Any such redesigns, required use of alternative materials, or limited availability of parts and components used in our products may detrimentally impact the performance of our products, add greater testing lead times for product introductions, reduce our product margins, or limit the markets for our products, and if we fail to comply with any present and future regulations, we could be subject to future fines, penalties, and restrictions, such as the suspension of manufacturing of our products or a prohibition on the sale of products we manufacture. Any of the foregoing could adversely affect our business, financial condition, or results of operations.

If we fail to maintain effective internal control over financial reporting in the future, the accuracy and timing of our financial reporting may be impaired, which could adversely affect our business and our stock price.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our testing may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses.

Our compliance with Section 404 requires that we incur substantial accounting expense and expend significant management time on compliance-related issues. We currently do not have an internal audit group, and we continue to evaluate our need for additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we do not comply with the requirements of Section 404, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by The Nasdaq Stock Market LLC, the SEC, or other regulatory authorities, which would require additional financial and management resources.

Impairment of our goodwill or other intangible assets could materially and adversely affect our business, operating results, and financial condition.

As of September 30, 2020, we had approximately \$151.5 million of goodwill and net intangible assets, including approximately \$106.5 million of goodwill and \$45.2 million of net intangible assets. These assets represent a significant portion of the assets recorded on our consolidated balance sheet and relate primarily to our acquisition of DVS Sciences, Inc. (DVS) in February 2014. In addition, if in the future we acquire additional businesses, technologies, or other intangible assets, a substantial portion of the value of such assets may be recorded as goodwill or intangible assets. In the fourth quarter of 2019, we concluded that certain of our patents and licenses were impaired and reduced the applicable carrying value to zero, recognizing a charge of \$0.4 million, which is reflected in accumulated amortization.

The carrying amounts of goodwill and intangible assets are affected whenever events or changes in circumstances indicate that their carrying amounts may not be recoverable. We review goodwill and indefinite lived intangible assets for impairment at least annually and more frequently under certain circumstances. Other intangible assets that are deemed to have finite useful lives will continue to be amortized over their useful lives but must be reviewed for impairment when events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. Events or changes in circumstances that could affect the likelihood that we will be required to recognize an impairment charge include declines in our stock price or market capitalization, declines in our market share or revenues, an increase in our losses, rapid changes in technology, failure to achieve the benefits of capacity increases and utilization, significant litigation arising out of an acquisition, or other matters. In particular, these or other adverse events or changes in circumstances may affect the estimated undiscounted future operating cash flows expected to be derived from our goodwill and intangible assets. Any impairment charges could have a material adverse effect on our operating results and net asset value in the quarter in which we recognize the impairment charge. We cannot provide assurances that we will not in the future be required to recognize impairment charges.

Our future capital needs are uncertain and we may need to raise additional funds in the future, which may cause dilution to stockholders or may be upon terms that are not favorable to us.

We have continued to experience losses and, if that trend continues, we may need to seek additional sources of financing. In addition, we may need to raise substantial additional capital for various purposes, including:

- expanding the commercialization of our products;
- funding our operations;
- furthering our research and development; and
- acquiring other businesses or assets and licensing technologies.

Our future funding requirements will depend on many factors, including:

- market acceptance of our products;
- the cost of our research and development activities;
- the cost of filing and prosecuting patent applications;
- the cost of defending any litigation including intellectual property, employment, contractual or other litigation;
- the cost and timing of regulatory clearances or approvals, if any;
- the cost and timing of establishing additional sales, marketing, and distribution capabilities;
- the cost and timing of establishing additional technical support capabilities;
- fluctuations in cash demands (e.g., due to interest or principal payments or payouts under existing cash compensation plans);
- variability in sales and timing of related cash collections;
- the effectiveness of our efficiency and cost-savings initiatives;
- the impact of any natural disasters or public health crises, such as the COVID-19 pandemic;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products, and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

To the extent we draw on our Revolving Credit Facility or otherwise incur additional indebtedness, the risks described above could increase. Further, if we increase our indebtedness, our actual cash requirements in the future may be greater than expected. Our cash flow from operations may not be sufficient to repay all of the outstanding debt as it becomes due, and we cannot assure you that we will be able to obtain additional funds on acceptable terms, or at all. The ongoing COVID-19 pandemic has led to significant disruption and volatility in the global capital markets, increasing the cost of—and adversely impacting access to—capital. We have a Sale Agreement with Jefferies to sell shares of our common stock having aggregate sales proceeds of up to \$50,000,000, from time to time, through an ATM equity offering program under which Jefferies acts as sales agent. During the third quarter of 2020, we sold approximately 2.5 million shares of our common stock pursuant to the Sale Agreement, for aggregate gross proceeds of \$20.9 million. Our net proceeds were approximately \$20.1 million, after deducting related expenses, including commissions of approximately \$0.6 million and issuance costs of approximately \$0.2 million. If we raise additional funds by issuing equity securities, either under the ATM program or otherwise, our stockholders may experience dilution. Debt financing in addition to the Revolving Credit Facility, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any additional debt or equity financing that we raise may contain terms that are not favorable to us or our stockholders, and our ability to raise additional capital may be adversely impacted by the impact of the COVID-19 pandemic on the economy.

If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we do not have or are unable to raise adequate funds, we may have to liquidate some or all of our assets, delay development or commercialization of our products, or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support, research and development, or other resources devoted to our products, or cease operations. Any of these factors could harm our operating results.

If we fail to comply with the covenants and other obligations under our Revolving Credit Facility, the lenders may be able to accelerate amounts owed under the facilities and may foreclose upon the assets securing our obligations.

In April 2020, we amended our Revolving Credit Facility, which provides for secured revolving loans in an aggregate amount of up to \$15.0 million, to extend the maturity date to August 2, 2022. The Revolving Credit Facility is secured by substantially all of our assets, other than intellectual property. The Revolving Credit Facility contains customary affirmative and negative covenants which, unless waived by the bank, limit our ability to, among other things, incur additional indebtedness, grant liens, make investments, repurchase stock, pay dividends, transfer assets, enter into affiliate transactions, undergo a change of control, or engage in merger and acquisition activity, including merging or consolidating with a third party. If we fail to comply with the covenants and our other obligations under the Revolving Credit Facility, the lenders would be able to accelerate the required repayment of amounts due under the Revolving Credit Agreement and, if they are not repaid, could foreclose upon the assets securing our obligations under the Revolving Credit Facility.

We are subject to risks related to taxation in multiple jurisdictions and if taxing authorities disagree with our interpretations of existing tax laws or regulations, our effective income tax rate could be adversely affected and we could have additional tax liability.

We are subject to income taxes in both the United States and certain foreign jurisdictions. Significant judgments based on interpretations of existing tax laws or regulations are required in determining the provision for income taxes. For example, we have made certain interpretations of existing tax laws or regulations based upon the operations of our business internationally and we have implemented intercompany agreements based upon these interpretations and related transfer pricing analyses. If the U.S. Internal Revenue Service or other taxing authorities disagree with the positions, our effective income tax rate could be adversely affected and we could have additional tax liability, including interest and penalties. From time to time, we may review our corporate structure and tax positions in the various international jurisdictions in which we operate and such review may result in changes to how we structure our international business operations, which may adversely impact our effective income tax rate. Our effective income tax rate could also be adversely affected by changes in the mix of earnings in tax jurisdictions with different statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in existing tax laws or tax rates, changes in the level of non-deductible expenses (including share-based compensation), changes in our future levels of research and development spending, mergers and acquisitions, or the result of examinations by various tax authorities. Payment of additional amounts as a result of changes in applicable tax law or upon final adjudication of any disputes could have a material impact on our results of operations and financial position.

Our ability to use net operating loss carryforwards to offset future taxable income for U.S. federal income tax purposes and other tax benefits may be limited.

Section 382 of the Internal Revenue Code of 1986, as amended (the Code), imposes an annual limitation on the amount of taxable income that may be offset by net operating loss carryforwards (NOLs) if a corporation experiences an “ownership change.” As provided in Section 382 of the Code, an “ownership change” occurs when a company’s “five-percent shareholders” collectively increase their ownership in the company by more than 50 percentage points (by value) over a rolling three-year period. Various states also have limitations on the use of state NOLs following an ownership change.

Future changes in our stock ownership, some of which are outside our control, could result in an ownership change under Section 382 of the Code. If we experience an ownership change, our ability to use our NOLs or other tax benefits could be substantially limited, which could significantly impair their value. There is no assurance that we will be able to fully utilize our NOLs or other tax benefits, which could adversely impact our results of operations.

We believe that these tax benefits are a valuable asset for us and we monitor our stock ownership to determine whether our NOLs are at material risk of limitation based on an ownership change pursuant to Section 382. If our board of directors determines a potential risk exists that our NOLs could be limited, it could elect to adopt a tax benefit preservation plan in an effort to protect our tax benefits. Adoption of a tax benefit preservation plan could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, us or a large block of our common stock.

Adverse conditions in the global economy and disruption of financial markets may significantly harm our revenue, profitability, and results of operations.

Adverse economic conditions in the U.S. and international markets, including the worldwide economic disruption related to the COVID-19 pandemic, have negatively affected our revenues and operating results and may continue to do so. Even before the current public health crisis took hold, the global credit and financial markets had been experiencing volatility and disruptions, including diminished liquidity and credit availability, increased concerns about inflation and deflation, and the downgrade of U.S. debt and exposure risks on other sovereign debts, decreased consumer confidence, lower economic growth, volatile energy costs, increased unemployment rates, and uncertainty about economic stability. Geopolitical events including

the COVID-19 pandemic, the United States government's adoption and expansion of trade restrictions, and the United Kingdom's withdrawal from the European Union have caused significant economic, market, political and regulatory uncertainty in some of our markets. Volatility and disruption of financial markets could limit our customers' ability to obtain adequate financing or credit to purchase and pay for our products in a timely manner or to maintain operations, which could result in a decrease in sales volume that could harm our results of operations. General concerns about the fundamental soundness of domestic and international economies may also cause our customers to reduce their purchases. Changes in governmental banking, monetary, and fiscal policies to address liquidity and increase credit availability may not be effective. Significant government investment and allocation of resources to assist the economic recovery of sectors that do not include our customers may reduce the resources available for government grants and related funding for life science, plant and animal research, and clinical research and development. Continuation or further deterioration of these financial and macroeconomic conditions could significantly harm our sales, profitability, and results of operations.

If we are unable to expand our direct sales and marketing force or distribution capabilities to adequately address our customers' needs, our business may be adversely affected.

We may not be able to market, sell, and, distribute our products effectively enough to support our planned growth. We sell our products primarily through our own sales force and through distributors in certain territories. Our future sales will depend in large part on our ability to continue to develop and substantially expand our direct sales force and to increase the scope of our marketing efforts. Our products are technically complex and used for highly specialized applications. As a result, we believe it is necessary to continue to develop a direct sales force that includes people with specific scientific backgrounds and expertise, and a marketing group with technical sophistication. We have experienced significant changes in our sales organization in the past year due to reorganizations and changes in leadership. In addition, as part of our cost reduction program to manage the impact of the COVID-19 pandemic, we implemented temporary enterprise-wide salary reductions, including with respect to our sales and marketing employees. Although all salaries have been restored to prior levels as of the date of this filing, any reinstatement of salary reductions or any other failure to maintain competitive levels of compensation may negatively impact our ability to maintain the skilled sales and marketing force necessary to support our business activities. As a result, our future success will depend largely on our ability to retain and motivate such personnel. Because competition for such employees is intense, we can provide no assurance that we will be able to retain them on favorable or commercially reasonable terms, if at all. Failure to attract and retain our current personnel or to build an efficient and effective sales and marketing force would negatively impact sales of our products and reduce our revenue and profitability.

In addition, we may continue to enlist one or more sales representatives and distributors to assist with sales, distribution, and customer support globally or in certain regions of the world. If we do seek to enter into such arrangements, we may not be successful in attracting desirable sales representatives and distributors, or we may not be able to enter into such arrangements on favorable terms. If our sales and marketing efforts, or those of any third-party sales representatives and distributors, are not successful, our technologies and products may not gain market acceptance, which would materially and adversely impact our business operations.

If we seek to implement a company-wide enterprise resource planning (ERP) system, such implementation could adversely affect our business and results of operations or the effectiveness of internal control over financial reporting.

We have considered implementing a company-wide ERP system to handle the business and financial processes within our operations and corporate functions. ERP implementations are complex and time-consuming projects that involve substantial expenditures on system software and implementation activities that can continue for several years. ERP implementations also require transformation of business and financial processes in order to reap the benefits of the ERP system. If we decide to implement a company-wide ERP system, our business and results of operations could be adversely affected if we experience operating problems and/or cost overruns during the ERP implementation process, or if the ERP system and the associated process changes do not give rise to the benefits that we expect. If we do not effectively implement the ERP system as planned or if the system does not operate as intended, our business, results of operations, and internal controls over financial reporting could be adversely affected.

Changes in accounting principles, or interpretations thereof, could have a significant impact on our financial position and results of operations.

We prepare our consolidated financial statements in accordance with U.S. GAAP. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting principles. A change in these principles can have a significant effect on our reported results and may even retroactively affect previously reported transactions. Additionally, the adoption of new or revised accounting principles may require that we make significant changes to our systems, processes and controls.

For example, the U.S.-based Financial Accounting Standards Board (FASB) is currently working together with the International Accounting Standards Board (IASB), on several projects to further align accounting principles and facilitate more comparable financial reporting between companies who are required to follow U.S. GAAP under SEC regulations and those who are required to follow International Financial Reporting Standards outside of the United States. These efforts by the FASB and IASB may result in different accounting principles under U.S. GAAP that may result in materially different financial results for us in areas including, but not limited to, principles for recognizing revenue and lease accounting. Additionally, significant changes to U.S. GAAP resulting from the FASB's and IASB's efforts may require that we change how we process, analyze and report financial information and that we change financial reporting controls. Additionally, the FASB issued new guidance (ASU 2014-09) *Revenue from Contracts with Customers (Topic 606)* which supersedes nearly all existing U.S. GAAP revenue recognition guidance. The new guidance was effective for our fiscal year 2018. We adopted ASU 2014-09 in the first quarter of 2018 using the modified retrospective method. Under the modified retrospective method, periods prior to the adoption of ASU 2014-09 are not restated and the cumulative effect of initially applying the new standard is reflected in the opening balance of accumulated deficit as of January 1, 2018. To date, the adoption has not had a material impact on our consolidated financial statements. Additional disclosures are required for significant differences between the reported results under the new standard and those that would have been reported under the legacy standard, which required us to make certain changes to our business processes and controls to support revenue recognition and disclosure under the new standard.

The FASB also issued Accounting Standards Update (ASU) 2016-02, *Leases (Topic 842)* (ASU 2016-02). The core principle is that lessees should recognize the assets and liabilities arising from leases on the balance sheet. Under the new standard, lessees will be required to recognize lease assets and liabilities for all leases, with certain exceptions, on their balance sheets. We adopted ASU 2016-02 as of January 1, 2019. The adoption of this standard had a material impact on our consolidated financial statements. We continue to identify the appropriate changes to our business processes, systems, and controls to support the new lease standard and the required disclosures under the new standard.

It is not clear if or when potential changes in accounting principles may become effective, whether we have the proper systems and controls in place to accommodate such changes and the impact that any such changes may have on our financial position and results of operations.

We have a significant amount of outstanding indebtedness, and our financial condition and results of operations could be adversely affected if we do not efficiently manage our liabilities.

We have significant outstanding convertible debt. As of September 30, 2020, we had outstanding \$1.1 million aggregate principal amount of our 2.75% Senior Convertible Notes due 2034 (2014 Notes) and \$55.0 million aggregate principal amount of our 5.25% convertible senior notes due 2024 (2019 Notes). The 2014 Notes will mature on February 1, 2034, unless earlier converted, redeemed, or repurchased in accordance with the terms of the 2014 Notes. Holders of the 2014 Notes may require us to repurchase all or a portion of their 2014 Notes on each of February 6, 2021, February 6, 2024, and February 6, 2029 at a repurchase price in cash equal to 100% of the principal amount of the Notes plus accrued and unpaid interest. The 2019 Notes will mature on December 1, 2024, unless earlier converted, or repurchased in accordance with the terms of the 2019 Notes. If we undergo a fundamental change (as defined in the terms of the indenture governing either the 2014 Notes or the 2019 Notes (collectively, the Convertible Notes)), holders of the applicable series of Convertible Notes may require us to repurchase such Convertible Notes in whole or in part for cash at a repurchase price equal to 100% of the principal amount of the applicable series of Convertible Notes plus accrued and unpaid interest. If we refinance the debt owed under the 2014 Notes or 2019 Notes, we may issue additional convertible notes or other debt, which could include additional company obligations and represent more dilution to existing stockholders and noteholders.

This significant amount of debt has important risks to us and our investors, including:

- requiring a portion of our cash flow from operations to make interest payments on this debt;
- increasing our vulnerability to general adverse economic and industry conditions;
- reducing the cash flow available to fund capital expenditures and other corporate purposes and to grow our business;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry; and
- limiting our ability to borrow additional funds as needed or take advantage of business opportunities as they arise.

In addition, to the extent we draw on our Revolving Credit Facility or otherwise incur additional indebtedness, the risks described above could increase. Further, if we increase our indebtedness, our actual cash requirements in the future may be greater than expected. Our cash flow from operations may not be sufficient to repay all of the outstanding debt as it becomes due, and we may not be able to borrow money, sell assets or otherwise raise funds on acceptable terms, or at all, to refinance our debt.

Risks Related to Intellectual Property

Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain.

Our commercial success depends in part on our ability to protect our intellectual property and proprietary technologies. We rely on patent protection, where appropriate and available, as well as a combination of copyright, trade secret, and trademark laws, and nondisclosure, confidentiality, and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We apply for patents covering our products and technologies and uses thereof, as we deem appropriate. However, we may fail to apply for patents on important products and technologies in a timely fashion or at all. Our pending U.S. and foreign patent applications may not issue as patents or may not issue in a form that will be sufficient to protect our proprietary technology and gain or keep our competitive advantage. Any patents we have obtained or do obtain may be subject to re-examination, reissue, opposition, or other administrative proceeding, or may be challenged in litigation, and such challenges could result in a determination that the patent is invalid or unenforceable. In addition, competitors may be able to design alternative methods or devices that avoid infringement of our patents. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

Furthermore, the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. For example:

- we might not have been the first to make the inventions covered by each of our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- the patents of others may have an adverse effect on our business; and
- others may independently develop similar or alternative products and technologies or duplicate any of our products and technologies.

To the extent our intellectual property, including licensed intellectual property, offers inadequate protection, or is found to be invalid or unenforceable, our competitive position and our business could be adversely affected.

We may be involved in lawsuits to protect or enforce our patents and proprietary rights, to determine the scope, coverage and validity of others' proprietary rights, or to defend against third-party claims of intellectual property infringement, any of which could be time-intensive and costly and may adversely impact our business or stock price.

Litigation may be necessary for us to enforce our patent and proprietary rights, determine the scope, coverage, and validity of others' proprietary rights, and/or defend against third-party claims of intellectual property infringement against us as well as against our suppliers, distributors, customers, and other entities with which we do business. Litigation could result in substantial legal fees and could adversely affect the scope of our patent protection. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us, and we might not be able to obtain licenses to technology that we require. Even if such licenses are obtainable, they may not be available at a reasonable cost. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our product margins or financial position. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products.

As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of impeding our entry into such markets or as a means to extract substantial license and royalty payments from us. Our commercial success may depend in part on our non-infringement of the patents or proprietary rights of third parties. Numerous significant intellectual property issues have been litigated, and will likely continue to be litigated, between existing and new participants in our existing and targeted markets. For example, some of our products provide for the testing and analysis of genetic material, and patent rights relating to genetic materials remain a developing area of patent law. A recent U.S. Supreme Court decision held, among other things, that claims to isolated genomic DNA occurring in nature are not patent eligible, while claims relating to synthetic DNA may be patent eligible. We expect the ruling will result in additional litigation in our industry. In addition, third parties may assert that we are employing their proprietary technology without authorization, and if they are successful in making such claims, we may be forced to enter into

license agreements, pay additional royalties or license fees, or enter into settlements that include monetary obligations or restrictions on our business.

Our customers have been sued for various claims of intellectual property infringement in the past, and we expect that our customers will be involved in additional litigation in the future. In particular, our customers may become subject to lawsuits claiming that their use of our products infringes third-party patent rights, and we could become subject to claims that we contributed to or induced our customer's infringement. In addition, our agreements with some of our suppliers, distributors, customers, and other entities with which we do business may require us to defend or indemnify these parties to the extent they become involved in infringement claims against us, including the claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify any of these third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our employees' former employers or other institutions or third parties with which such employees may have been previously affiliated.

Many of our employees were previously employed at universities or other life science or plant and animal research companies, including our competitors or potential competitors. In the future, we may become subject to claims that our employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or other third parties or institutions with which our employees may have been previously affiliated. Litigation may be necessary to defend against these claims. For example, we were a defendant in litigation brought against us and one of our non-executive employees by Thermo alleging, among other claims, misappropriation of proprietary information and breach of contractual and fiduciary obligations. While we resolved our dispute with Thermo in July 2017, if we fail in defending against similar claims brought in the future, we could be subject to injunctive relief against us. A loss of key research personnel work product could hamper or prevent our ability to commercialize certain potential products or a loss of or inability to hire key marketing, sales or research and development personnel could adversely affect our future product development, sales and revenues, any of which could severely harm our business. Even if we are successful in defending against any similar claims brought in the future, litigation could result in substantial costs and be a distraction to management.

We depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from selling our products, which would have an adverse effect on our business.

We rely on licenses in order to be able to use various proprietary technologies that are material to our business, including our core IFC, multi-layer soft lithography, and mass cytometry technologies. In some cases, we do not control the prosecution, maintenance, or filing of the patents to which we hold licenses, or the enforcement of these patents against third parties. Additionally, our business and product development plans anticipate and may substantially depend on future in-license agreements with additional third parties, some of which are currently in the early discussion phase. For example, Fluidigm Canada Inc., or Fluidigm Canada, an Ontario corporation and wholly owned subsidiary of Fluidigm Sciences, was party to an interim license agreement, now expired, with Nodality, Inc., or Nodality, under which Nodality granted Fluidigm Canada a worldwide, non-exclusive, research use only, royalty bearing license to certain cytometric reagents, instruments, and other products. While we were able to secure a license under a new license agreement with Nodality, we cannot provide assurances that we will always be able to obtain suitable license rights to technologies or intellectual property of other third parties on acceptable terms, if at all.

In-licensed intellectual property rights that are fundamental to our business being operated present numerous risks and limitations. For example, all or a portion of the license rights granted may be limited for research use only, and in the event we attempt to expand into diagnostic applications, we would be required to negotiate additional rights, which may not be available to us on commercially reasonable terms, if at all.

Our rights to use the technology we license are also subject to the negotiation and continuation of those licenses. Certain of our licenses contain provisions that allow the licensor to terminate the license upon specific conditions. Our rights under the licenses are subject to our continued compliance with the terms of the license, including the payment of royalties due under the license. Because of the complexity of our products and the patents we have licensed, determining the scope of the license and related royalty obligation can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the license. If a licensor believed we were not paying the royalties due under the license or were otherwise not in compliance with the terms of the license, the licensor might attempt to revoke the license. If such an attempt were successful and the license is terminated, we might be barred from marketing, producing, and selling some or all of our products, which would have an adverse effect on our business. Potential

disputes between us and one of our existing licensors concerning the terms or conditions of the applicable license agreement could result, among other risks, in substantial management distraction; increased expenses associated with litigation or efforts to resolve disputes; substantial customer uncertainty concerning the direction of our product lines; potential infringement claims against us and/or our customers, which could include efforts by a licensor to enjoin sales of our products; customer requests for indemnification by us; and, in the event of an adverse determination, our inability to operate our business as currently operated. Termination of material license agreements could prevent us from manufacturing and selling our products unless we can negotiate new license terms or develop or acquire alternative intellectual property rights that cover or enable similar functionality. Any of these factors would be expected to have a material adverse effect on our business, operating results, and financial condition and could result in a substantial decline in our stock price.

We are subject to certain manufacturing restrictions related to licensed technologies that were developed with the financial assistance of U.S. governmental grants.

We are subject to certain U.S. government regulations because we have licensed technologies that were developed with U.S. government grants. In accordance with these regulations, these licenses provide that products embodying the technologies are subject to domestic manufacturing requirements. If this domestic manufacturing requirement is not met, the government agency that funded the relevant grant is entitled to exercise specified rights, referred to as “march-in rights,” which if exercised would allow the government agency to require the licensors or us to grant a non-exclusive, partially exclusive, or exclusive license in any field of use to a third party designated by such agency. All of our microfluidic systems revenue is dependent upon the availability of our IFCs, which incorporate technology developed with U.S. government grants. Our genomics instruments, including microfluidic systems, and IFCs are manufactured at our facility in Singapore. The federal regulations allow the funding government agency to grant, at the request of the licensors of such technology, a waiver of the domestic manufacturing requirement. Waivers may be requested prior to any government notification. We have assisted the licensors of these technologies with the analysis of the domestic manufacturing requirement, and, in December 2008, the sole licensor subject to the requirement applied for a waiver of the domestic manufacturing requirement with respect to the relevant patents licensed to us by this licensor. In July 2009, the funding government agency granted the requested waiver of the domestic manufacturing requirement for a three-year period commencing in July 2009. In June 2012, the licensor requested a continued waiver of the domestic manufacturing requirement with respect to the relevant patents, but the government agency has not yet taken any action in response to this request. If the government agency does not grant the requested waiver or the government fails to grant additional waivers of such requirement that may be sought in the future, then the U.S. government could exercise its march-in rights with respect to the relevant patents licensed to us. In addition, the license agreement under which the relevant patents are licensed to us contains provisions that obligate us to comply with this domestic manufacturing requirement. We are not currently manufacturing instruments and IFCs in the United States that incorporate the relevant licensed technology. If our lack of compliance with this provision constituted a material breach of the license agreement, the license of the relevant patents could be terminated or we could be compelled to relocate our manufacturing of microfluidic systems and IFCs to the United States to avoid or cure a material breach of the license agreement. Any of the exercise of march-in rights, the termination of our license of the relevant patents or the relocation of our manufacturing of microfluidic systems and IFCs to the United States could materially adversely affect our business, operations and financial condition.

We are subject to certain obligations and restrictions relating to technologies developed in cooperation with Canadian government agencies.

Some of our Canadian research and development is funded in part through government grants and by government agencies. The intellectual property developed through these projects is subject to rights and restrictions in favor of government agencies and Canadians generally. In most cases the government agency retains the right to use intellectual property developed through the project for non-commercial purposes and to publish the results of research conducted in connection with the project. This may increase the risk of public disclosure of information relating to our intellectual property, including confidential information, and may reduce its competitive advantage in commercializing intellectual property developed through these projects. In certain projects, we have also agreed to use commercially reasonable efforts to commercialize intellectual property in Canada, or more specifically in the province of Ontario, for the economic benefit of Canada and the province of Ontario. These restrictions will limit our choice of business and manufacturing locations, business partners and corporate structure and may, in certain circumstances, restrict our ability to achieve maximum profitability and cost efficiency from the intellectual property generated by these projects. In one instance, a dispute with the applicable government funded entity may require mediation, which could lead to unanticipated delays in our commercialization efforts to that project. One of our Canadian government funded projects is also subject to certain limited “march-in” rights in favor of the government of the Province of Ontario, under which we may be required to grant a license to our intellectual property, including background intellectual property developed outside the scope of the project, to a responsible applicant on reasonable terms in circumstances where the government determines that such a license is necessary in order to alleviate emergency or extraordinary health or safety needs or for public use. In addition, we must provide reasonable assistance to the government in obtaining similar licenses from third

parties required in connection with the use of its intellectual property. Instances in which the government of the Province of Ontario has exercised similar “march-in” rights are rare; however, the exercise of such rights could materially adversely affect our business, operations and financial condition.

Risks Related to Our Common Stock

Our stock price may fluctuate significantly, particularly if holders of substantial amounts of our stock attempt to sell, and holders may have difficulty selling their shares based on current trading volumes of our stock. In addition, numerous other factors could result in substantial volatility in the trading price of our stock.

Our stock is currently traded on the Nasdaq Global Select Market (Nasdaq), but we can provide no assurance that we will be able to maintain an active trading market on Nasdaq or any other exchange in the future. The trading volume of our stock tends to be low relative to our total outstanding shares, and we have several stockholders who hold substantial blocks of our stock. As of December 31, 2019, we had 69,956,397 shares of common stock outstanding, and stockholders holding at least 5% of our stock, individually or with affiliated persons or entities, collectively beneficially owned or controlled approximately 46.3% of such shares and one stockholder beneficially owned approximately 9.8% of our outstanding common stock. Sales of large numbers of shares by any of our large stockholders could adversely affect our trading price, particularly given our relatively small historic trading volumes. If stockholders holding shares of our common stock sell, indicate an intention to sell, or if it is perceived that they will sell, substantial amounts of their common stock in the public market, the trading price of our common stock could decline. Moreover, if there is no active trading market or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares. In addition, the concentration of ownership of our outstanding common stock (approximately 46.3% held by our top six stockholders) means that a relatively small number of stockholders have significant control over the outcomes of stockholder voting.

In addition, the trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- the impact of public health crises, including the COVID-19 pandemic, on global financial markets;
- actual or anticipated quarterly variation in our results of operations or the results of our competitors;
- announcements or communications by us or our competitors relating to, among other things, new commercial products, technological advances, significant contracts, commercial relationships, capital commitments, acquisitions or sales of businesses, and/or misperceptions in or speculation by the market regarding such announcements or communications;
- issuance of new or changed securities analysts’ reports or recommendations for our stock;
- developments or disputes concerning our intellectual property or other proprietary rights;
- commencement of, or our involvement in, litigation;
- market conditions in the life science, plant and animal research, and contract research organization sectors;
- failure to complete significant sales;
- manufacturing disruptions that could occur if we are unable to successfully expand our production in our current or an alternative facility;
- any future sales of our common stock or other securities in connection with raising additional capital or otherwise;
- any major change to the composition of our board of directors or management; and
- general economic conditions and slow or negative growth of our markets.

The stock market in general, and market prices for the securities of technology-based companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock regardless of our operating performance. In several recent situations where the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. As discussed in the “Legal Proceedings” section of this Quarterly Report on Form 10-Q, a class action securities lawsuit against us is currently pending. While we are continuing to defend such action vigorously, the defense of this action and any additional actions can be costly, divert the time and attention of our management, and harm our operating results, and any judgment against us or any future stockholder litigation could result in substantial costs.

Future sales of our common stock in the public market could cause our stock price to fall.

Our stock price could decline as a result of sales of a large number of shares of our common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

In addition, in the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such future issuance, including any issuances pursuant to our ATM equity offering program under our Sale Agreement with Jefferies, could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

We will have broad discretion over the use of the proceeds to us from our ATM equity offering program and may apply the proceeds to uses that do not improve our operating results or the value of your securities.

We will have broad discretion to use the net proceeds to us from our ATM equity offering program, and investors will be relying solely on the judgment of our board of directors and management regarding the application of these proceeds. Investors will not have the opportunity, as part of their investment decision, to assess whether the proceeds are being used appropriately. Our use of the proceeds may not improve our operating results or increase the value of the securities offered pursuant to the ATM equity offering program.

If securities or industry analysts publish unfavorable research about our business or cease to cover our business, our stock price and/or trading volume could decline.

The trading market for our common stock may rely, in part, on the research and reports that equity research analysts publish about us and our business. We do not have any control of the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control or changes in our management, including provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 10,000,000 shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairman of the board, the chief executive officer or the president;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into three classes, Class I, Class II, and Class III, with each class serving staggered three-year terms;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors; and
- require a super-majority of votes to amend certain of the above-mentioned provisions.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of

Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

We have never paid cash dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have paid no cash dividends on any of our classes of capital stock to date and currently intend to retain our future earnings to fund the development and growth of our business. In addition, we cannot pay any cash dividends on any of our classes of common stock without approval from the lender under our Revolving Credit Facility, and may become subject to covenants under future debt arrangements that place restrictions on our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be stockholders' sole source of gain for the foreseeable future.

Any conversions of the 2014 Notes or 2019 Notes will dilute the ownership interest of our existing stockholders and may otherwise depress the price of our common stock.

Any conversion of some or all of the 2014 Notes or 2019 Notes will dilute the ownership interests of our existing stockholders. Any sales in the public market of our common stock issuable upon such conversion could also adversely affect prevailing market prices of our common stock. In addition, holders of the 2014 Notes or 2019 Notes may hedge their position in such Convertible Notes by entering into short positions with respect to the underlying common stock. As a result, any anticipated conversion of the 2014 Notes or 2019 Notes could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

The documents listed in the Exhibit List, which follows below, are incorporated by reference or are filed with this quarterly report on Form 10-Q, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

EXHIBIT LIST

<u>Exhibit Number</u>	<u>Description</u>	<u>Incorporated by Reference From Form</u>	<u>Incorporated by Reference From Exhibit Number</u>	<u>Date Filed</u>
10.1*	Contract by and between the National Institutes of Health and the registrant effective as of July 30, 2020, as amended September 28, 2020.	Filed herewith		
10.2*	Second Amended and Restated License Agreement between California Institute of Technology and the registrant effective as of May 1, 2004.	Filed herewith		
10.2A*	First Addendum, effective as of March 29, 2007, to Second Amended and Restated License Agreement between California Institute of Technology and the registrant effective as of May 1, 2004.	Filed herewith		
10.3*	Co-Exclusive License Agreement between President and Fellows of Harvard College and the registrant effective as of October 15, 2000.	Filed herewith		
10.3A*	First Amendment to Co-Exclusive License Agreement between President and Fellows of Harvard College and the registrant effective as of October 15, 2000.	Filed herewith		
10.4*	Co-Exclusive License Agreement between President and Fellows of Harvard College and the registrant effective as of October 15, 2000.	Filed herewith		
10.5*	Co-Exclusive License Agreement between President and Fellows of Harvard College and the registrant effective as of October 15, 2000.	Filed herewith		
10.6*	Letter Agreement between President and Fellows of Harvard College and the registrant dated December 22, 2004.	Filed herewith		
31.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 of Chief Executive Officer.	Filed herewith		
31.2	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 of Chief Financial Officer.	Filed herewith		
32.1 ⁽¹⁾	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 of Chief Executive Officer.	Filed herewith		
32.2 ⁽¹⁾	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 of Chief Executive Officer.	Filed herewith		
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	Filed herewith		
101.SCH	XBRL Taxonomy Extension Schema Document	Filed herewith		
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith		
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith		
101.LAB	XBRL Taxonomy Extension Label Document	Filed herewith		
101.PRE	XBRL Taxonomy Extension Presentation Document	Filed herewith		

(1) In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

* Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

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.

FLUIDIGM CORPORATION

Dated: November 6, 2020

By: /s/ Stephen Christopher Linthwaite
Stephen Christopher Linthwaite
President and Chief Executive Officer

Dated: November 6, 2020

By: /s/ Vikram Jog
Vikram Jog
Chief Financial Officer

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS <i>OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30</i>		1. REQUISITION NUMBER 5763920		PAGE OF 1 / 34	
2. CONTRACT NO. 75N92020C00009		3. AWARD/ EFFECTIVE DATE		4. ORDER NUMBER.	
7. FOR SOLICITATION INFORMATION CALL:		a. NAME LINDA SMITH		b. TELEPHONE NUMBER (No collect calls) +1 301 827-7741	
9. ISSUED BY CODE NHLBI National Institutes of Health National Heart, Lung, and Blood Institute Bethesda, MD 20892-7511		10. THIS ACQUISITION IS <input checked="" type="checkbox"/> UNRESTRICTED OR <input type="checkbox"/> SET ASIDE: % FOR: <input type="checkbox"/> SMALL BUSINESS <input type="checkbox"/> WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED BUSINESS PROGRAM NAICS: 334516 <input type="checkbox"/> HUBZONE SMALL BUSINESS PROGRAM NAICS: 334516 BUSINESS <input type="checkbox"/> EDWOSB <input type="checkbox"/> SERVICE-DISABLED <input type="checkbox"/> 8(A) VETERAN-OWNED SIZE STANDARD: 1,000 SMALL BUSINESS		15. SOLICITATION NUMBER	
11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED <input checked="" type="checkbox"/> SEE SCHEDULE		12. DISCOUNT TERMS TDP, BTHOFF		8. OFFER DUE DATE/LOCAL TIME	
15 DELIVER TO CODE TDP, BTHOFF Two Democracy Plaza, Bethesda Off C 2 Democracy Plaza 6707 Democracy Blvd Bethesda MD 20817		13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		13b. RATING	
17a. CONTRACTOR/ CODE OFFEROR FACILITY CODE		18a. PAYMENT WILL BE MADE BY CODE NHLBI INV-BR-A		14. METHOD OF SOLICITATION <input type="checkbox"/> RFQ <input type="checkbox"/> IFB <input type="checkbox"/> RFP	
FLUIDIGM CORPORATION: 1157584 2 TOWER PLACE SUITE 2000 SOUTH SAN FRANCISCO CA 940801826 TELEPHONE NO. -		Approved By, NHLBI Branch A Invoice Paid By: NIH Commercial Accounts Br 2115 East Jefferson St, MSC 8500 Room 4B-432 Bethesda, MD 20892-8500			
17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER		18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED <input type="checkbox"/> SEE ADDENDUM			
19. ITEM NO.		20. SCHEDULE OF SUPPLIES/SERVICES		21. QUANTITY	
22. UNIT		23. UNIT PRICE		24. AMOUNT	
1		NIBID: 75N92020C00009 Rapid Acceleration of Diagnostics (RADx) Program: Tech Project # 6114 Fluidigm - Advanta Dx SARS-CoV-2 RT-PCR Assay for Saliva Period of Performance: 07/30/2020 to 07/29/2021 Stage 1 - Test Verification Obligated Amount: [***] Delivery To: Bldg 31/RM 1C31 Continued ... (Use Reverse and/or Attach Additional Sheets as Necessary)		[***]	
25. ACCOUNTING AND APPROPRIATION DATA		26. TOTAL AWARD AMOUNT (For Govt. Use Only) \$12,151,000.00			
<input type="checkbox"/> 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA <input type="checkbox"/> ARE <input type="checkbox"/> ARE NOT ATTACHED		<input checked="" type="checkbox"/> 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA <input checked="" type="checkbox"/> ARE <input checked="" type="checkbox"/> ARE NOT ATTACHED			
Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.					
<input type="checkbox"/> 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.		<input type="checkbox"/> 29. AWARD OF CONTRACT: OFFER DATED . YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:			
30a. SIGNATURE OF OFFEROR/CONTRACTOR /s/ S. Christopher Linthwaite		1 16B. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER) /s/ Roxane S. Burkett -S Digitally signed by Roxane S. Burkett -S Date: 2020.07.30 077:36:45 -04'00'			
30b. NAME AND TITLE OF SIGNER (Type or print) S. Christopher Linthwaite, President and CEO		30c. DATE SIGNED 7/29/2020		31b. NAME OF CONTRACTING OFFICER (Type or print) ROXANE S. BURKETT	
				31c. DATE SIGNED	

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
2	Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: 08/08/2020 Stage 1A - Design Review Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: 09/12/2020				[***]

32a. QUANTITY IN COLUMN 21 HAS BEEN

RECEIVED INSPECTED ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED:

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE		32c. DAT	32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
2e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE			32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
			32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
33. SHIP NUMB PARTIAL FINAL	34. VOUCHER NUMBER	35. AMOUNT VERIFIED CORRECT	36. PAYMENT COMPLETE PARTIAL FINAL	
38. S/R ACCOUNT NUMBER	39. S/R VOUCHER NUMBER	40. PAID BY		
41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT			42a. RECEIVED BY (Print)	
41b. SIGNATURE AND TITLE OF CERTIFYING OFFICERFFI		41c. DATE		42b. RECEIVED AT (Location)
				42c. DATE REC'D (YY!MM!DD)
				42d. TOTAL CONTAINERS

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SERVICES

This Letter Contract forms a preliminary understanding between Fluidigm Corporation and the National Institutes of Health (NIH) and is issued as a result of the Rapid Acceleration of Diagnostics Advanced Technology Platforms (RADx-ATP) to increase the testing capacity of high throughput labs by scaling up late stage testing platforms for detecting SARS-CoV-2, the virus that causes COVID-19. Issuance of this Letter Contract authorizes the Contractor to immediately begin the activities necessary to perform the requirements as identified in the Statement of Objectives covering the full range of activities needed to increase capacity and optimize throughput necessary to distribute a viable product to the public.

The scope of work executed under this contract, includes completing the validation, approval, and production processes in order to deliver a viable product in a scaled up capacity to the U.S. public. Fluidigm technology to support this effort will be to scale up the Integrated Fluidic Circuit (IFC) and completion of the multiplex assay development system for rapid acceleration of testing.

This Letter Contract has been issued based on the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the Point of Care Technology Research Network (POCTRN) application review process. The Contractor's inability to meet the requirements as defined within this Letter Contract and proposed within the POCTRN application process may result in the termination of the Letter Contract in accordance with the termination clauses contained herein.

ARTICLE B.2. PRICES

- a. The total Firm Fixed Price (FFP) amount for this Letter Contract is \$12,151,000.

Payment Schedule <i>[See complete breakdown in Deliverable Schedule]</i>	
Milestone	Amount
Stage 1 – Test Verification	[***]
Stage 1A – Design Review	[***]
Total	\$12,151,000

ARTICLE B.3. ADVANCE UNDERSTANDINGS

- a. The parties acknowledge and agree that the situation around COVID-19 is highly dynamic, evolving rapidly, and subject to significant uncertainty. The Letter Contract is being executed on an expedited timeline to meet an urgent and compelling government need without the benefit of prior negotiation. Thus, the parties will negotiate in good faith to ensure that the definitized contract reflects an appropriate allocation of risk and responsibility and that it is consistent with the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through Letter Contract issuance. Until the Performance Work Statement (PWS) is finalized the Statement of Objective (SOO) will govern.
- b. The parties anticipate that the definitive contract resulting from this Letter Contract will include a

negotiated firm fixed price not to exceed \$36,834,000. The amount of funding provided for this Letter Contract is stated in Article B.2 above, the contractor shall not incur costs in excess of this amount.

- c. Commercial Item Status: The services provided by the Contractor under the Letter Contract and any definitized contract constitute commercial item services, and the terms of any definitized contract will reflect that understanding.
- d. Performance Work Statement: The parties will negotiate the Performance Work Statement in the process of contract definitization to fairly reflect the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between application submission through letter contract issuance.
- e. HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.
- f. The parties agree prior to negotiate further the terms of milestone payments to include in the definitized contract. In the negotiation, the parties will consider terms addressing liquidation of milestone payments.
- g. Successful performance under this contract requires the Contractor obtain and maintain an Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA); the Contractor shall copy us on all FDA correspondence related to the project, including email communications to and from the FDA. The FDA EUA services provided under this Letter Contract constitute a commercial service to detect SARS-CoV-2.
- h. Fair Pricing: The Rapid Acceleration of Diagnostics (RADx) application review process determined the cost per test is competitive with the current market price. The Contractor must comply with applicable federal law to ensure that prices to consumers are offered at fair market rate and at a rate consistent with the objective to increase and improve testing in the United States and its territories.
- i. In accordance with the goals of the RADx program, the tests produced under this contract are to be sold within the U.S. and its territories; provided, however, that, to the extent there is insufficient demand within the U.S. and its territories for the tests produced up to the additional manufacturing capacity funded by NIH and then available (as described in the Schedule of Deliverables), contractor will be permitted to sell such tests outside the U.S. and its territories. The factors, process and mechanism to determine whether contractor has insufficient demand for the tests up to the then-available capacity will be determined in the definitive contract.
- j. Sharing Data and Reports: The Contractor will be required to provide data and reports (e.g., manufacturing, supply chain, production rates), which NIH will use to evaluate completion or achievement of milestones, progress toward deliverables, and compliance with the requirements of this Letter Contract. NIH may use the data to coordinate with other U.S. Government Agencies to accelerate development and deployment of innovative COVID-19 diagnostic tests, and ensure effective stewardship of federal funds. Sharing data within the federal government enables NIH to discuss the project's challenges and progress with federal agencies offering scientific, manufacturing, and logistics expertise. To ensure that innovations are available to the public as quickly as possible, NIH will leverage

established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, and the Department of Defense, and partnerships with State agencies to propel technologies developed by RADx into widespread use.

- k. Contractor Facilities: The contractor shall certify that they will maintain their Facility and Equipment in satisfactory operating condition, as required to enable the contractor to perform the deliverables and achieve the milestones in accordance with the Statement of Objectives and all other applicable laws, regulations, rules or orders. Routine repairs, preventive maintenance, and service contracts for the Facility and Equipment shall be arranged by contractor at no additional cost to the Government.
- l. FAR 52.212-4 (l), the Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.
- m. Letter Contract Termination: In accordance with FAR 52.212-4(m), the Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.
- n. Security and Privacy of Protected Health Information (PHI) processed under this contract: The Contractor , shall meet the definition of either a Covered Entity or Business Associate under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The contractor shall therefore comply with the HIPAA regulatory standards set forth in the Code of Federal Regulations (CFR) 45 C.F.R. Part 160, Part 162, and Part 164. To the extent that the Contractor engages subcontractors or other Business Associates to provide services under this Contract, and such Subcontractors or Business Associates will receive or create protected health information (PHI) on behalf of the contractor, the contractor shall obtain satisfactory assurances from its business associate that the business associate will appropriately safeguard the protected health information. The satisfactory assurances must be in writing, whether in the form of a contract or other agreement between the Contractor and the business associate. In the event of a suspected or known security or privacy breach, in addition to following the procedures set forth in 45 C.F.R. Part 164, the contractor shall also immediately notify the NIH via the Contracting Officer (CO)and the Contracting Officer's Representative (COR).
- o. The parties agree to address HHS Information Security and Privacy Requirements, as applicable, during definitization of the contract.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF OBJECTIVES

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 Objectives, dated July 27, 2020, set forth in SECTION J – List of Attachments, attached hereto and made a part of this Letter Contract. Work to be performed shall be consistent with the application and preliminary work file submitted by the Contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through Letter Contract issuance.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format only. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: <http://www.hhs.gov/web/508/index.html> under "Making Files Accessible."

Reporting requirements TBD.

Placeholder: De-identified data for NIH research database

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional instructions or specifications applicable to this contract other than the delivery instructions contained herein.

SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized Contracting Officer's Representative (COR) will perform inspection and acceptance of deliverables to be performed and the milestones to be achieved.
- b. Inspection and acceptance will be performed as identified in the contract requirements.

SECTION F - DELIVERIES OR PERFORMANCE ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of the contract is anticipated to be July 30, 2020 through July 29, 2021.

ARTICLE F.2. DELIVERIES

Satisfactory performance shall be deemed to occur upon performance of the work described in the Statement of Objectives Article in SECTION C of this Letter Contract and upon notice and acceptance by the Contracting Officer, or the duly authorized representative, in accordance with the stated deliverables schedule.

The deliverables or documentation there of shall be submitted to the Contracting Officer or designated Contracting Officer Representative (COR).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER (CO)

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

Name: Roxane Burkett
Telephone: 301-827-7535
Email: burkettr@nih.nhlbi.gov

The Contracting Officer is the only person with authority to act as agent of the Government under this task order. 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 reimbursement to the Contractor for any costs incurred during the performance of this contract;
- 5) otherwise change any terms and conditions of this contract; or
- 6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract.

All correspondence (including invoices) that proposes or otherwise involves waivers, deviations, or modifications to requirement shall be provided to the CO issuing the task order and the COR supporting the CO.

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

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

Olga Hartman, PhD
Telephone: 443-350-7696
Email: olga.hartman.civ@mail.mil

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) interpreting the Statement of Objectives and any other technical performance requirements;
- (3) performing technical evaluation as required;
- (4) performing technical inspections and acceptances required by this Letter Contract; and
- (5) assisting in the resolution of technical problems encountered during performance.

The Government may unilaterally change the COR designation.

ARTICLE G.3. PRIMARY PROGRAM MANAGER

The Primary Program Manager specified in this task order is considered to be essential to work performance. At least 30 days prior to any changes to the individual listed below to other programs or task orders (or as soon as reasonably 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 change request (including proposed substitutions for primary program manager) to permit evaluation by the Government of the impact on performance under this task order. The Contractor shall not replace any primary program manager without the written consent of the Contracting Officer. The Government may modify the task order to add or delete primary program manager at the request of the contractor or Government. In no case shall the individual's effort exceed 100% across all task orders.

[***]

[***]

ARTICLE G.4. INVOICE SUBMISSION

In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all task order payment requests:

- a. The Contract Title is: "Rapid Acceleration of Diagnostics (RADx) Program: Tech Project # 6114 Fluidigm – Advanta Dx SARS-CoV-2 RT-PCR Assay for Saliva"
 - b. The Contract Line Items are defined within the Section 20. Schedule of Supplies/Services of the Standard Form 1449.
 - c. Invoice Instructions are attached and made part of this task order. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.
1. Payment requests shall be submitted to the offices identified below. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.
 - a. One copy of the invoice shall be submitted to the approving official at the following email addresses:
NHLBI Branch B Central Mailbox (NHLBIContractsBranchB@mail.nih.gov)

NIH centralized invoice email box: invoicing@nih.gov
 2. E-Mail: 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.
 3. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests (invoices):
 - a. Name of the Office of Acquisitions. The Office of Acquisitions for this task order is **NHLBI**.
 - b. Central Point of Distribution. For the purpose of this Task Order, the Central Point of Distribution is **NHLBI Branch B Invoices**.
 - c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is*

assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.] If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

- d. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
- e. Invoice Matching Option. This Task Order requires a **two-way** match.
- f. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.
- g. PRISM/NBS Line Item Number and associated PRISM/NBS Line Item Period of Performance (see SF 1449, Attachment #2).

(d) Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6088.

SECTION H - ADDITIONAL CONTRACT CLAUSES

ARTICLE H.1. CONFIDENTIALITY OF INFORMATION

- a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.
- b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
- c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
- d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.
- e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination

from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

- f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.
- g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ARTICLE H.2. PUBLICATION AND PUBLICITY

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, the Contractor shall acknowledge the support of the National Institutes of Health 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 National Institutes of Health, Department of Health and Human Services, under Contract No: 75N92020C00009."

ARTICLE H.3. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to 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 website to file a complaint on-line is: <http://oig.hhs.gov/fraud/hotline/> and the mailing address is:

US Department of Health and Human Services Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489 Washington, D.C. 20026

PART II - CONTRACT CLAUSES SECTION I - CONTRACT CLAUSES

Selections will be made by the Contracting Officer during definitization

ARTICLE I.1. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, (unless otherwise noted), 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.

- a. FAR Clause 52.212-3 Offeror Representations and Certifications – Commercial Items (Jun 2020)
- a. FAR Clause 52.212-4 Contract Terms and Conditions – Commercial Items (Oct 2018)
- b. FAR Clause 52.203-13, Contractor Code of Business Ethics and Conduct (October 2015)
- c. FAR Clause 52.204-2, Security Requirements (August 1996).
- d. FAR Clause 52.204-9, Personal Identity Verification of Contractor Personnel (January 2011).
- e. FAR Clause 52.204-13, System for Award Management Maintenance
- f. FAR Clause 52.204-18 Commercial and Government Entity Code Maintenance (July 2016)
- g. FAR Clause 52.204-23 Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities

- h. FAR Clause 52.209-10, Prohibition on Contracting With Inverted Domestic Corporations(November 2015).
- i. FAR Clause 52.222-4, Contract Work Hours and Safety Standards - Overtime Compensation -General (May 2014).
- j. FAR Clause 52.222-29, Notification of Visa Denial (April 2015).
- k. FAR Clause 52.223-15, Energy Efficiency in Energy-Consuming Products (December 2007).
- l. FAR Clause 52.224-1, Privacy Act Notification (April 1984).
- m. FAR Clause 52.224-2, Privacy Act (April 1984).
- n. FAR Clause 52.227-1, Authorization and Consent (Jun 2020).
- o. FAR Clause 52.227-3 Patent Indemnity (Apr 1984).
- p. FAR Claus 52.227-11 Patent Rights-Ownership by the Contractor (May 2014).
- q. FAR Clause 52.227-14, Rights in Data - General (May 2014).
- r. FAR Clause 52.227-14, Rights in Data - General (May 2014) Alternate II (Dec 2007).
- s. FAR Clause 52.232-40, Providing Accelerated Payments to Small Business Subcontractors (Dec 2013)

ARTICLE I.3. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during definitization. This contract incorporates the following clauses in full text.

1. FAR 52.216-23 - EXECUTION AND COMMENCMENT OF WORK (APR 1984)

The Contractor shall indicate acceptance of this letter contract by signing One Copy of the contract and returning them to the Contracting Officer not later than July 29, 2020 at 4:00 p.m. Eastern. Upon acceptance by both parties, the Contractor shall proceed with performance of the work, including purchase of necessary materials.

2. FAR 52.216-24 - LIMITATION OF GOVERNMENT LIABILITY (APR 1984)

- (a) In performing this contract, the Contractor is not authorized to make expenditures or incur obligations exceeding \$12,151,000 dollars.
- (b) The maximum amount for which the Government shall be liable if this contract is terminated is \$12,151,000 dollars.

3. FAR 52.216-25 - CONTRACT DEFINITIZATION (OCT 2010)

(a) A Firm Fixed Price (FFP) definitive contract is contemplated. The Contractor agrees to begin promptly negotiating with the Contracting Officer the terms of a definitive contract that will include (1) all clauses required by the Federal Acquisition Regulation (FAR) on the date of execution of the letter contract, (2) all clauses required by law on the date of execution of the definitive contract, and (3) any other mutually agreeable clauses, terms, and conditions. The Contractor agrees to submit a Firm Fixed Price proposal, including data other than certified cost or pricing data, and certified cost or pricing data, in accordance with FAR 15.408, Table 15-2, supporting its proposal.

- (b) The schedule for definitizing this contract is as follows:
 Estimated date for start of negotiations: 8/3/2020
 Target date for definitization: 9/25/2020

Definitization Schedule	Date
Statement of Work Review	7/27/2020

Issuance of Letter Contract	7/30/2020
Letter Contract Post Award Kick Off meeting	7/31/2020
Contractor Price Proposal Submittal	8/5/2020
Business and Technical Review	8/12/2020
Negotiations Start	8/13/2020
Request Budget and Price Breakdown	9/7/2020
Definitization of Letter Contract	9/25/2020

(c) If agreement on a definitive contract to supersede this letter contract is not reached by the target date in paragraph (b) of this section, or within any extension of it granted by the Contracting Officer, the Contracting Officer may, with the approval of the head of the contracting activity, determine a reasonable price or fee in accordance with subpart 15.4 and part 31 of the FAR, subject to Contractor appeal as provided in the Disputes clause. In any event, the Contractor shall proceed with completion of the contract, subject only to the Limitation of Government Liability clause.

(1) After the Contracting Officer's determination of price or fee, the contract shall be governed by-

- (i) All clauses required by the FAR on the date of execution of this letter contract for either fixed-price or cost-reimbursement contracts, as determined by the Contracting Officer under this paragraph (c);
- (ii) All clauses required by law as of the date of the Contracting Officer's determination; and
- (iii) Any other clauses, terms, and conditions mutually agreed upon.

(2) To the extent consistent with paragraph (c)(1) of this section, all clauses, terms, and conditions included in this letter contract shall continue in effect, except those that by their nature apply only to a letter contract.

4. FAR Clause 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 websites) 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)

5. FAR 52.214-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items (Jul 2020)

- (a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:
- (1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).
 - (2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).
 - (3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).
 - (4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).
 - (5) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).
 - (6) 52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items. Selections will be made by the Contracting Officer during definitization:

- ___ (1) [52.203-6](#), Restrictions on Subcontractor Sales to the Government (June 2020), with *Alternate I* (Oct 1995) ([41 U.S.C. 4704](#) and [10 U.S.C. 2402](#)).
- ___ (2) [52.203-13](#), Contractor Code of Business Ethics and Conduct (Jun 2020) ([41 U.S.C. 3509](#)).
- ___ (3) [52.203-15](#), Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (Jun 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)
- ___ (4) [52.204-10](#), Reporting Executive Compensation and First-Tier Subcontract Awards (Jun 2020) (Pub. L. 109-282) ([31 U.S.C. 6101 note](#)).
- ___ (5) [Reserved].
- ___ (6) [52.204-14](#), Service Contract Reporting Requirements (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).
- ___ (7) [52.204-15](#), Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).
- ___ (8) [52.209-6](#), Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Jun 2020) ([31 U.S.C. 6101 note](#)).
- ___ (9) [52.209-9](#), Updates of Publicly Available Information Regarding Responsibility Matters (Oct 2018) ([41 U.S.C. 2313](#)).
- ___ (10) [Reserved].
- ___ (11) (i) [52.219-3](#), Notice of HUBZone Set-Aside or Sole-Source Award (Mar 2020) ([15 U.S.C. 657a](#)).
___ (ii) Alternate I (Mar 2020) of [52.219-3](#).
- ___ (12) (i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Mar 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).
___ (ii) Alternate I (Mar 2020) of 52.219-4.
- ___ (13) [Reserved]
- ___ (14) (i) 52.219-6, Notice of Total Small Business Set-Aside (Mar 2020) of 52.219-6 (15 U.S.C. 644).
___ (ii) Alternate I (Mar 2020) of [52.219-6](#) .
- ___ (15) (i) 52.219-7, Notice of Partial Small Business Set-Aside (Mar 2020) (15 U.S.C. 644).
___ (ii) Alternate I (Mar 2020) of [52.219-7](#).
- ___ (16) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).
- ___ (17) (i) 52.219-9, Small Business Subcontracting Plan (Jun 2020) (15 U.S.C. 637(d)(4)).
___ (ii) Alternate I (Nov 2016) of 52.219-9.
___ (iii) Alternate II (Nov 2016) of 52.219-9.
___ (iv) Alternate III (Jun 2020) of 52.219-9.
___ (v) Alternate IV (Jun 2020) of 52.219-9
- ___ (18) (i) 52.219-13, Notice of Set-Aside of Orders (Mar 2020) (15 U.S.C. 644(r)).
___ (ii) Alternate I (Mar 2020) of [52.219-13](#).
- ___ (19) 52.219-14, Limitations on Subcontracting (Mar 2020) (15 U.S.C. 637(a)(14)).
- ___ (20) 52.219-16, Liquidated Damages-Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
- ___ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Mar

2020) (15 U.S.C. 657f).

- ___ (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (May 2020) (15 U.S.C. 632(a)(2)).
- ___ (ii) Alternate I (MAR 2020) of 52.219-28.
- ___ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Mar 2020) (15 U.S.C. 637(m)).
- ___ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Mar2020) (15 U.S.C. 637(m)).
- ___ (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (Mar 2020)(15 U.S.C. 644(r)).
- ___ (26) 52.219-33, Nonmanufacturer Rule (Mar 2020) (15U.S.C. 637(a)(17)).
- ___ (27) 52.222-3, Convict Labor (Jun 2003) (E.O.11755).
- ___ (28) 52.222-19, Child Labor- Cooperation with Authorities and Remedies (Jan2020) (E.O.13126)
- ___ (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
- ___ (30) (i) [52.222-26](#), Equal Opportunity (Sep 2016) (E.O.11246).
- ___ (ii) Alternate I (Feb 1999) of [52.222-26](#).
- ___ (31) (i) [52.222-35](#), Equal Opportunity for Veterans (Jun 2020) ([38 U.S.C. 4212](#)).
- ___ (ii) Alternate I (Jul 2014) of [52.222-35](#).
- ___ (32) (i) [52.222-36](#), Equal Opportunity for Workers with Disabilities (Jun 2020) ([29 U.S.C. 793](#)).
- ___ (ii) Alternate I (Jul 2014) of [52.222-36](#).
- ___ (33) [52.222-37](#), Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).
- ___ (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
- ___ (35) (i) 52.222-50, Combating Trafficking in Persons (Jan 2019) ([22 U.S.C. chapter 78](#) and E.O. 13627).
- ___ (ii) Alternate I (Mar 2015) of [52.222-50](#) ([22 U.S.C. chapter 78](#) and E.O. 13627).
- ___ (36) [52.222-54](#), Employment Eligibility Verification (Oct 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in [22.1803](#).)
- ___ (37) (i) [52.223-9](#), Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) ([42 U.S.C. 6962\(c\)\(3\)\(A\)\(ii\)](#)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- ___ (ii) Alternate I (May 2008) of [52.223-9](#) ([42 U.S.C. 6962\(i\)\(2\)\(C\)](#)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- ___ (38) [52.223-11](#), Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).
- ___ (39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).
- ___ (40) (i) 52.223-13, Acquisition of EPEAT®-Registered Imaging Equipment (Jun 2014) (E.O.s 13423 and 13514).
- ___ (ii) Alternate I (Oct 2015) of [52.223-13](#).
- ___ (41) (i) [52.223-14](#), Acquisition of EPEAT®-Registered Televisions (Jun 2014) (E.O.s 13423 and 13514).
- ___ (ii) Alternate I (Jun2014) of [52.223-14](#).
- ___ (42) [52.223-15](#), Energy Efficiency in Energy-Consuming Products (May 2020) (42 U.S.C. 8259b).

- ___ (43) (i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (Oct 2015) (E.O.s 13423 and 13514).
 - ___ (ii) Alternate I (Jun 2014) of [52.223-16](#).
 - ___ (44) [52.223-18](#), Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020) (E.O. 13513).
 - ___ (45) 52.223-20, Aerosols (Jun 2016) (E.O. 13693).
 - ___ (46) 52.223-21, Foams (Jun2016) (E.O. 13693).
 - ___ (47) (i) 52.224-3 Privacy Training (Jan 2017) (5 U.S.C. 552 a).
 - ___ (ii) Alternate I (Jan 2017) of [52.224-3](#).
 - ___ (48) [52.225-1](#), Buy American-Supplies (May 2014) (41 U.S.C. chapter 83).
 - ___ (49) (i) 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act (May 2014) (41 U.S.C.chapter83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43).
 - ___ (ii) Alternate I (May 2014) of 52.225-3.
 - ___ (iii) Alternate II (May 2014) of 52.225-3.
 - ___ (iv) Alternate III (May 2014) of [52.225-3](#).
 - ___ (50) [52.225-5](#), Trade Agreements (Oct 2019) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).
 - ___ (51) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
 - ___ (52) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302Note).
 - ___ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov2007) (42 U.S.C. 5150).
 - ___ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov2007) (42 U.S.C. 5150).
 - ___ (55) 52.229-12, Tax on Certain Foreign Procurements (Jun 2020).
 - ___ (56) [52.232-29](#), Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
 - ___ (57) 52.232-30, Installment Payments for Commercial Items (Jan2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f))
 - ___ (58) 52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct2018) (31 U.S.C. 3332).
 - ___ (59) 52.232-34, Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).
 - ___ (60) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).
 - ___ (61) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).
 - ___ (62) 52.242-5, Payments to Small Business Subcontractors (Jan 2017) (15 U.S.C. 637(d)(13)).
 - ___ (63) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) ([46 U.S.C. Appx. 1241\(b\)](#) and [10 U.S.C. 2631](#)).
 - ___ (ii) Alternate I (Apr 2003) of 52.247-64.
 - ___ (iii) Alternate II (Feb 2006) of [52.247-64](#).
- (c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:
- ___ (1) [52.222-41](#), Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter67).
 - ___ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (May

2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

- ___ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (Aug 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
- ___ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (May 2014) (29U.S.C.206 and 41 U.S.C. chapter 67).
- ___ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) (41 U.S.C. chapter 67).
- ___ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) (41 U.S.C. chapter 67).
- ___ (7) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).
- ___ (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
- ___ (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) ([42 U.S.C. 1792](#)).

- (d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR 2.101, on the date of award of this contract, and does not contain the clause at 52.215-2, Audit and Records-Negotiation.
- (1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.
 - (2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.
 - (3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.
- (e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-
- (i) [52.203-13](#), Contractor Code of Business Ethics and Conduct (Jun 2020) ([41 U.S.C. 3509](#)).
 - (ii) [52.203-19](#), Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

- (iii) [52.204-23](#), Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).
 - (iv) [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).
 - (v) [52.219-8](#), Utilization of Small Business Concerns (Oct 2018) ([15 U.S.C. 637\(d\)\(2\)](#) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR [19.702\(a\)](#) on the date of subcontract award, the subcontractor must include [52.219-8](#) in lower tier subcontracts that offer subcontracting opportunities.
 - (vi) [52.222-21](#), Prohibition of Segregated Facilities (Apr 2015).
 - (vii) [52.222-26](#), Equal Opportunity (Sep 2015) (E.O.11246).
 - (viii) [52.222-35](#), Equal Opportunity for Veterans (Jun 2020) ([38 U.S.C. 4212](#)).
 - (ix) [52.222-36](#), Equal Opportunity for Workers with Disabilities (Jun 2020) ([29 U.S.C. 793](#)).
 - (x) [52.222-37](#), Employment Reports on Veterans (Jun 2020) ([38 U.S.C. 4212](#)).
 - (xi) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
Flow down required in accordance with paragraph (f) of FAR clause [52.222-40](#).
 - (xii) [52.222-41](#), Service Contract Labor Standards (Aug2018) ([41 U.S.C. chapter 67](#)).
 - (xiii) (A) [52.222-50](#), Combating Trafficking in Persons (Jan 2019) ([22 U.S.C. chapter 78](#) and E.O 13627).
(B) Alternate I (Mar2015) of [52.222-50](#) ([22 U.S.C. chapter 78](#) and [E.O. 13627](#)).
 - (xiv) [52.222-51](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May2014) ([41 U.S.C. chapter 67](#)).
 - (xv) [52.222-53](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May2014) ([41 U.S.C. chapter 67](#)).
 - (xvi) [52.222-54](#), Employment Eligibility Verification (Oct 2015) (E.O. 12989).
 - (xvii) [52.222-55](#), Minimum Wages Under Executive Order 13658 (Dec 2015).
 - (xviii) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
 - (xix) (A) [52.224-3](#), Privacy Training (Jan 2017) ([5 U.S.C. 552a](#)).
(B) Alternate I (Jan 2017) of 52.224-3.
 - (xx) [52.225-26](#), Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
 - (xxi) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
 - (xxii) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.
- (2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J LIST OF ATTACHMENTS

1. Statement of Objectives
 - i. Appendix 1: Contract Deliverables

Contract number: 75N92020C00009

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Statement of Objectives

Program Title: Rapid Acceleration of Diagnostics (RADx) – Tech

Project Title: Rapid Acceleration of Diagnostics (RADx) Program: Tech Project # 6114 Fluidigm – Advanta Dx SARS-CoV-2RT-PCR Assay for Saliva

Agency: National Institute of Biomedical Imaging and Bioengineering (NIBIB) / National Institutes of Health (NIH)

1. Background

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) has a requirement for proposals to provide up to \$500 million across multiple projects to rapidly produce innovative SARS-CoV-2 diagnostic tests that will assist the public's safe return to normal activities. Rapid Acceleration of Diagnostics (RADx), is a fast-track technology development program that leverages the National Institutes of Health (NIH) Point-of-Care Technology Research Network (POCTRN). RADx will support novel solutions that build the U.S. capacity for SARS-CoV-2 testing up to 100-fold above what is achievable with standard approaches. RADx is structured to deliver innovative testing strategies to the public as soon as late summer 2020 and is an accelerated and comprehensive multi-pronged effort by NIH to make SARS-CoV-2 testing readily available to every American.

2. Purpose and Objectives

NIBIB is providing substantial support to accelerate the development, validation, and commercialization of innovative point-of-care and home-based tests, as well as improvements to clinical laboratory tests, that can directly detect SARS-CoV-2, the virus that causes COVID-19. NIBIB will support the full range of product development including commercialization and product distribution. The ultimate goal of the RADx program

– across multiple projects/contracts – is to make millions of tests per week available to the American public, particularly those most vulnerable to and/or disproportionately impacted by COVID-19, in the late summer of 2020, and having even more tests available in time for the 2020–2021 flu season.

To meet the accelerated timelines, RADx has assembled a national network of expert technical, clinical, manufacturing, and regulatory advisors who will provide individualized assistance for project development and commercialization. Funding for projects selected for this program will be dependent on successfully meeting aggressive project milestones. Through the POCTRN grants, NIBIB provides financial and in-kind support to accelerate the entire product life-cycle, from design to market, for projects that meet milestones successfully. To ensure that innovations are available to the public as quickly as possible, NIH will leverage established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, the Department of Defense, as well as commercial and private entities to propel technologies developed by RADx into widespread use.

The RADx program will consider innovations at all stages of readiness to circumvent current limitations to SARS-CoV-2 testing capacity, including:

- Early stage: transformative innovations based on novel testing strategies that have potential for major scale up
- Mid stage: technologies using novel testing strategies that have demonstrated capability but need further validation, regulatory approval, and scale up
- Advanced stage (RADx ATP): modification and optimization of existing SARS-CoV-2 testing approaches, including clinical laboratory tests, that can dramatically increase testing capacity. Note: This arm of the RADx program is addressed under separate Acquisition Plan.

Design features might include technical innovations that:

- Improve analytical performance, e.g., sensitivity, specificity, dynamic range, limit of detection, reliability, accuracy, speed (time to test result) and throughput
- Enhance operational performance through, e.g., development of a patient- and user-friendly design, use of alternative sampling strategies (e.g., saliva, exhaled breath), integration with mobile-devices, designs for home-based use or strategies to overcome bottlenecks with current testing approaches
- Improve access and reduce the cost of testing.

3. Scope

RADx-Tech is a two-phase program. All applications undergo an intensive week-long risk assessment by a panel of expert technical, clinical, manufacturing, and regulatory advisors. If the proposed technology meets viability metrics, projects may be selected to enter phase one.

Phase one, performed under separate funding mechanism, consists of an accelerated research and development program in which the awardee receives both financial support and in-kind services through RADx grant funding. This outcome of this work is a fully instantiated technology ready for clinical validation, regulatory authorization, production and commercialization.

Phase two, or Work Package 2, of the program, executed under this contract, includes completing the validation, approval, and production processes in order to deliver a viable product in a scaled up capacity to the U.S. public.

4. Performance Objectives (Required Results)

- A. Contract recipients have completed major research and development efforts and are focused in phase two on completion of required clinical validation, preparation of regulatory submissions, scale-up of production capabilities, and preparation for full commercialization of their product – a testing technology. Every contract will encompass similar expectations and milestones concerned with:
 - 1. meeting regulatory requirements, resulting in regulatory authorization for sale and use of the test;
 - 2. instantiation of agreed-upon production capacity;
 - 3. meeting agreed-upon production goals; and
 - 4. implementation of an agreed-upon commercial strategy to bring the test to market in a timeframe that will impact the COVID-19 pandemic as soon as possible.
- B. Contract funding in phase two is structured in order to reduce risk to the Government, and is dependent on achievement of specific milestones in the Schedule of Deliverables, according to the Payment Schedule.
- C. The contractor must use a SARS-Cov-2 test with FDA EUA (or will have EUA near the time of award), indicating a combination of sensitivity, specificity, and usability appropriate to the intended use according to FDA and/or CDC guidance, as applicable.
- D. The contractor must make the product available for a confidential independent regulatory/validation assessment. The independent assessor will be selected by the Government and specified in the contract.
- E. The contractor must provide a risk mitigation plan for each identified risk and update and inform

NIH on any changes/newly identified risks in an ongoing manner.

5. Contract Type

The contract type is Firm Fixed Price.

6. Place of Performance

Place of Performance will be at the contractor's site(s).

7. Period of Performance

The period of performance of the contract is anticipated to be July 30, 2020 through July 29, 2021.

8. Deliverables/Delivery Schedule

See the attached Appendix 1: Schedule of Deliverables.

9. Other Requirements

- A. The contractor must meet regularly (at least weekly) with NIH officials to update on progress toward deliverables; anticipated and ongoing issues and problems; and timelines for deliverable completion. When guided by NIH officials, the contractor must be willing to collaborate and cooperate under reasonable confidentiality terms with external organizations as needed to meet the contract goals in a manner which will not infringe contractor commercial or intellectual property rights.

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.

Appendix 1 - Deliverables

No.	Objective Defined	Milestone Defined	Deliverable	Success Criteria	Est. Deliverable Due Date	Stage
1	[***]	[***]	[***]	[***]	[***]	1
2	[***]	[***]	[***]	[***]	[***]	2
3	[***]	[***]	[***]	[***]	[***]	3
4	[***]	[***]	[***]	[***]	[***]	3
5	[***]	[***]	[***]	[***]	[***]	4
6	[***]	[***]	[***]	[***]	[***]	4
7	[***]	[***]	[***]	[***]	[***]	5
8	[***]	[***]	[***]	[***]	[***]	5

SubTasks

No.	Objective Defined	Milestone Defined	Deliverable	Success Criteria	Est. Deliverable Due Date	Stage
A	[***]	[***]	[***]	[***]	[***]	1A
B **	[***]	[***]	[***]	[***]	[***]	1A
C	[***]	[***]	[***]	[***]	[***]	2A

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE	PAGE OF PAGES 1 / 34
2. AMENDMENT/MODIFICATION NO. P00001	3. EFFECTIVE DATE 09/25/2020	4. REQUISITION/PURCHASE REQ. NO. 5830960	5. PROJECT NO. (If applicable)	
6. ISSUED BY CODE National Institutes of Health National Heart, Lung, and Blood Institute Bethesda, MD 20892-7511	NHLBI	7. ADMINISTERED BY (If other than item 6) CODE National Institutes of Health National Institute of Biomedical Imaging and Bioengineering Bethesda, MD 20892-7511		NIBIB
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) FLUIDIGM CORPORATION:1157584 2 TOWER PLACE SUITE 2000 SOUTH SAN FRANCISCO CA 940801826		(x)	9A. AMENDMENT OF SOLICITATION NO.	
CODE			9B. DATED (SEE ITEM 11)	
FACILITY CODE		X	10A. MODIFICATION OF CONTRACT/ORDER NO. 75N92020C00009	
			10B. (SEE ITEM 13) 07/30/2020	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

12. ACCOUNTING AND APPROPRIATION DATA (If required) Net Increase: \$21,865,056.00

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

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	OTHER (Specify type of modification and authority)
X	FAR 52.216-25 – Contract Definitization

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

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
TITLE: RADx Tech Project # 6114 Fluidigm Corporation, Inc. "Advanta Dx SARS-CoV-2 RT-PCR Assay for Saliva"

PURPOSE: To definitize the letter contract.
Delivery Location Code: TDP, BTHOFF
Two Democracy Plaza, Bethesda Off C
2 Democracy Plaza
6707 Democracy Blvd
Bethesda MD 20817 US

Continued ...

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

15A. NAME AND TITLE OF SIGNER (Type or print) Andrew Quong, Chief Science Officer		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) ROXANE S. BURKETT	
15B. CONTRACTOR/OFFEROR /s/ Andrew Quong (Signature of person authorized to sign)	Digitally signed by Andrew Quong Date: 2020.09.28 13:10:54 -07'00'	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA /s/ Roxane S. Burkett -S (Signature of Contracting Officer!)
			Digitally signed by Roxane S. Burkett -S Date: 2020.09.28 17:34:18 -04'00'
			16C. DATE SIGNED

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED 75N92020C00009/P00001	PAGE OF 2 / 34
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NAME OF OFFEROR OR CONTRACTOR
FLUIDIGM CORPORATION:1157584

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
3	Payment: Approved By, NHLBI Branch A Invoice Paid By: NIH Commercial Accounts Br 2115 East Jefferson St, MSC 8500 Room 4B-432 Bethesda, MD 20892-8500 Period of Performance: [***] Add Item 3 as follows: Operation established - Phase I Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***]				[***]
4	Add Item 4 as follows: Submit FDA EUA Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***]				[***]
5	Add Item 5 as follows: Clinical Samples Obligated Amount: [***] Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***]				[***]
6	Add Item 6 as follows: Facility Construction Initiated Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Continued ...				[***]

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
75N92020C00009/P00001

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3 / 34

NAME OF OFFEROR OR CONTRACTOR
FLUIDIGM CORPORATION:1157584

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
7	Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***] Add Item 7 as follows: Additional Production Lines Initiated Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***] Add Item 8 as follows:				[***]
8	Full production capacity on all 3 lines. Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***]				[***]

PART I – THE SCHEDULE

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SERVICES

This contract is part of the Rapid Acceleration of Diagnostics (RADx) Tech program which is structured to deliver innovative testing strategies to the public and is an accelerated and comprehensive multi-pronged effort by NIH to make SARS-CoV-2 testing readily available to every American. The scope of work executed under this contract includes completing the validation, approval, and production processes in order to deliver a viable product in a scaled-up capacity to the U.S. public. Fluidigm technology to support this effort will be to scale up the Integrated Fluidic Circuit (IFC) and completion of the multiplex assay development system for rapid acceleration of testing.

ARTICLE B.2. PRICES

a. The total Firm Fixed Price (FFP) amount for this contract is \$34,016,056.

Prism Line Item	Milestone	Description	Date	Amount
1	1	Stage 1 Test Verification - [***]	[***]	[***]
2	A1	Stage 1A- Design Review - [***]	[***]	[***]
3	2	Operation established - Phase I - [***]	[***]	[***]
4	A2	Submit FDA EUA - [***]	[***]	[***]
5	A3	Clinical samples – [***]	[***]	[***]
6	3	Facility Construction Initiated - [***]	[***]	[***]
7	4	Additional Production Lines Initiated - [***]	[***]	[***]

8	5	Full production capacity on all 3 lines - [***]	[***]	[***]
	Total			\$34,016,056

ARTICLE B.3. ADVANCE UNDERSTANDINGS

- a. Commercial Item Status: The services provided by the Contractor under this definitized contract constitutes commercial item services.
- b. HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.
- c. Liquidated Damages – Milestone-Based Payments
 If the Contractor fails to deliver the supplies or perform the services within the time specified in this contract, and fails to cure within the time specified by the Government and the Government terminates this contract in whole or in part for cause, the Contractor shall, in place of actual damages, pay to the Government liquidated damages in the amount of 33% of the amount(s) already disbursed to date under the contract. Any liquidated damaged owed by the Contractor shall be paid to the Government no later than 6 months from the date of termination.

 The Contractor will not be charged with liquidated damages when the delay in delivery or performance is beyond the control and without the fault or negligence of the Contractor as defined in FAR Clause 52.212-4, Contract Terms and Conditions- Commercial Items, incorporated in this contract.
- d. Successful performance under this contract requires the Contractor obtain and maintain an Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA); the Contractor shall copy us on all FDA correspondence related to the project, including email communications to and from the FDA. The FDA EUA services provided under this Contract constitute a commercial service to detect SARS-CoV-2.
- e. Fair Pricing: The Rapid Acceleration of Diagnostics (RADx) application review process determined the cost per test is competitive with the current market price. The Contractor must comply with applicable federal law to ensure that prices to consumers are offered at fair market rate and at a rate consistent with the objective to increase and improve testing in the United States.

- f. Security and Privacy of Protected Health Information (PHI) processed under this contract: In the event the Contractor meets the definition of either a Covered Entity or Business Associate under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Contractor shall comply with the HIPAA regulatory standards set forth in the Code of Federal Regulations (CFR) 45 C.F.R. Part 160, Part 162, and Part 164. To the extent that the Contractor engages subcontractors or other Business Associates to provide services under this Contract, and such Subcontractors or Business Associates will receive or create protected health information (PHI) on behalf of the contractor, the contractor shall obtain satisfactory assurances from its business associate that the business associate will appropriately safeguard the protected health information. The satisfactory assurances must be in writing, whether in the form of a contract or other agreement between the Contractor and the business associate. In the event of a suspected or known security or privacy breach, in addition to following the procedures set forth in 45 C.F.R. Part 164, the contractor shall also immediately notify the NIH via the Contracting Officer (CO) and the Contracting Officer's Representative (COR).
- g. Sharing Data and Reports: The Contractor will be required to provide data and reports (e.g., manufacturing, supply chain, production rates), which NIH will use to evaluate completion or achievement of milestones, progress toward deliverables, and compliance with the requirements of this contract. NIH may use the data to coordinate with other U.S. Government Agencies to accelerate development and deployment of innovative COVID-19 diagnostic tests, and ensure effective stewardship of federal funds. The reports and data shall not be disclosed outside of the U.S. Government. Sharing data within the federal government enables NIH to discuss the project's challenges and progress with federal agencies offering scientific, manufacturing, and logistics expertise. To ensure that innovations are available to the public as quickly as possible, NIH will leverage established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, and the Department of Defense, and partnerships with State agencies to propel technologies developed by RADx into widespread use.
- h. Contractor Facilities: The contractor shall certify that they will maintain their Facility and Equipment in satisfactory operating condition, as required to enable the contractor to perform the deliverables and achieve the milestones in accordance with the Statement of Objectives and all other applicable laws, regulations, rules or orders. Routine repairs, preventive maintenance, and service contracts for the Facility and Equipment beyond that accounted for in the contract shall be arranged by contractor at no additional cost to the Government.
- i. The novel coronavirus (COVID-19) pandemic has introduced new cybersecurity risks both at the NIH and across the globe. NIH and NIBIB recognize that the high profile nature of the RADx response may attract the attention of highly motivated malicious actors and want vendors to understand that the risks are real and there is a strong interest in protecting the valued work being conducted through these contracts. NIH and NIBIB are asking vendors to consider their current security posture and to make all reasonable efforts to protect their environment, information technology, and the products that are being produced. NIST Special Publication 800-171 can be a useful tool or measuring stick to understand your current security posture as it relates to government computer security standards. Templates can be found at <https://csrc.nist.gov/publications/detail/sp/800-171/rev-2/final>.
- j. Contract Termination: In accordance with FAR 52.212-4 (l) Termination for the Government's convenience. The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work.

Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

- k. **Contract Termination:** In accordance with FAR 52.212-4(m), the Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.
- l. Any imported materials must be FDA-approved for use in the U.S.
- m. In accordance with the goals of the RADx program, during the Period of Performance (as defined below) the tests manufactured under this contract are to be sold within the U.S. and its territories; provided, however, that, to the extent there is insufficient demand within the U.S. and its territories for the tests produced up to the additional manufacturing capacity funded by NIH and then available (as described in the Schedule of Deliverables), contractor will be permitted to sell such tests outside the U.S. and its territories. The factors, process and mechanism to determine whether contractor has insufficient demand for the tests up to the then-available capacity will be determined on a case by case basis and with approval of the Contracting Officer.
- n. Purchase of clinical samples is permitted under this contract and identified as a separate line item. If samples are not purchased this line item will not be billed against and therefore deobligated from the contract.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF OBJECTIVES

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 Objectives, dated July 27, 2020 and the Performance Work Statement (PWS) dated August 31, 2020, set forth in SECTION J – List of Attachments, attached hereto and made a part of this Contract. Work to be performed shall be consistent with the application and preliminary work file submitted by the Contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through contract award.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format only. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: <http://www.hhs.gov/web/508/index.html> under "Making Files Accessible."

The following reporting requirements shall be submitted electronically to the Contracting Officer and Contracting Officer's Representative in accordance with the due dates specified below:

Item No.	Reporting Requirements	Due Date
1	Bi-weekly Production Status Report – to include the following: <ul style="list-style-type: none"> • current plant production capacity and output on a per-week basis, • a breakdown of capacity and output on a per-line/per week basis, • a description of any issues/problems encountered with plans for solution/mitigation (e.g., delays in meeting deliverables, supply chain issues, design/validation issues, etc.) • sales reporting to include the name and kind of organization, as well as the number of IFCs sold to that organization during the reporting period. Sales reports may be submitted in every other bi-weekly report (i.e. monthly). 	[***]
2	Final Report - Summary of salient results of the entire contract period, including number of lines built, production capacity over time, production output over time, and a summary of the sales reports. It shall include evidence of sustained production at capacity levels or higher assuming demand has not decreased.	[***]

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional instructions or specifications applicable to this contract other than the delivery instructions contained herein.

SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized Contracting Officer's Representative (COR) will perform inspection and acceptance of deliverables to be performed and the milestones to be achieved.

b. Inspection and acceptance will be performed utilizing the success criteria outlined in the deliverable schedule.

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of the contract is [***].

ARTICLE F.2. DELIVERIES

Satisfactory performance shall be deemed to occur upon performance of the work described in the Statement of Objectives Article in SECTION C of this Contract and upon notice and acceptance by the Contracting Officer, or the duly authorized representative, in accordance with the stated deliverables schedule as listed in the Performance Work Statement (PWS) (See Attachment 2).

The deliverables or documentation shall be submitted to the Contracting Officer and designated Contracting Officer Representative (COR) by email.

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER (CO)

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

Name: Roxane Burkett
Telephone: 301.827.7535
Email: burkettr@nhlbi.nih.gov

The Contracting Officer is the only person with 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 Objectives or Performance Work Statement;
- 2) modify or extend the period of performance;
- 3) change the deliverables or milestones schedule;
- 4) authorize reimbursement to the Contractor for any costs incurred during the performance of this Contract;
- 5) otherwise change any terms and conditions of this Contract;

All correspondence (including invoices) that proposes or otherwise involves waivers, deviations, or modifications to requirement shall be provided to the CO issuing this Contract and the COR supporting the CO.

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

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

Olga Hartman, PhD
Telephone: 443-350-7696
Email: olga.hartman.civ@mail.mil

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) interpreting the Statement of Objectives 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 the COR designation.

ARTICLE G.3. PRIMARY PROGRAM MANAGER

The Primary Program Manager specified in this contract is considered to be essential to work performance. At least 30 days prior to any changes to the individual listed below to other programs or contracts (or as soon as reasonably 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 change request (including proposed substitutions for primary program manager) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not replace any primary program manager without the written consent of the Contracting Officer. The Government may modify the contract to add or delete primary program manager at the request of the Contractor or Government. In no case shall the individual's effort exceed 100% across all contracts.

[***]

[***]

ARTICLE G.4. INVOICE SUBMISSION

In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all contract payment requests:

- a. The Contract Title is: RADx Tech Fluidigm 6114 – "Advanta Dx SARS-CoV-2 RT-PCR Assay for Saliva"
- b. The Contract Line Items are defined within the Section 20. Schedule of Supplies/Services of the Standard Form 1449.
- c. Invoice Instructions are attached and made part of this Contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.
 1. Payment requests shall be submitted to the offices identified below. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in this Contract or requested by the Contracting Officer.

- a. One copy of the invoice shall be submitted to the approving official at the following email addresses:

NHLBI Branch B Central Mailbox (NHLBIContractsBranchB@mail.nih.gov)

NIH centralized invoice email box: invoicing@nih.gov

2. E-Mail: The Contractor shall submit an electronic copy of the payment request to the approving official. 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.
3. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests (invoices):
- a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is **NHLBI**.
 - b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is **NHLBI Branch B Invoices**.
 - c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
 - d. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
 - e. Invoice Matching Option. This Contract requires a **two-way** match.
 - f. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.
 - g. PRISM/NBS Line Item Number and associated PRISM/NBS Line Item Period of Performance (see Section B – PRICES/OPTION).
- d. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6088.

SECTION H - ADDITIONAL CONTRACT CLAUSES

ARTICLE H.1. CONFIDENTIALITY OF INFORMATION

- a. Confidential information, as used in this article, means information or data of a personal

nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

- b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this Contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the Contract. Failure to agree will be settled pursuant to the "Disputes" clause.
- c. If it is established elsewhere in this Contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
- d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.
- e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.
- f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.
- g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ARTICLE H.2. PUBLICATION AND PUBLICITY

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, the Contractor shall acknowledge the support of the National Institutes of Health 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 National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N92020C0009."

In addition to acknowledging NIH funding, the Contractor shall refer any media inquiries relating to the role of the US Government in their contract to the COR within one day for a response.

ARTICLE H.3. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to 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 website to file a complaint on-line is: <http://oig.hhs.gov/fraud/hotline/> and the mailing address is:

US Department of Health and Human Services Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489 Washington, D.C. 20026

ARTICLE H.4. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-74 (December 2015)

- a. Pursuant to Section 508 of the Rehabilitation Act of 1973(29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed, acquired, or maintained under this contract or order must comply with the "Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at <http://www.hhs.gov/web/508>. The complete text of Section 508 Final Provisions can be accessed at <http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards>.
- b. The Section 508 accessibility standards applicable to this contract or order are identified below. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.
- c. The Section 508 accessibility standards applicable to this contract are:
 - 300 – Functional Performance Requirements
 - 500 – Software Standards General
 - 600 – Support Services & Documentation Standards
 - WCAG Level A Requirements
 - WCAG Level AA Requirements
- d. In the event of a modification(s) to this contract or order, which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS Web site: (<http://www.hhs.gov/web/508>). If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

- e. If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at <http://www.hhs.gov/web/508>. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(End of clause)

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text.

1. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

- a. FAR Clause 52.202-1 Definitions
- b. FAR Clause 52.203-6 Restrictions on Subcontractor Sales to the Government.
 - i. Alternate I 52.203-6
- c. FAR Clause 52.203-13, Contractor Code of Business Ethics and Conduct (October 2015)
- d. FAR Clause 52.203-17 Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights.
- e. FAR Clause 52.204-9, Personal Identity Verification of Contractor Personnel (January 2011).
- f. FAR Clause 52.204-13, System for Award Management Maintenance
- g. FAR Clause 52.204-18 Commercial and Government Entity Code Maintenance (July 2016)
- h. FAR Clause 52.204-23 Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
- i. FAR Clause 52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services of Equipment (Aug 2020)
- j. FAR Clause 52.209-10, Prohibition on Contracting With Inverted Domestic Corporations(November 2015).
- k. FAR Provision 52.212-3, Offeror Representations and Certifications – Commercial Items (Jun 2020)
- l. FAR Clause 52.212-4 Contract Terms and Conditions – Commercial Items (Oct 2018)
- m. FAR Clause 52.222-4, Contract Work Hours and Safety Standards - Overtime Compensation -General (May 2014).
- n. FAR Clause 52.222-29, Notification of Visa Denial (April 2015).
- o. FAR Clause 52.223-15, Energy Efficiency in Energy-Consuming Products (December 2007).

- p. FAR Clause 52.227-11 Patent Rights-Ownership by the Contractor
- q. FAR Clause 52.227-14, Rights in Data - General (May 2014).
- r. FAR Clause 52.227-14, Rights in Data - General (May 2014) Alternate II (Dec 2007).
- s. FAR Clause 52.232-40, Providing Accelerated Payments to Small Business Subcontractors

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

- a. HHSAR Clause 352.227-70, Publications and Publicity

ARTICLE I.2. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

This contract incorporates the following clauses in full text.

i. FAR Clause 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 websites) 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)

ii. **FAR 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders- Commercial Items (Aug 2020)**

- (a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:
- (1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).
 - (2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).
 - (3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).
 - (4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).
 - (5) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).
 - (6) 52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).
- (b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:
[Contracting Officer check as appropriate.] –
- (1) [52.203-6](#), Restrictions on Subcontractor Sales to the Government (June 2020), with *Alternate I* (Oct 1995) ([41 U.S.C. 4704](#) and [10 U.S.C. 2402](#)).
- (2) [52.203-13](#), Contractor Code of Business Ethics and Conduct (Jun 2020) ([41 U.S.C. 3509](#))).
- (3) [52.203-15](#), Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (Jun 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)

- (4) [52.204-10](#), Reporting Executive Compensation and First-Tier Subcontract Awards (Jun 2020) (Pub. L. 109-282) ([31 U.S.C. 6101 note](#)).
- (5) [Reserved].
- (6) [52.204-14](#), Service Contract Reporting Requirements (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).
- (7) [52.204-15](#), Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).
- (8) [52.209-6](#), Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Jun 2020) ([31 U.S.C. 6101 note](#)).
- (9) [52.209-9](#), Updates of Publicly Available Information Regarding Responsibility Matters (Oct 2018) ([41 U.S.C. 2313](#)).
- (10) [Reserved].
- (11) (i) [52.219-3](#), Notice of HUBZone Set-Aside or Sole-Source Award (Mar 2020) ([15 U.S.C. 657a](#)).
- (ii) Alternate I (Mar 2020) of [52.219-3](#).
- (12) (i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Mar 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).
- (ii) Alternate I (Mar 2020) of 52.219-4.
- (13) [Reserved]
- (14) (i) 52.219-6, Notice of Total Small Business Set-Aside (Mar 2020) of 52.219-6 (15 U.S.C. 644).
- (ii) Alternate I (Mar 2020) of [52.219-6](#) .
- (15) (i) 52.219-7, Notice of Partial Small Business Set-Aside (Mar 2020) (15 U.S.C. 644).
- (ii) Alternate I (Mar 2020) of [52.219-7](#).
- (16) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).
- (17) (i) 52.219-9, Small Business Subcontracting Plan (Jun 2020) (15 U.S.C. 637(d)(4)).
- (ii) Alternate I (Nov 2016) of 52.219-9.
- (iii) Alternate II (Nov 2016) of 52.219-9.
- (iv)Alternate III (Jun 2020) of 52.219-9.
- (v)Alternate IV (Jun 2020) of 52.219-9
- (18) (i) 52.219-13, Notice of Set-Aside of Orders (Mar 2020) (15 U.S.C. 644(r)).
- (ii) Alternate I (Mar 2020) of [52.219-13](#).
- (19) 52.219-14, Limitations on Subcontracting (Mar 2020) (15 U.S.C. 637(a)(14)).
- (20) 52.219-16, Liquidated Damages-Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
- (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Mar 2020) (15 U.S.C. 657f).
- (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (May 2020) (15 U.S.C. 632(a)(2)).
- (ii) Alternate I (MAR 2020) of 52.219-28.
- (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Mar 2020) (15 U.S.C. 637(m)).
- (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Mar2020) (15 U.S.C. 637(m)).
- (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (Mar 2020)(15 U.S.C.

- 644(r)).
- ___ (26) 52.219-33, Nonmanufacturer Rule (Mar 2020) (15U.S.C. 637(a)(17)).
 - _X_ (27) 52.222-3, Convict Labor (Jun 2003) (E.O.11755).
 - _X_ (28) 52.222-19, Child Labor- Cooperation with Authorities and Remedies (Jan2020) (E.O.13126)
 - _X_ (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
 - _X_ (30) (i) [52.222-26](#), Equal Opportunity (Sep 2016) (E.O.11246).
 - ___ (ii) Alternate I (Feb 1999) of [52.222-26](#).
 - ___ (31) (i) [52.222-35](#), Equal Opportunity for Veterans (Jun 2020) ([38 U.S.C. 4212](#)).
 - ___ (ii) Alternate I (Jul 2014) of [52.222-35](#).
 - ___ (32) (i) [52.222-36](#), Equal Opportunity for Workers with Disabilities (Jun 2020) ([29 U.S.C. 793](#)).
 - ___ (ii) Alternate I (Jul 2014) of [52.222-36](#).
 - ___ (33) [52.222-37](#), Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).
 - _X_ (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
 - _X_ (35) (i) 52.222-50, Combating Trafficking in Persons (Jan 2019) ([22 U.S.C. chapter 78](#) and E.O. 13627).
 - ___ (ii) Alternate I (Mar 2015) of [52.222-50](#) ([22 U.S.C. chapter 78](#) and E.O. 13627).
 - ___ (36) [52.222-54](#), Employment Eligibility Verification (Oct 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in [22.1803](#).)
 - ___ (37) (i) [52.223-9](#), Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) ([42 U.S.C. 6962\(c\)\(3\)\(A\)\(ii\)](#)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
 - ___ (ii) Alternate I (May 2008) of [52.223-9](#) ([42 U.S.C. 6962\(i\)\(2\)\(C\)](#)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
 - ___ (38) [52.223-11](#), Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).
 - ___ (39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).
 - ___ (40) (i) 52.223-13, Acquisition of EPEAT®-Registered Imaging Equipment (Jun 2014) (E.O.s 13423 and 13514).
 - ___ (ii) Alternate I (Oct 2015) of [52.223-13](#).
 - ___ (41) (i) [52.223-14](#), Acquisition of EPEAT®-Registered Televisions (Jun 2014) (E.O.s 13423 and 13514).
 - ___ (ii) Alternate I (Jun2014) of [52.223-14](#).
 - ___ (42) [52.223-15](#), Energy Efficiency in Energy-Consuming Products (May 2020) (42 U.S.C. 8259b).
 - ___ (43) (i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (Oct 2015) (E.O.s 13423 and 13514).
 - ___ (ii) Alternate I (Jun 2014) of [52.223-16](#).
 - _X_ (44) [52.223-18](#), Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020) (E.O. 13513).
 - ___ (45) 52.223-20, Aerosols (Jun 2016) (E.O. 13693).
 - ___ (46) 52.223-21, Foams (Jun2016) (E.O. 13693).
 - ___ (47) (i) 52.224-3 Privacy Training (Jan 2017) (5 U.S.C. 552 a).
 - ___ (ii) Alternate I (Jan 2017) of [52.224-3](#).
 - ___ (48) [52.225-1](#), Buy American-Supplies (May 2014) (41 U.S.C. chapter 83).

- (49) (i) 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act (May 2014) (41 U.S.C. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43).
 - (ii) Alternate I (May 2014) of 52.225-3.
 - (iii) Alternate II (May 2014) of 52.225-3.
 - (iv) Alternate III (May 2014) of [52.225-3](#).
 - (50) [52.225-5](#), Trade Agreements (Oct 2019) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).
 - (51) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
 - (52) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
 - (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (42 U.S.C. 5150).
 - (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (42 U.S.C. 5150).
 - (55) 52.229-12, Tax on Certain Foreign Procurements (Jun 2020).
 - (56) [52.232-29](#), Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
 - (57) 52.232-30, Installment Payments for Commercial Items (Jan 2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
 - (58) 52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct 2018) (31 U.S.C. 3332).
 - (59) 52.232-34, Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).
 - (60) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).
 - (61) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).
 - (62) 52.242-5, Payments to Small Business Subcontractors (Jan 2017) (15 U.S.C. 637(d)(13)).
 - (63) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) ([46 U.S.C. Appx. 1241\(b\)](#) and [10 U.S.C. 2631](#)).
 - (ii) Alternate I (Apr 2003) of 52.247-64.
 - (iii) Alternate II (Feb 2006) of [52.247-64](#).
- (c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:
[Contracting Officer check as appropriate.]
- (1) [52.222-41](#), Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter 67).
 - (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
 - (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (Aug 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
 - (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
 - (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May

2014) (41 U.S.C. chapter 67).

___ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) (41 U.S.C. chapter 67).

___ (7) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).

___ (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).

___ (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) ([42 U.S.C. 1792](#)).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR 2.101, on the date of award of this contract, and does not contain the clause at 52.215-2, Audit and Records-Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-

(i) [52.203-13](#), Contractor Code of Business Ethics and Conduct (Jun 2020) ([41 U.S.C. 3509](#)).

(ii) [52.203-19](#), Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(iii) [52.204-23](#), Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(iv) [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

(v) [52.219-8](#), Utilization of Small Business Concerns (Oct 2018) ([15 U.S.C. 637\(d\)\(2\)](#) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in

FAR [19.702\(a\)](#) on the date of subcontract award, the subcontractor must include [52.219-8](#) in lower tier subcontracts that offer subcontracting opportunities.

(vi) [52.222-21](#), Prohibition of Segregated Facilities (Apr 2015).

(vii) [52.222-26](#), Equal Opportunity (Sep 2015) (E.O.11246).

(viii) [52.222-35](#), Equal Opportunity for Veterans (Jun 2020) ([38 U.S.C. 4212](#)).

(ix) [52.222-36](#), Equal Opportunity for Workers with Disabilities (Jun 2020) ([29 U.S.C. 793](#)).

(x) [52.222-37](#), Employment Reports on Veterans (Jun 2020) ([38 U.S.C. 4212](#)).

(xi) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).

Flow down required in accordance with paragraph (f) of FAR clause [52.222-40](#).

(xii) [52.222-41](#), Service Contract Labor Standards (Aug2018) ([41 U.S.C. chapter 67](#)).

(xiii) (A) [52.222-50](#), Combating Trafficking in Persons (Jan 2019) ([22 U.S.C. chapter 78](#) and E.O 13627).

(B) Alternate I (Mar2015) of [52.222-50](#) ([22 U.S.C. chapter 78](#) and [E.O. 13627](#)).

(xiv) [52.222-51](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May2014) ([41 U.S.C. chapter 67](#)).

(xv) [52.222-53](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May2014) ([41 U.S.C. chapter 67](#)).

(xvi) [52.222-54](#), Employment Eligibility Verification (Oct 2015) (E.O. 12989).

(xvii) [52.222-55](#), Minimum Wages Under Executive Order 13658 (Dec 2015).

(xviii) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).

(xix) (A) [52.224-3](#), Privacy Training (Jan 2017) ([5 U.S.C. 552a](#)).

(B) Alternate I (Jan 2017) of 52.224-3.

(xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

(xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(xxii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

- a. Statement of Objectives
- b. Performance Work Statement
Appendix 1: Cost-Price Quote
Appendix 2: Quality Assurance Surveillance Plan (QASP)

Exhibit 10.2

2020.LICI.001.B

California Institute of Technology

SECOND AMENDED AND RESTATED LICENSE AGREEMENT

THIS SECOND AMENDED AND RESTATED LICENSE AGREEMENT (“Agreement”), effective May 1, 2000 (the “Effective Date”) with a second restatement date as of May 1, 2004 (the “Second Restatement Date”), between **CALIFORNIA INSTITUTE OF TECHNOLOGY**, 1200 East California Boulevard, Pasadena, California 91125 (“Caltech”) and **FLUIDIGM CORPORATION**, 7100 Shoreline Court, South San Francisco, California 94080 (formerly Mycometrix Corporation) (“Licensee”).

WHEREAS, Caltech has been engaged in basic research in the field of microfluidics;

WHEREAS, that research led to the United States patents, patent applications and other inventions listed in Exhibit A, which are owned, solely or jointly, by Caltech;

WHEREAS, Licensee is desirous of obtaining, and Caltech wishes to grant to Licensee, an exclusive license (or the maximum rights Caltech can grant) to the Licensed Patents (as defined in Section 1.5) and Improvements thereof in the Field (as defined in Sections 1.4 and 1.3, respectively) and an exclusive license to the Technology (as defined in Section 1.9);

WHEREAS, the Caltech and Licensee have entered into a prior License Agreement made as of May 1, 2000, and an Amended and Restated License Agreement made as of June 1, 2002, which the parties now wish to further amend and restate as set forth herein.

NOW, THEREFORE, the parties agree as follows:

ARTICLE 1

DEFINITIONS

1.1 **“Affiliate”** shall mean, with respect to Licensee, any entity which controls, is controlled by or is under common control with Licensee. An entity shall be regarded as in control of another entity for purposes of this definition if it owns or controls fifty percent (50%) or more of the shares of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority). **“Affiliate”** shall mean, with respect to Caltech, any research entity which is operated or managed as a facility under Caltech.

1.2 **“Deductible Expenses”** means (i) all trade, cash and quantity credits, discounts, refunds or government rebates; (ii) amounts for claims, allowances or credits for returns, retroactive price reductions, or chargebacks; (iii) packaging, handling fees and prepaid freight, sales taxes, duties and other governmental charges (including value added tax); and (iv) provisions for uncollectible accounts determined in accordance with reasonable accounting practices, consistently applied to all products of the selling party. For the removal of doubt, Net Sales shall not include sales by Licensee to its Affiliates for resale, provided that if Licensee sells a Licensed Product to an Affiliate for resale, Net Sales shall include the amounts invoiced by such Affiliate to third parties on the resale of such Licensed Product. In the event that Licensee grants a sublicense hereunder, and receives payments based upon the Sublicensee’s sales of Licensed Products, Licensee may upon notice to Caltech modify this definition of **“Net Sales”** for purposes of calculating royalties payable to Caltech on such Sublicensee’s sales to be the same as the definition of **“Net Sales”** on which such royalties to Licensee are calculated.

1.3 **“Field”** means [***]

Certain identified information marked with [*] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.**

[***]

1.4 **“Improvements”** shall mean all Caltech rights (whether or not Caltech has sole or joint rights) in any improvement or invention conceived and reduced to practice or otherwise developed in or arising from research in the Field as conducted by Dr. Stephen Quake, researchers of the Quake laboratory, or in collaboration with members of the Frances Arnold or Axel Scherer laboratories, whether invented solely by Caltech researchers or jointly with (i) Licensee or (ii) other researchers without an obligation of assignment to Caltech.

1.5 **“Licensed Patents”** means the patent applications listed in Exhibit A hereto; any patents issuing on such patent applications, all divisionals, continuations, continuations-in-part, patents of addition, substitutions, registrations, reissues, reexaminations or extensions of any kind with respect to any of the existing patents and any foreign counterparts of such patent applications and patents, and Improvements.

1.6 **“Licensed Product”** means products covered by a Valid Claim of a Licensed Patent in the country in which such product is sold or products in which the Technology is utilized.

1.7 **“Net Sales”** means the total amount invoiced to third parties on sales of Licensed Products for which royalties are due under Article 4 below, less, to the extent allocable to such invoiced amounts, Deductible Expenses.

1.8 **“Sublicensee”** shall mean any non-Affiliate third party to whom Licensee has granted the right under the Licensed Patents and Technology to manufacture and sell Licensed Products, with respect to Licensed Products made and sold by such third party.

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1.9 **“Technology”** means all proprietary information, know-how, procedures, methods, prototypes, designs, technical data, reports, and data owned by Caltech that are necessary or useful in the development of products in the Field covered by any issued patent or pending patent application within the Licensed Patents, and which relate to such products.

1.10 **“Valid Claim”** means a claim of an issued and unexpired patent or a claim of a pending patent application within the Licensed Patents which has not been held unpatentable, invalid or unenforceable by a court or other government agency of competent jurisdiction and has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise; provided, however, that if the holding of such court or agency is later reversed by a court or agency with overriding authority, the claim shall be reinstated as a Valid Claim with respect to Net Sales made after the date of such reversal. Notwithstanding the foregoing provisions of this Section 1.10, if a claim of a pending patent application within the Licensed Patents has not issued as a claim of an issued patent within the Licensed Patents, within five (5) years after the filing date from which such claim takes priority, such pending claim shall not be a Valid Claim for purposes of this Agreement.

ARTICLE 2

PATENT LICENSE GRANT

2.1 Caltech hereby grants to Licensee an exclusive, royalty-bearing, worldwide license, with the right to grant and authorize sublicenses, under the Licensed Patents and Technology to make, have made, use, import, offer for sale and sell Licensed Products, practice any method or procedure and otherwise exploit the Licensed Patents and Technology.

2.2 These licenses are subject to: (a) the reservation of Caltech’s right to make, have made, and use Licensed Products for noncommercial educational and research purposes, but not for sale or other distribution to third parties; and (b) the rights of the U.S. Government under Title 35, United States Code, Section 200 et seq., including but not limited to the grant to the U.S. government of a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced any invention conceived or first actually reduced to practice in the performance of work for or on behalf of the U.S. Government throughout the world. These licenses are not

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transferable by Licensee except as provided in Section 16.4, but Licensee shall have the right to grant non-exclusive or exclusive sublicenses hereunder, provided that:

(a) License shall include all its sublicensing income in Licensee's reports to Caltech, as provided in Section 9.2, and Licensee shall pay royalties thereon to Caltech pursuant to Section 4.2 and 4.4;

(b) Licensee shall furnish Caltech within thirty (30) days of the execution thereof, a true and complete copy of each sublicense and any changes or additions thereto;

(c) License may grant sublicenses of no greater scope than the license granted under Section 2.1; and

Each sublicense granted by Licensee shall include provisions similar in all material respects to those of Articles 6, 12, 15, 16 and Section 2.2.

ARTICLE 3

IMPROVEMENTS

3.1 The parties acknowledge that Exhibit A includes all Improvements disclosed by Caltech to Licensee between May 1, 2000 and the Second Restatement Date, and elected by Licensee as of the Second Restatement Date. Caltech shall notify Licensee in writing of Improvements made after the Second Restatement Date and during the term of the Agreement. Upon receipt of an invention disclosure constituting an Improvement, Licensee can elect to add such Improvement and any related patent filings to Exhibit A hereof to be within the Licensed Patents. Thereafter, Licensee shall be responsible for patent prosecution and costs associated with such elected Improvement in accordance with Article 11 herein, as well as to issue additional stock pursuant to Section 5.3. No less than at each anniversary of the Second Restatement Date, Exhibit A shall be updated by the parties to reflect the inclusion of all Improvements so elected, as well as updates on all Licensed Patents.

ARTICLE 4

ROYALTIES

4.1 With respect to Licensed Products manufactured or sold by Licensee in a country in which such manufacture or sale is covered by a Valid Claim of a Licensed Patent, Licensee agrees to pay Caltech [***] of Net Sales of such Licensed Products wherein the Licensed Products are instruments or apparatus directly used for the reading and/or analysis of data from other Licensed Products, including microfluidic chips that are Licensed Products, and [***] of Net Sales of Licensed Products by Licensee for all such other Licensed Products, including microfluidic chips that are Licensed Products, Royalties due under this Section 4.1 shall be payable on a country-by-country and Licensed Product-by-Licensed Product basis until the expiration of the last-to-expire issued Valid Claim covering such Licensed Product in such country.

4.2 With respect to Licensed Products manufactured or sold by Sublicensees in a country in which such manufacture or sale is covered by a Valid Claim of a Licensed Patent, Licensee agrees to pay Caltech [***] of the revenues received by Licensee from Sublicensees' Net Sales of such Licensed Products wherein the Licensed Products are instruments or apparatus directly used for the reading and/or analysis of data from other Licensed Products, including microfluidic chips that are Licensed Products, and [***] of the revenues received by Licensee from Sublicensees' Net Sales of Licensed Products for all such other Licensed Products, including microfluidic chips that are Licensed Products. Royalties due under this Section 4.2 shall be payable on a country-by-country and Licensed Product-by-Licensed Product basis until the expiration of the last-to-expire issued Valid Claim covering such Licensed Product in such country.

4.3 With respect to Licensed Products manufactured or sold by Licensee in a country in which such manufacture or sale is not covered by Valid Claim of a Licensed Patent but the Technology is utilized, Licensee agrees to pay Caltech [***] of Net Sales of such Licensed Products by Licensee, wherein the Licensed Products are instruments or

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apparatus directly used for the reading and/or analysis of data from other Licensed Products, including microfluidic chips that are Licensed Products, and [***] of Net Sales of Licensed Products by Licensee for all such other Licensed Products, including microfluidic chips that are Licensed Products. Royalties due under this Section 4.3 shall be payable on a country-by-country and Licensed Product-by-Licensed Product basis for a period of [***] years from the Effective Date or the issuance of a U.S. patent that covers the Licensed Product, whichever first occurs.

4.4 With respect to Licensed Products manufactured or sold by Sublicensees in a country in which such manufacture or sale is not covered by a Valid Claim of a Licensed Patent but the Technology is utilized, Licensee agrees to pay Caltech [***] of the revenues received by Licensee from Sublicensees' Net Sales of such Licensed Products wherein the Licensed Products are instruments or apparatus directly used for the reading and/or analysis of data from other Licensed Products, including microfluidic chips that are Licensed Products, and [***] of the revenues received by Licensee from Sublicensees' Net Sales of Licensed Products for all such other Licensed Products, including microfluidic chips that are Licensed Products. Royalties due under this Section 4.4 shall be payable on a country-by-country and Licensed Product-by-Licensed Product basis for a period of [***] years from the Effective Date or the issuance of a U.S. patent that covers the Licensed Product, whichever first occurs.

4.5 Notwithstanding the above, it is understood and agreed that Caltech shall not be entitled to any share of amounts received by Licensee for equity, debt, pilot studies, to support research or development activities to be undertaken by Licensee, research and development or other performance based milestones, the achievement by Licensee or Sublicensee of specified milestones or benchmarks relating to the development of Licensed Products, the license or sublicense of any intellectual property other than the Licensed Patents, reimbursement for patent or other expenses, or with respect to products other than Licensed Products.

4.6 In the event that a Licensed Product is sold in combination with one or more other products or other items that are not Licensed Products, Net Sales for such combination products will be reasonably calculated on a country-by-country and Licensed Product-by-Licensed

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Product basis by Licensee by multiplying the Net Sales of that combination by a fraction equal to the relative value of the combination attributable to the Licensed Product, in relation to the relative value of the combination, as reasonably determined by Licensee in good faith. In addition, in the event that a Licensed Product is not sold in combination with one or more other products or other items that are not Licensed Products, but instead comprises multiple components, some of which would constitute a Licensed Product if sold separately (each, a "Licensed Component"), and the others would not constitute a Licensed Product if sold separately, then Net Sales for such Licensed Product will be calculated by multiplying the Net Sales of such Licensed Product by the fraction A/B , where A is the gross selling price of the Licensed Component sold separately and B is the gross selling price of such Licensed Product. If no such separate sales are made by Licensee, its Affiliate or Sublicensee, Net Sales for such Licensed Product shall be calculated by multiplying Net Sales of such Licensed Product by the fraction $C/(C+D)$, where C is the fully allocated cost of the Licensed Component and D is the fully allocated cost of the other components.

4.7 Commencing on January 1, 2004, and continuing for each anniversary thereof during the term of this Agreement, if Licensee has not paid, during the preceding calendar year, a minimum of [***] in royalties under Sections 4.1, 4.2, 4.3, and 4.4, Licensee agrees to pay, on or before March 1 of that calendar year, an additional royalty for the prior calendar year equal to the difference between [***] and any lower amount paid under Sections 4.1, 4.2, 4.3, and 4.4 for the prior calendar year.

4.8 In the event Licensee or Sublicensee becomes obligated to pay amounts to a third party with respect to a Licensed Product for patent rights of a third party, Licensee may deduct [***] of the amounts owing to such third party (prior to reductions) from the amount owing to Caltech for such Licensed Product; provided, however, the amounts otherwise due to Caltech shall not be so reduced by more than [***].

4.9 For the purpose of determining royalties payable under this Agreement, any royalties or other revenues Licensee receives from Sublicensees in currencies other than U.S. dollars and any Net Sales denominated in currencies other than U.S. dollars shall be converted

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into U.S. dollars according to Licensee's reasonable standard internal conversion procedures, including Licensee's standard internal rates and conversion schedule.

4.10 No more than one royalty payment shall be due with respect to a sale of a particular Licensed Product. No multiple royalties shall be payable because any Licensed Product, or its manufacture, sale or use is covered by more than one Valid Claim in a given country. No royalty shall be payable under this Article 4 with respect to Licensed Products distributed for use in research and/or development or as promotional samples or otherwise distributed without charge to third parties.

4.11 Any sublicenses granted by Licensee, including, without limitation, any nonexclusive sublicenses, shall remain in effect in the event this license terminates pursuant to Article 12; provided, the financial obligations of each Sublicensee to Caltech shall be limited to the amounts Licensee shall be obligated to pay Caltech for the activities of such Sublicensee pursuant to this Agreement.

4.12 Royalties due under this Article 4 shall be payable on a country-by-country and Licensed Product-by-Licensed Product basis until the expiration of the last-to-expire issued Valid Claim covering such Licensed Product in such country, if the manufacture or sale of such Licensed Product was at the time of the first commercial sale in such country covered by a Valid Claim. Otherwise, royalties due under this Article 4 shall be payable on a country-by-country and Licensed Product-by-Licensed Product basis until [***] whichever first occurs.

4.13 Notwithstanding the provisions of this Article 4, no royalty shall be payable to Caltech with respect to any sales of Licensed Products to the U.S. Government on sales made solely to permit the U.S. Government to practice or have practiced or have practiced or sue on its behalf any invention or process covered by the Licensed Patents.

ARTICLE 5

LICENSEE EQUITY INTEREST

5.1 In accordance with the License Agreement of May 1, 2000, Licensee issued to Caltech, in consideration of Licensee's receipt of the intangible property rights granted under

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that License Agreement (which rights are carried forward herein), [***] shares of common stock of Licensee, pursuant to the terms of a reasonable and customary stock issuance agreement. Further, it is acknowledged that, as partial consideration for entering into the first Amended and Restated License Agreement of June 1, 2002, with the reformation of the initial License Agreement of May 1, 2000 and the associated restatements and amendments (including, but not limited to, an updated Exhibit A), Licensee issued to Caltech [***] shares of common stock of Licensee.

5.2 Caltech agrees that, in the event of any underwritten or public offering of securities of Licensee or a Affiliate, Caltech shall comply with and agree to any reasonable restriction on the transfer of equity interest, or any part thereof, imposed by an underwriter, and shall perform all acts and sign all necessary documents required with respect thereto.

5.3 If Licensee wishes at its sole discretion to license hereunder any Improvements disclosed by Caltech to Licensee during a twelve (12) month period beginning with June 1, 2003, and for each anniversary thereafter (each twelve month period will be referred to as an "Improvement Period"), Licensee shall notify Caltech in writing accordingly within thirty (30) days after the end of each Improvement Period. For the first two (2) Improvement Periods, Licensee agrees to issue to Caltech, in consideration of Licensee's election to receive additional intangible property rights to all Improvements disclosed to Licensee during an Improvement Period, [***] shares of common stock of Licensee, pursuant to the terms of a reasonable and customary stock issuance agreement. Thereafter, Licensee is hereby granted an option by Caltech that Licensee can exercise during the final year of the first two (2) Improvement Period on an annual basis on the same terms and conditions. The consideration of this option was partially paid by the [***] shares granted by Licensee to Caltech as referenced in Section 5.1 of this Agreement. Further, it is acknowledged that pursuant to the initial License Agreement of May 1, 2000 and the first Amended and Restated License Agreement of June 1, 2002, Licensee elected to receive additional intangible property rights to Improvements disclosed to Licensee by Caltech during May 1, 2000 through May 31, 2003, in consideration of the issuance to Caltech by Licensee of [***] shares of common stock of Licensee (which represents the [***] share grant under Section 5.1 above and [***] shares pursuant to the parties'

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Letter Agreement dated June 19, 2003, paragraph #3), receipt of which shares Caltech hereby acknowledges.

ARTICLE 6
DUE DILIGENCE

6.1 Licensee agrees to use commercially reasonable efforts to introduce commercial Licensed Product(s) as soon as practical, consistent with sound and reasonable business practices and judgments. Licensee shall be deemed to have satisfied its obligations under this Section if Licensee has an ongoing and active research program or marketing program, as appropriate, directed toward production and use of one or more Licensed Products. Any efforts of Licensee's Sublicensees shall be considered efforts of Licensee for the sole purpose of determining Licensee's compliance with its obligation under this Section.

6.2 After the first year from the Effective Date, Caltech shall have the right, no more often than once each year, to require Licensee to report to Caltech in writing on its progress in introducing commercial Licensed Product(s) in the United States.

6.3 If Licensee is not fulfilling its obligations under Section 6.1 with respect to the Field and Caltech so notifies Licensee in writing, Caltech and Licensee shall negotiate in good faith any additional efforts to be taken by Licensee. If the parties do not reach agreement within ninety (90) days, the parties shall submit the issue to arbitration as provided in Article 14 to determine whether any additional efforts shall be required of Licensee. If subsequent to the conclusion of such arbitration proceedings Licensee then fails to make any required efforts, and does not remedy that failure within sixty (60) days after further written notice to Licensee, Caltech may convert the license granted in Section 2.1 to a nonexclusive license in any part of the Field in which Licensee is not fulfilling its obligations under Section 6.1, and the royalties payable under this Agreement shall be reduced by [***] for Licensed Products in the Field sold under such a nonexclusive license.

ARTICLE 7

INFRINGEMENT BY THIRD PARTY

7.1 Both Caltech and Licensee agree to notify the other in writing should either party become aware of infringement of the Licensed Patents. Licensee, upon notice to Caltech, shall have the sole right to initiate an action against the infringer at Licensee's expense, either in Licensee's name or in Caltech's name if so required by law, Licensee shall have sole control of the action.

7.2 If Licensee, its Affiliate or Sublicensee, distributor or other customer is sued by a third party charging infringement of patent rights that dominate a claim of the Licensed Patents or that cover the development, manufacture, use, distribution or sale of a Licensed Product, Licensee will promptly notify Caltech. As between the parties to this Agreement, Licensee shall have sole control of the defense in any such action(s).

7.3 If a declaratory judgment action alleging invalidity unenforceability or noninfringement of any of the Licensed Patents is brought against Licensee and/or Caltech, Licensee may elect to have sole control of the action, and if Licensee so elects it shall bear all the costs of the action. Licensee also may elect to undertake and have sole control of the defense of any interference, opposition or similar action with respect to the Licensed Patents providing it bears all the costs of such action.

7.4 In the event Licensee institutes a legal action pursuant to Section 7.1, within thirty (30) days after receipt of notice of Licensee's intent to institute such legal action, Caltech shall have the right to jointly prosecute such action and to fund up to one-half ($\frac{1}{2}$) the costs of such action. Caltech shall fully cooperate with and supply all assistance reasonably requested by Licensee, including by using commercially reasonable efforts to have its employees testify when requested and to make available relevant records, papers, information, samples, specimens, and the like. Licensee shall bear the reasonable expenses incurred by Caltech in providing such assistance and cooperation as is requested pursuant to this Section 7.4. Licensee shall keep Caltech reasonably informed of the progress of the legal action, and Caltech shall be entitled to be represented by counsel in connection with such legal action at its own expense. Licensee's

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reasonable and customary expenses for such action (including attorneys' fees and expert fees) shall be fully creditable against royalties owed to Caltech hereunder, provided that in no one year shall such expenses to be credited against more than [***] of royalty payments to Caltech. Any remaining expenses may be carried over and credited against royalties owed in future years.

7.5 Licensee shall have the light to settle any claims, but only upon terms and conditions that are reasonably acceptable to Caltech. Should Licensee elect to abandon such an action other than pursuant to a settlement with the alleged infringer that is reasonably acceptable to Caltech, Licensee shall give timely notice to Caltech who, if it so desires, may continue the action; provided, however, that the sharing of expenses and any recovery in such suit shall be as agreed upon between the parties.

7.6 Any amounts paid to Licensee by third parties as the result of an action pursuant to this Article 7 (such as in satisfaction of a judgment or pursuant to a settlement) shall first be applied to reimbursement of the unreimbursed expenses (including attorneys' fees and expert fees) incurred by Licensee and then to the payment to Caltech of any royalties against which were credited expenses of the action in accordance with Section 7.4. Any remainder shall be divided between the parties as follows:

(a) To the extent the amount recovered reflects lost profits, Licensee shall retain the remainder, less the amount of any royalties that would have been due Caltech on sales of Licensed Product lost by Licensee as a result of the infringement had Licensee made such sales, provided that (i) Licensee shall in any event retain at least [***] of the remainder; and (ii) Caltech shall receive an amount equal to the royalties it would have received if such sales had been made by Licensee, provided such amount shall in no event exceed [***] of the remainder; or

(b) To the extent the amount recovered does not reflect lost profits, such amount shall be shared by Caltech and Licensee pro rata according to the respective percentages of costs borne by each in such action; provided, however, that in no event shall Caltech receive less than twenty-five percent (25%) of such amount.

ARTICLE 8
BENEFITS OF LITIGATION,
EXPIRATION OR ABANDONMENT

8.1 In a case where one or more patents or particular claims thereof within the Licensed Patents expire, or are abandoned, or are declared invalid or unenforceable or otherwise construed by a court of last resort or by a lower court from whose decree no appeal is taken, or certiorari is not granted within the period allowed therefor, then the effect thereof hereunder shall be:

(a) that such patents or particular claims shall, as of the date of expiration or abandonment or final decision as the case may be, cease to be included within the Licensed Patents for the purpose of this Agreement;

(b) that such construction so placed upon the Licensed Patents by the court shall be followed from and after the date of entry of the decision, and royalties shall thereafter be payable by Licensee only in accordance with such construction; and

(c) In the event that Licensee challenges the validity of Licensed Patents, Licensee may not cease paying royalties as of the date validity of the claims in issue are challenged, but rather may cease paying royalties as to those claims only after a final adjudication of invalidity of those claims.

8.2 In the event that any of the contingencies provided for in Section 8.1 occurs, Caltech agrees to renegotiate in good faith with Licensee a reasonable royalty rate under the remaining Licensed Patents which are unexpired and in effect and under which Licensee desires to retain a License.

ARTICLE 9
RECORDS, REPORTS AND PAYMENTS

9.1 Licensee shall keep records and books of account in respect of all Licensed Products made and sold by Licensee or its Affiliates under this Agreement and of royalties or other revenues Licensee receives from Sublicensees other than Licensee's Affiliates for the sale

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of Licensed Products. Caltech shall have the right at its own cost, during Licensee's business hours, no more often than annually, to have an independent certified public accounting firm of nationally recognized standing to examine such records and books. Licensee shall keep the same for at least three (3) years after it pays Caltech the royalties due for such Licensed Products and require Licensee's Affiliates to do the same. The accounting firm shall disclose to Caltech only whether or not the reports are correct and the amount of any discrepancies. Caltech shall, and shall cause its accounting firm to, not disclose to any third party any confidential information learned through an examination of such records and books.

9.2 Following the first commercial sale of a Licensed Product, on or before the last day of each February, May, August and November for so long as royalties are payable under this Agreement, Licensee shall render to Caltech a report in writing, setting forth Net Sales and the number of units of Licensed Products sold during the preceding calendar quarter by Licensee and its Affiliates, and the royalties or other revenues received by Licensee from Net Sales of Licensed Products made by Licensee's Sublicensees other than Affiliates during the preceding calendar quarter. Each such report shall also set forth an explanation of the calculation of the royalties payable hereunder and be accompanied by payment of the royalties shown by said report to be due Caltech. Notwithstanding foregoing, if (i) Caltech materially breaches this Agreement, (ii) Licensee gives Caltech written notice of the breach, and (iii) Caltech has not cured the breach by the time a payment is due under this Section, then Licensee may make the required payment into an interest bearing escrow account to be released when the breach is cured, less any damages that may be payable to Licensee by virtue of Caltech's breach. Royalty reports which are not challenged by Caltech or amended by Licensee within thirty-six (36) months after receipt by Caltech shall be conclusively presumed correct and not subject to challenge, audit, or amendment.

ARTICLE 10

CONFIDENTIALITY

10.1 Except as provided herein, each party shall maintain in confidence, and shall not use for any purpose or disclose to any third party, information disclosed by the other party in writing and marked "Confidential" or that is disclosed orally and confirmed in writing as

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confidential within forty-five (45) days following such disclosure (collectively, "Confidential Information"). Confidential Information shall not include any information that is; (i) already known to the receiving party at the time of disclosure hereunder, (ii) now or hereafter becomes publicly known other than through acts or omissions of the receiving party, (iii) disclosed to the receiving party by a third party under no obligation of confidentiality to the disclosing party, (iv) disclosed as required by securities or other applicable laws or pursuant to legal requirement, or (v) disclosed to actual or prospective investors or corporate partners, or to a party's accountants, attorneys, and other professional advisors. All reports provided to Caltech by Licensee pursuant to this Agreement shall be treated as confidential information of Licensee, pursuant to this Section 10.1. The terms of this Agreement shall be treated as confidential information of Licensee, pursuant to this Section 10.1.

10.2 Notwithstanding the provisions of Section 10.1 above, Licensee may use or disclose confidential information comprising the Licensed Patents and Technology to the extent necessary to exercise its rights hereunder (including commercialization and/or sublicensing of the Licensed Patents and Technology) or fulfill its obligations and/or duties hereunder and in filing for, prosecuting or maintaining any proprietary rights, prosecuting or defending litigation, complying with applicable governmental regulations and/or submitting information to tax or other governmental authorities.

ARTICLE 11

PATENT PROSECUTION AND PATENT COSTS

11.1 Licensee shall have the right to apply for, prosecute and maintain during the term of this Agreement, the Licensed Patents. Caltech shall provide Licensee with timely disclosures regarding Improvements and potential Improvements. The application filings, prosecution, maintenance and payment of all fees and expenses, including legal fees, relating to such Licensed Patents shall be the responsibility of Licensee, provided that Licensee shall pay for all reasonable fees and expenses, including reasonable legal fees, incurred in such application filings, prosecution and maintenance. Caltech shall provide Licensee with all information necessary or useful for the filing and prosecution of such Licensed Patents and shall cooperate fully with Licensee so that Licensee may establish and maintain such rights. Patent attorneys

chosen by Licensee shall handle all patent filings and prosecutions, on behalf of Caltech, provided, however, Caltech shall be entitled to review and comment upon and approve all actions undertaken in the prosecution of all patents and applications. Caltech shall provide any comments or approvals hereunder promptly.

11.2 In the event Licensee declines to apply for, prosecute or maintain any Licensed Patents, Caltech shall have the right to pursue the same at Caltech's expense and Licensee shall have no rights under Caltech's interest therein. If Licensee decides not to apply for, prosecute or maintain any Licensed Patents, Licensee shall give sufficient and timely notice to Caltech so as to permit Caltech to apply for, prosecute and maintain such Licensed Patents. In such event, Licensee shall provide Caltech with all information necessary or useful for the filing and prosecution of such Licensed Patents and shall cooperate fully with Caltech so that Caltech may establish and maintain such rights.

11.3 Licensee shall reimburse Caltech for all reasonable out-of-pocket expenses incurred by Caltech for the filing for, prosecution and maintenance of the Licensed Patents Rights. Such expenses shall be reimbursed following receipt by Licensee from Caltech of (i) an invoice covering such fees (including copies of invoices for legal fees describing the legal services performed in reasonable detail) and (ii) reasonably satisfactory evidence that such fees were paid. Initially, payments shall be made in six (6) equal quarterly installments due within ten days after the end of the first six (6) full calendar quarters, effective twenty-four (24) months from the Effective Date of this Agreement. Subsequent payments under this Section 11.3 shall be made to Caltech within sixty (60) days following receipt by Licensee from Caltech of (i) an invoice covering such fees (including copies of invoices for legal fees describing the legal services performed in reasonable detail) and (ii) reasonably satisfactory evidence that such fees were paid. If Licensee elects to no longer pay the expenses of a patent or patent application within the Licensed Patents in any country, Licensee shall notify Caltech not less than thirty (30) days prior to such action. In the event that Licensee elects not to pay such expenses the license granted to Licensee hereunder shall terminate. [***] of patent expenses paid by Licensee in conjunction with foreign patent costs shall be creditable against earned royalties due Caltech in the respective territory covered by the patent or patents that are foreign filed.

ARTICLE 12

TERMINATION

12.1 The term of this Agreement shall commence upon the Effective Date and shall terminate on a country-by-country and Licensed Product by Licensed Product basis upon the expiration of the last to expire Licensed Patent in such country. Caltech shall have the right to terminate this Agreement, subsequent to and subject to the outcome of arbitration proceedings pursuant to Article 14, prior to the date it would otherwise expire pursuant to this Section 12.1 if Licensee fails to make any payment due hereunder and Licensee continues to fail to make the payment, either to Caltech directly or by placing any disputed amount into an interest bearing escrow account to be released when the dispute is resolved, for a period of sixty (60) days after receiving written notice from Caltech specifying Licensee's failure. If this Agreement expires pursuant to the first sentence of this Section 12.1, Licensee shall retain a nonexclusive, perpetual, royalty-free, worldwide license, with the right to sublicense, under the Licensed Patents and Technology, to research, develop, make, use, sell, offer for sale and import Licensed Products.

12.2 If either party materially breaches this Agreement, the other party may elect to give the breaching party written notice describing the alleged breach. If the breaching party has not cured such breach within sixty (60) days after receipt of such notice, the notifying party will be entitled, in addition to any other rights it may have under this Agreement, to terminate this Agreement effective immediately; provided, however, that if either party receives notification from the other of a material breach and if the party alleged to be in default notifies the other party in writing within thirty (30) days of receipt of such default notice that it disputes the asserted default, the matter will be submitted to arbitration as provided in Article 14 of this Agreement. In such event, the nonbreaching party shall not have the right to terminate this Agreement until it has been determined in such arbitration proceeding that the other party materially breached this Agreement, and the breaching party fails to cure such breach within ninety (90) days after the conclusion of such arbitration proceeding.

12.3 Licensee shall have the right to terminate this Agreement either in its entirety or as to any jurisdiction or any part of the Licensed Patents or Technology upon thirty (30) days

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written notice. If Licensee does so, it shall submit all required reports and make all required payments in accordance with Section 9.2

12.4 In the event of any termination or expiration of the term of this Agreement, Licensee shall have the right to use or sell Licensed Products on hand on the date of such termination or expiration and to complete Licensed Products in the process of manufacture at the time of such termination or expiration and use or sell the same, provided that Licensee shall submit the applicable royalty report described in Section 9.2, along with the royalty payments required above in accordance with Section 4.1 for sale of such Licensed Products, provided that the Licensed Products are still covered by a Valid Claim following such termination or expiration.

12.5 Termination of this Agreement for any reason shall not release any party hereto from any liability which, at the time of such termination, has already accrued to the other party or which is attributable to a period prior to such termination, nor preclude either party from pursuing any rights and remedies it may have hereunder or at law or in equity which accrued or are based upon any event occurring prior to such termination.

12.6 Section 5.2 and Articles 10, 12, 14, and 16 of this Agreement shall survive termination of this Agreement for any reason.

12.7 If Licensee is acquired by or merges into a third party (i.e., Licensee is not a surviving company in the merger), then Caltech may terminate its obligations to disclose and grant licenses to Improvements by providing notice to Licensee of that termination. The remainder of the Agreement and the licenses granted hereunder (including prior licenses granted to Improvements) continues.

ARTICLE 13

WARRANTIES AND NEGATION OF

WARRANTIES, IMPLIED LICENSES AND AGENCY

13.1 Caltech represents and warrants that (i) it owns all right, title and interest in and to the Licensed Patents and Technology, (ii) it has the right to enter into this Agreement, (iii) it has not granted and will not grant during the term of this Agreement rights in or to any Licensed

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Patents or Technology that are inconsistent with the rights granted to Licensee herein, (iv) to Caltech's knowledge, there are no claims of third parties that would call into question the rights of Caltech to grant to Licensee the rights contemplated hereunder; (v) to Caltech's knowledge, practice of the Licensed Patents will not infringe intellectual property rights of third parties; (vi) except for the Licensed Patents, as of the effective date of the Agreement, to Caltech's belief and knowledge, Caltech does not own or control any patents or patent applications that would dominate any practice of the Licensed Patents or Technology, and (vii) there are no threatened or pending actions, suits, investigations, claims, or proceedings in any way relating to the Licensed Patents or Technology.

13.2 Nothing in this Agreement shall be construed as:

(a) a representation or warranty of Caltech as to the validity or scope of Licensed Patents or any claim thereof; or

(b) an obligation to bring or prosecute actions or suits against third parties for infringement.

(c) conferring by implication, estoppel or otherwise, any license or rights under any existing patents of Caltech other than Licensed Patents, regardless of whether such other patents are dominant or subordinate to Licensed Patents. Notwithstanding the foregoing, and to the extent legally permissible, Caltech hereby grants Licensee a right of first refusal as to such dominant or subordinate patents, providing that a Caltech faculty member does not wish to personally commercialize the technology embodied in such patents.

13.3 CALTECH MAKES NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND ASSUMES NO RESPONSIBILITIES WHATEVER WITH RESPECT TO THE USE, SALE, OR OTHER DISPOSITION BY LICENSEE OF LICENSED PRODUCT(S).

13.4 Caltech shall indemnify, defend and hold harmless Licensee from and against any and all losses, damages, costs and expenses (including attorneys' fees) arising out of a material breach by Caltech of its representations and warranties ("Claims"), provided that (i) Caltech is notified promptly of any Claims, (ii) Licensee has the sole right to control and defend or settle

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any litigation within the scope of this indemnity, and (iii) all indemnified parties cooperate to the extent necessary in the defense of any Claims.

ARTICLE 14

ARBITRATION

14.1 Any dispute under this Agreement which is not settled by mutual consent shall be finally settled by binding arbitration, conducted in accordance with the Commercial Arbitration Rules of the American Arbitration Association by one (1) independent, neutral arbitrator appointed in accordance with said rules. The arbitration shall be held in San Francisco, California. The arbitrators shall determine what discovery shall be permitted, consistent with the goal of limiting the cost and time that the parties must expend for discovery; provided the arbitrators shall permit such discovery as they deem necessary to permit an equitable resolution of the dispute. Any written evidence originally in a language other than English shall be submitted in English translation accompanied by the original or a true copy thereof. Except as otherwise expressly provided in this Agreement, the costs of the arbitration, including administrative and arbitrator(s)' fees, shall be shared equally by the parties and each party shall bear its own costs and attorneys' and witness' fees incurred in connection with the arbitration. A disputed performance or suspended performances pending the resolution of the arbitration must be completed within a reasonable time period following the final decision of the arbitrator(s). Any arbitration subject to this Article shall be completed within one (1) year from the filing of notice of a request for such arbitration. The arbitration proceedings and the decision shall not be made public without the joint consent of the parties and each party shall maintain the confidentiality of such proceedings and decision unless otherwise permitted by the other party. Any decision which requires a monetary payment shall require such payment to be payable in United States dollars, free of any tax or other deduction. The parties agree that the decision shall be the sole, exclusive and binding remedy between them regarding any and all disputes, controversies, claims and counterclaims presented to the arbitrators. Any award may be entered in a court of competent jurisdiction for a judicial recognition of the decision and an order of enforcement.

ARTICLE 15

PRODUCT LIABILITY

15.1 Licensee agrees that Caltech shall have no liability to Licensee or to any purchasers or users of Licensed Products made or sold by Licensee for any claims, demands, losses, costs, or damages suffered by Licensee, or purchasers or users of such Licensed Products, or any other party, which may result from personal injury, death, or property damage related to the manufacture, use, or sale of such Licensed Products ("Product Claims"). Licensee agrees to defend, indemnify, and hold harmless Caltech, its trustees, officers, agents, and employees from any such Product Claims, provided that (i) Licensee is notified promptly of any Product Claims, (ii) Licensee has the sole right to control and defend or settle any litigation within the scope of this indemnity, (iii) all indemnified parties cooperate in the defense of any Product Claims, and (iv) the Product Claims do not involve or relate to a material breach by Caltech of its representations and warranties.

15.2 At such time as Licensee begins to sell or distribute Licensed Products (other than for the purpose of obtaining regulatory approvals), Licensee shall at its sole expense, procure and maintain policies of comprehensive general liability insurance in amounts not less than [***] in annual aggregate and naming those indemnified under Section 15.1 as additional insureds. Such comprehensive general liability insurance shall provide (i) product liability coverage and (ii) broad form contractual liability coverage for Licensee's indemnification under Section 15.1. In the event the aforesaid product liability coverage does not provide for occurrence liability, Licensee shall maintain such comprehensive general liability insurance for a reasonable period of not less than five (5) years after it has ceased commercial distribution or use of any Licensed Product.

15.3 Licensee shall provide Caltech with written evidence of Such insurance upon request of Caltech. Licensee shall provide Caltech with notice at least fifteen (15) days prior to any cancellation, non-renewal or material change in such insurance, to the extent Licensee receives advance notice of such matters from its insurer. If Licensee does not obtain replacement insurance providing comparable coverage within ninety (90) days following the date of such cancellation, non-renewal or material change, Caltech shall have the right to terminate this

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Agreement effective at the end of such ninety (90) day period without any additional waiting period; provided that if Licensee uses reasonable efforts but is unable to obtain the required insurance at commercially reasonable rates, Caltech shall not have the right to terminate this Agreement, and Caltech instead shall cooperate with Licensee to either grant a waiver of Licensee's obligations under this Article or assist Licensee in identifying a carrier to provide such insurance or in developing a program for self-insurance or other alternative measures.

ARTICLE 16

MISCELLANEOUS

16.1 Licensee agrees that it shall not use the name of Caltech, or California Institute of Technology, in any advertising or publicity material, or make any form of representation or statement which would constitute an express or implied endorsement by Caltech of any Licensed Product, and that it shall not authorize others to do so, without first having obtained written approval from Caltech, except as may be required by governmental law, rule or regulation.

16.2 Licensee agrees to mark the appropriate U.S. patent number or numbers on all Licensed Products made or sold in the United States in accordance with all applicable governmental laws, rules and regulations, and to require its Sublicensees to do the same.

16.3 This Agreement sets forth the complete agreement of the parties concerning the subject matter hereof. No claimed oral agreement in respect thereto shall be considered as any part hereof. No waiver of or change in any of the terms hereof subsequent to the execution hereof claimed to have been made by any representative of either party shall have any force or effect unless in writing, signed by duly authorized representatives of the parties.

16.4 This Agreement shall be binding upon and inure to the benefit of any successor or assignee of Caltech. This Agreement is not assignable by Licensee without the prior written consent of Caltech, except that Licensee may assign this Agreement without the prior written consent of Caltech, to any Affiliate, or in connection with the sale or transfer of all or substantially all the assets of Licensee relating to the Licensed Products or services utilizing the methods within the Licensed Patents. Any permitted assignee shall succeed to all of the rights and obligations of Licensee under this Agreement.

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16.5 This Agreement is subject in all respects to the laws and regulations of the United States of America, including the Export Administration Act of 1979, as amended, and any regulations thereunder.

16.6 This Agreement shall be deemed to have been entered into in California and shall be construed and enforced in accordance with California law.

16.7 Any notice or communication required or permitted to be given or made under this Agreement shall be addressed as follows:

Caltech: Office of Technology Transfer
California Institute of Technology
1200 East California Boulevard (MC 210-85)
Pasadena, CA 91125
Fax No.: (626) 356-2486

Licensee: Fluidigm Corporation
7100 Shoreline Court
South San Francisco, CA 94080
Attn: President
Fax No: (650) 871-7195
Phone: (650) 266-6000

Either party may notify the other in writing of a change of address or fax number, in which event any subsequent communication relative to this Agreement shall be sent to the last said notified address or number, provided, however, that the parties shall deliver all material notices under this Agreement by registered mail or overnight delivery service. All notices and communications relating to this Agreement shall be deemed to have been given when received.

16.8 Nothing in this Agreement will impair Licensee's right to independently acquire, license, develop for itself, or have others develop for it, intellectual property and technology performing similar functions as the Licensed Patents and Technology or to market and distribute products other than Licensed Products based on such other intellectual property and technology.

16.9 NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY.

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16.10 The relationship of Licensee and Caltech established by this Agreement is that of independent contractors, Nothing in this Agreement shall be construed to create any other relationship between Licensee and Caltech. Neither party shall have any right, power or authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other.

16.11 Licensee agrees that a Licensed Product which embodies a patented invention or is produced through the use thereof for sale in the United States shall be manufactured substantially in the United States to the extent required by 35 U.S.C. Section 204.

16.12 Neither party shall lose any rights hereunder or be liable to the other party for damages or losses (except for payment obligations) on account of failure of performance by the defaulting party if the failure is occasioned by war, strike, fire, Act of God, earthquake, flood, lockout, embargo, governmental acts or orders or restrictions, failure of suppliers, or any other reason where failure to perform is beyond reasonable control and not caused by the negligence or intentional conduct or misconduct of the nonperforming party, and such party has exerted all reasonable efforts to avoid or remedy such force majeure; provided, however, that in no event shall a party be required to settle any labor dispute or disturbance.

16.13 In the event that any provisions of this Agreement are determined to be invalid or unenforceable by a court of competent jurisdiction, the remainder of the Agreement shall remain in full force and effect without said provision. The parties shall in good faith negotiate a substitute clause for any provision declared invalid or unenforceable, which shall most nearly approximate the intent of the parties in entering this Agreement.

16.14 This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

16.15 The headings of the several Sections are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

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16.16 Whenever provision is made in this Agreement for either party to secure the consent or approval of the other, that consent or approval shall not unreasonably be withheld or delayed, and whenever in this Agreement provisions are made for one party to object to or disapprove a matter, such objection or disapproval shall not unreasonably be exercised.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed:

Date: 4/29/04

CALIFORNIA INSTITUTE OF TECHNOLOGY
(Caltech)

By: /s/ Lawrence Gilbert
Name: Lawrence Gilbert
Title: Senior Director
Office of Technology Transfer

Date: April 28, 2004

FLUIDIGM CORPORATION
(Licensee)

By: /s/ Gajus Worthington
Name: Gajus Worthington
Title: President and CEO

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Exhibit A
Licensed Patents

Date: April 22, 2004

Confidential

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Exhibit A

Licensed Patents

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Exhibit A

Licensed Patents

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Exhibit A

Licensed Patents

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Exhibit A

Licensed Patents

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Exhibit A

Licensed Patents

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Exhibit A

Licensed Patents

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Exhibit A

Licensed Patents

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Exhibit A

Licensed Patents

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Exhibit A

Licensed Patents

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Exhibit A

Licensed Patents

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Exhibit A

Licensed Patents

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Exhibit A

Licensed Patents

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Exhibit A

Licensed Patents

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Exhibit A

Licensed Patents

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Exhibit A

Licensed Patents

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Exhibit A

Licensed Patents

[***]

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Exhibit A

Licensed Patents

[***]

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ADDENDUM TO
SECOND AMENDED AND RESTATED LICENSE AGREEMENT

THIS ADDENDUM TO SECOND AMENDED AND RESTATED LICENSE AGREEMENT (this "Addendum") dated as of March 29, 2007 (the "Addendum Date"), is entered into between CALIFORNIA INSTITUTE OF TECHNOLOGY ("Caltech"), having an address at 1200 East California Boulevard, Pasadena, California 91125, and FLUIDIGM CORPORATION ("Licensee"), having a principal place of business at 7100 Shoreline Court, South San Francisco, California 94080, with respect to the following facts:

A. The parties entered into the Second Amended and Restated License Agreement (the "Agreement") effective May 1, 2000, with a second restatement date as of May 1, 2004. All terms used, but not defined herein, shall have the respective meanings set forth in the Agreement.

B. On the terms and conditions of this Addendum, the parties desire to clarify and modify certain provisions to the Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the parties agree as follows:

1. Licensed Patents and Improvements.

1.1 The Agreement is amended by deleting Exhibit A to the Agreement and by replacing it with Exhibit A to this Addendum.

1.2 Caltech represents that it has disclosed to Licensee all Improvements arising prior to the Addendum Date.

1.3 The parties acknowledge that Exhibit A to this Addendum includes (a) all Improvements disclosed by Caltech to Licensee prior to the Addendum Date, and elected by Licensee to be included in the scope of the license grant by Caltech to Licensee under the Agreement, and (b) all updates on all Licensed Patents as of the Addendum Date. Caltech confirms that Licensee has taken all action on its part that is necessary for all subject matter included in Exhibit A to this Addendum to be included in the scope of the license grant by Caltech to Licensee under the Agreement.

2. Licensee Equity Interest and Improvement Periods.

2.1 Notwithstanding anything to the contrary in Article 5 of the Agreement, the Improvement Periods shall be those periods from June 1, 2003 through May 31, 2004, from June 1, 2004 through May 31, 2005, from [***]

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2.2 Notwithstanding anything to the contrary in Article 5 of the Agreement, (a) Licensee shall issue to Caltech [***] [***] shares of common stock of Licensee, pursuant to the terms of a reasonable and customary stock issuance agreement, and (b) the parties acknowledge that the issuance of such shares (in addition to the shares issued by Licensee to Caltech prior to the Second Restatement Date) shall be in full satisfaction of Licensee's obligations to issue shares or otherwise make payments to Caltech pursuant to the Agreement.

3. Royalty Reports.

The parties acknowledge (a) that the royalty reports received by Caltech under Section 9.2 of the Agreement prior to the Addendum Date are presumed correct and not subject to challenge, audit or amendment, and (b) that the format of, and the methodology used by Licensee in preparing, the royalty reports under Section 9.2 of the Agreement are mutually acceptable and in compliance with the terms and conditions of the Agreement.

4. Patent Costs.

Notwithstanding anything to the contrary in Article 11 of the Agreement, Licensee shall have no obligation to reimburse Caltech for any costs or expenses incurred by Caltech in connection with the Licensed Patents that have not been reimbursed by Licensee prior to the Addendum Date.

5. Further Assurances.

Each party shall take such further actions, and execute such further documents and instruments, as reasonably requested by the other party to effectuate the grant of licenses and rights from Caltech to Licensee under the Agreement and otherwise to enable Licensee to enjoy the full benefit thereof.

6. Miscellaneous.

6.1 This Addendum shall be effective for all purposes as of the Addendum Date. Except as otherwise expressly modified by this Addendum, the Agreement shall remain in full force and effect in accordance with its terms.

6.2 This Addendum shall be governed by, interpreted and construed in accordance with the laws of the State of California, without regard to conflicts of law principles.

6.3 This Addendum may be executed in counterparts, each of which shall be deemed to be an original and together shall be deemed to be one and the same document.

Certain identified information marked with [*] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.**

IN WITNESS WHEREOF, the parties have caused this Addendum to be duly executed and delivered effective as of the Addendum Date.

CALIFORNIA INSTITUTE OF TECHNOLOGY

By: /s/ Lawrence Gilbert
(Signature)

Lawrence Gilbert
(Printed Name)

SR DR Tech Transfer
(Title)

FLUIDIGM CORPORATION

By: /s/ Gajus V. Worthington
(Signature)

Gajus V. Worthington
(Printed Name)

CEO
(Title)

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EXHIBIT A
[TO BE ATTACHED]

[***]

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Appendix 1.7 Fluidigm Patent Family
US Cases

[***]

Page 1

Certain identified information marked with [*] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.**

Appendix 1.7 Fluidigm Patent Family
US Cases

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Page 2

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Appendix 1.7 Fluidigm Patent Family
US Cases

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Page 3

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Appendix 1.7 Fluidigm Patent Family
US Cases

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Page 4

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Appendix 1.7 Fluidigm Patent Family
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Page 5

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Appendix 1.7 Fluidigm Patent Family
US Cases

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Page 6

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Appendix 1.7 Fluidigm Patent Family
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Appendix 1.7 Fluidigm Patent Family
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Appendix 1.7 Fluidigm Patent Family
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Page 11

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Appendix 1.7 Fluidigm Patent Family
International Cases

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Page 1

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Appendix 1.7 Fluidigm Patent Family
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Appendix 1.7 Fluidigm Patent Family
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Appendix 1.7 Fluidigm Patent Family
International Cases

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Appendix 1.7 Fluidigm Patent Family
International Cases

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Appendix 1.7 Fluidigm Patent Family
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Appendix 1.7 Fluidigm Patent Family
International Cases

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Page 10

4060.LICI.006 Harvard

CO-EXCLUSIVE LICENSE AGREEMENT

Between

President and Fellows of Harvard College

And

Mycometrix Corporation

Effective as of October 15, 2000

Re: Harvard Case [***]

In consideration of the mutual promises and covenants set forth below, the parties hereto agree as follows:

ARTICLE I
DEFINITIONS

As used in this Agreement, the following terms shall have the following meanings:

- 1.1 **ACADEMIC RESEARCH PURPOSES:** use of PATENT RIGHTS for academic research or other not-for-profit scholarly purposes which are undertaken at a non-profit or governmental institution that does not use the PATENT RIGHTS in the production or manufacture of products for sale or the performance of services for a fee.
- 1.2 **AFFILIATE:** any entity which controls, is controlled by, or is under common control with a party by ownership or control of at least fifty percent (50%) of the voting stock or other ownership. Unless otherwise specified, the term LICENSEE includes AFFILIATES.
- 1.3 **FIELD:** use of PATENT RIGHTS to develop, manufacture, use, offer for sale, sell, or import components and products in FIELD I and/or FIELD II:

FIELD I: [***]

FIELD II: [***]

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- 1.4 HARVARD: President and Fellows of Harvard College, a nonprofit Massachusetts educational corporation having offices at the Office for Technology and Trademark Licensing, Holyoke Center, Suite 727, 1350 Massachusetts Avenue, Cambridge, Massachusetts 02138.
- 1.5 LICENSED PROCESSES: the processes covered by at least one VALID CLAIM included within the PATENT RIGHTS.
- 1.6 LICENSED PRODUCTS: products covered by at least one VALID CLAIM included within the PATENT RIGHTS or products made or services provided in accordance with or by means of LICENSED PROCESSES.
- 1.7 LICENSEE: Mycometrix Corporation, a corporation organized under the laws of California having its principal offices at 213 East Grand Avenue, South San Francisco, CA 94080.
- 1.8 NET SERVICE INCOME: SERVICE INCOME less LICENSEE's actual direct and indirect cost for research, development and/or services provided.
- 1.9 NET SALES: the amount actually received for sales, leases, or other transfers of LICENSED PRODUCTS, less:
- (i) customary trade, quantity or cash discounts and non-affiliated brokers' or agents' commissions actually allowed and taken;
 - (ii) amounts repaid or credited by reason of rejection or return;
 - (iii) to the extent separately stated on purchase orders, invoices, or other documents of sale, taxes levied on and/or other governmental charges made as to production, sale, transportation, delivery or use and paid by or on behalf of LICENSEE; and
 - (iv) reasonable charges for delivery or transportation provided by third parties and cost of insurance in transit, if separately stated.

NET SALES also includes the fair market value of any non-cash consideration received by LICENSEE for the sale, lease, or transfer of LICENSED PRODUCTS.

If a LICENSED PRODUCT is sold as a combination product containing the LICENSED PRODUCT and one or more other components, NET SALES shall be calculated by multiplying the gross amount invoiced for the sale of the combination product by the fraction $A/A+B$ where A is the average gross selling price of the LICENSED PRODUCT sold separately by LICENSEE and B is the average gross selling price of such other components of the combination products sold separately by LICENSEE during the relevant royalty payment period.

In the event that LICENSEE grants a sublicensee hereunder, and receives payments based upon SUBLICENSEE's sales of LICENSED PRODUCTS, LICENSEE may upon approval from HARVARD (which shall not be unreasonably withheld) modify the definition of NET SALES for the purposes of calculating royalties payable to HARVARD on such SUBLICENSEE's sales to be the same as the definition of NET SALES on which such royalties to LICENSEE are calculated.

- 1.10 **SERVICE INCOME:** the total financial consideration received by LICENSEE for commercial services performed on a fee-for-service basis using the LICENSED PRODUCTS or LICENSED PROCESSES by LICENSEE under a contract with a third party, where such services are based primarily on the use of fully functional LICENSED PRODUCTS or LICENSED PROCESSES (as applicable) for their intended commercial use (such as, for example, where LICENSEE performs commercial-scale genotyping services for a pharmaceutical company on a fee-for-service basis using fully developed microfluidics chips comprising LICENSED PRODUCTS). SERVICE INCOME shall not include amounts received in connection with research and/or development of LICENSED PRODUCTS or LICENSED PROCESSES themselves.
- 1.11 **PATENT RIGHTS:** The applications and patents as listed in Appendix A of this Agreement, the allowed claims of such applications, the inventions described and claimed therein, and any divisions or continuations of the applications and patents as listed in Appendix A, and specific claims of any continuations-in-part of such applications to the extent the specific claims are directed to subject matter described in the applications and patents listed in Appendix A in a manner sufficient to support such specific claims under 35 U.S.C., patents issuing thereon or reissues thereof, and any and all foreign patents and patent applications corresponding thereto, all to the extent owned or controlled by HARVARD.
- 1.12 **SUBLICENSE INCOME:** the amount paid to LICENSEE by a third party (other than an AFFILIATE of LICENSEE) (a) for the sublicensing of PATENT RIGHTS to a third party as well as (b) for the related licensing of LICENSEE's own patent rights or know-how or LICENSEE's in-licensed non-HARVARD technologies, including but not limited to (i) license fees, (ii) milestone payments, (iii) royalties, (iv) the fair market value in cash of any non-cash consideration for such sublicense, and (v) in the event that LICENSEE receives any payment for equity in consideration for the grant of sublicense rights that included a premium over the fair market value of such equity, the amount of such premium. LICENSEE shall be responsible for determining such fair market value with reasonable business judgment.
- 1.13 **SUBLICENSEE:** any non-AFFILIATE granted a sublicense of any of the rights HARVARD has granted to LICENSEE under Section 3.1.
- 1.14 **TERRITORY:** Worldwide.

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- 1.15 VALID CLAIM: either (i) a claim of an issued patent that has not been held unenforceable or invalid by an agency or a court of competent jurisdiction in any unappealable or unappealed decision or (ii) a claim of a published, pending patent application, which claim is substantially identical to a corresponding claim in a subsequently issued patent having priority to the patent application.
- 1.16 The terms “Public Law 96-517” and “Public Law 98-620” include all amendments to those statutes.
- 1.17 The terms “sold” and “sell” include, without limitation, leases and other transfers and similar transactions.

ARTICLE II REPRESENTATIONS

- 2.1 HARVARD is owner by assignment from [***], in the US and foreign patent applications corresponding thereto, and in the inventions described and claimed therein. Inventorship will be finalized in the near future.
- 2.2 HARVARD has authority to issue licenses under PATENT RIGHTS.
- 2.3 HARVARD is committed to the policy that ideas or creative works produced at HARVARD should be used for the greatest possible public benefit, and believes that every reasonable incentive should be provided for the prompt introduction of such ideas into public use, all in a manner consistent with the public interest.
- 2.4 LICENSEE is prepared and intends to diligently develop the invention and to bring products to market which are subject to this Agreement, specifically including one or more products in the FIELD selected from a [***].
- 2.5 LICENSEE is desirous of obtaining a co-exclusive license in the FIELD and in the TERRITORY in order to practice the PATENT RIGHTS in the United States and in certain foreign countries, and to manufacture, use and sell in the commercial market the products made in accordance therewith, and HARVARD is desirous of granting such a license to LICENSEE in accordance with the terms of this Agreement.

ARTICLE III GRANT OF RIGHTS

- 3.1 HARVARD hereby grants to LICENSEE and LICENSEE accepts, subject to the terms and conditions hereof, in the TERRITORY a co-exclusive commercial license under PATENT

RIGHTS in FIELD I and in FIELD II to make and have made, to use and have used, to sell and have sold, and to offer for sale and have offered for sale the LICENSED PRODUCTS, and to practice the LICENSED PROCESSES, for the life of the PATENT RIGHTS. HARVARD will grant no more than two commercial licenses in FIELD I at any time and will grant no more than two commercial licenses in FIELD II at any time and HARVARD will not grant other licenses in the FIELD except as required by HARVARD's obligations in Section 3.2(a) or as permitted Section 3.2(b). Such co-exclusive license shall include the right to grant sublicenses under the following circumstances: (i) LICENSEE can demonstrate that it has added significant value to the PATENT RIGHTS to be sublicensed, and that such a sublicense also contains a substantial and essentially simultaneous license of LICENSEE owned intellectual property, or (ii) LICENSEE grants a sublicense under other HARVARD patent rights licensed exclusively to LICENSEE which are dominated by PATENT RIGHTS, and such sublicense under PATENT RIGHTS is necessary to practice such other HARVARD patent rights.

3.2 The granting and exercise of this license is subject to the following conditions:

- (a) HARVARD's "Statement of Policy in Regard to Inventions, Patents and Copyrights," dated August 10, 1998, Public Law 96-517, Public Law 98-620. In addition, this Agreement is subject to HARVARD's obligations under agreements with other sponsors of research, provided that such obligations are not in conflict with the rights granted hereunder. Any right granted in this Agreement greater than that permitted under Public Law 96-517, or Public Law 98-620, shall be subject to modification as may be required to conform to the provisions of those statutes.
- (b) HARVARD reserves the right to make and use, and grant to others non-exclusive licenses to make and use solely for ACADEMIC RESEARCH PURPOSES the subject matter described and claimed in PATENT RIGHTS.
- (c) LICENSEE shall use commercially reasonable efforts to effect introduction of the LICENSED PRODUCTS into the commercial market as soon as practicable, consistent with sound and reasonable business practice and judgment; thereafter, until the expiration of this Agreement, LICENSEE shall endeavor to keep LICENSED PRODUCTS reasonably available to the public.
- (d) At any time after three years from the effective date of this Agreement and as HARVARD's sole remedy for such non-performance, HARVARD may increase the license maintenance royalty under Section 4.4 to [***] (\$[***]) dollars each in FIELD I and in FIELD II in year 2004 and [***] (\$[***]) dollars each in FIELD I and FIELD II per year each year beginning in 2005, if in HARVARD's reasonable judgment, the Progress Reports furnished by LICENSEE do not demonstrate that LICENSEE has satisfied at least one of the following conditions, which non-performance is not cured within ninety (90) days following the written notification of such by HARVARD to LICENSEE:

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- (i) has put the licensed subject matter into commercial use in at least one of the countries hereby licensed, directly or through a sublicense, and is keeping the licensed subject matter reasonably available to the public; or
 - (ii) is engaged in research, development, manufacturing, marketing or sublicensing activity appropriate to achieving 3.2(d)(i).
- (e) In all sublicenses granted by LICENSEE hereunder, LICENSEE shall include a requirement that the SUBLICENSEE use commercially reasonable efforts to bring the subject matter of the sublicense into commercial use. LICENSEE shall further provide in such sublicenses that such sublicenses are subject and subordinate to the terms and conditions of this Agreement, except: (i) the SUBLICENSEE may not further sublicense; and (ii) the rate of royalty on NET SALES paid by the SUBLICENSEE to the LICENSEE. Copies of the relevant provisions of all sublicense agreements shall be provided promptly to HARVARD. HARVARD agrees to maintain any information contained in such provisions in confidence, except as otherwise required by law, however, HARVARD may include in its usual reports annual amounts of royalties paid.
- (f) A license in any other field of use in addition to the FIELD shall be the subject of a separate agreement and shall require LICENSEE's submission of evidence, satisfactory to HARVARD, demonstrating LICENSEE's willingness and ability to develop and commercialize in such other field of use the kinds of products or processes likely to be encompassed in such other fields.
- (g) To the extent that federal funds are used to support research leading to a patent or patent application in the PATENT RIGHTS, LICENSEE shall cause any LICENSED PRODUCT produced for sale by LICENSEE or SUBLICENSEES in the United States to be manufactured substantially in the United States during the period of exclusivity of this license in the United States.

3.4 All rights reserved to the United States Government and others under Public Law 96-517, and Public Law 98-620, shall remain and shall in no way be affected by this Agreement.

ARTICLE IV ROYALTIES

4.1 LICENSEE shall pay to HARVARD a non-refundable license royalty fee in the sum of [***] dollars (\$[***]) payable within thirty (30) days of the execution date of this Agreement.

4.2 (a) In consideration of the right and license granted herein, LICENSEE shall pay to HARVARD during the term of this Agreement a royalty of [***] percent ([***]) on NET SALES of LICENSED PRODUCTS sold by LICENSEE.

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(b) In the event that a single LICENSED PRODUCT or LICENSED PROCESS is covered by HARVARD intellectual property in addition to PATENT RIGHTS, which is licensed to LICENSEE under other agreements as of the date of this Agreement, then the total royalty payment due HARVARD under all such agreements including this Agreement shall be [***] percent ([***) of NET SALES. LICENSEE shall notify HARVARD of the identity of each license agreement that includes patent rights covering the product or process, and HARVARD shall distribute the royalties evenly among such agreements.

(c) As consideration for the rights granted hereunder, LICENSEE shall pay to HARVARD during the term of this Agreement a royalty in the form of stock of LICENSEE as follows:

- (i) LICENSEE shall issue to HARVARD [***] shares of the Common Stock of LICENSEE (“Shares”) pursuant to the terms of a mutually acceptable Stock Subscription Agreement, provided, however, that HARVARD shall be subject to and enter into appropriate agreements and related documents as required of other stockholders of LICENSEE.
- (ii) HARVARD represents and warrants to LICENSEE that:
 - (1) HARVARD is acquiring the Shares for its own account for investment and not with a view to, or for sale in connection with any distribution thereof, nor with any present intention of distributing or selling the same; and HARVARD has no present or contemplated agreement, undertaking, arrangement, obligation, indebtedness or commitment providing for the disposition thereof.
 - (2) HARVARD has full power and authority to enter into and to perform this Agreement in accordance with its terms.
 - (3) HARVARD has sufficient knowledge and experience in investing in companies similar to LICENSEE so as to be able to evaluate the risks and merits of its investment in LICENSEE and is able financially to bear the risks thereof.
- (iii) Each certificate representing the Shares shall bear a legend substantially in the following form:

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“The shares represented by this certificate have not been registered under the Securities Act of 1933 or any state securities law and they may not be sold or otherwise transferred by any person, including a pledgee, unless (1) either (a) a registration statement with respect to such shares shall be effective under the Securities Act of 1933, as amended, or (b) the Corporation shall have received an opinion of counsel satisfactory to the Corporation that an exemption from registration under such Act is then available, and (2) there shall have been compliance with all applicable securities laws.”

“The shares represented by this certificate are subject to a mutually agree-upon Stock Purchase and Right of First Refusal Agreement with this Corporation, a copy of which Stock Purchase and Right of First Refusal Agreement is available for inspection at the offices of the Corporation or may be made available upon request.”

The foregoing legend shall be removed from the certificates representing any Shares, at the request of the holder thereof, at such time as they become eligible for resale pursuant to the Securities Act of 1933, as amended.

If at any time prior to the time the Shares are eligible for resale pursuant to an exemption from registration under the Securities Act of 1933, as amended, LICENSEE proposes to register any of its Common Stock, under the Securities Act of 1933, except at LICENSEE's initial public offering or any offering pursuant to Forms S-4 or S-8, LICENSEE shall offer HARVARD the opportunity to have its Shares registered under the registration statement to be filed at such time. HARVARD will be offered the right to register its Shares under the same terms, conditions and restrictions as other shareholders with piggyback registration rights and the inclusion of any Shares in such registration statement shall be subject to the approval of the underwriters of such offering

(iv) HARVARD's ownership rights to Shares shall not be affected should the license pursuant to this Agreement be converted to a non-exclusive one.

(d) In the case of sublicenses, LICENSEE shall also pay to HARVARD a royalty of [***] of SUBLICENSE INCOME. If compensation for such a sublicense of PATENT RIGHTS is bundled with compensation received for the sublicensing of the other HARVARD patent rights licensed to LICENSEE under other agreements as of the date of this Agreement, LICENSEE shall pay HARVARD only [***] of the total compensation received no matter how many license agreements from HARVARD are involved. In such a case, LICENSEE shall notify HARVARD of the identity of each license agreement involved and HARVARD shall distribute its [***] of

compensation equally among those license agreements, including this Agreement.

(e) LICENSEE shall pay HARVARD [***] of NET SERVICE INCOME. If SERVICE INCOME is bundled with service income under another license to LICENSEE as of the date of this Agreement, LICENSEE shall pay a royalty of [***] of NET SERVICE INCOME received from each and every third party ("Third Party") to which services are provided. LICENSEE shall notify HARVARD of the identity of each license agreement involved in the services and HARVARD shall distribute its [***] of compensation equally among those license agreements, including this Agreement.

(f) If other co-exclusive licenses in the same FIELD and TERRITORY are granted after the date this Agreement is executed, the above financial compensation shall not exceed the financial compensation to be paid by other licensees in the same FIELD and TERRITORY during the term of the co-exclusive license provided LICENSEE accepts any less favorable terms included in such other license. If stock is part of the financial compensation to be paid by other licensees in the same FIELD and TERRITORY, the fair market value of the stock shall be the same as the price per share which other investors paid in the last round of financing unless the stock is publicly traded.

- 4.3 On sales between LICENSEE and its AFFILIATES for resale or incorporation into products, the royalty shall be paid on the NET SALES of the AFFILIATE. On sales between LICENSEE and sublicensees for resale, the royalty shall be paid on the SUBLICENSE INCOME.
- 4.4 No later than January 1 of each calendar year indicated below, LICENSEE shall pay to HARVARD the following non-refundable license maintenance royalty and/or advance on royalties. Such payments shall be credited against running royalties due for that calendar year and Royalty Reports shall reflect such a credit. Such payments shall not be credited against milestone payments (if any) nor against royalties due for any subsequent calendar year nor against such payments due under any other agreements with HARVARD.

	FIELD I	FIELD II
January 1, 2002	[***]	[***]
January 1, 2003	[***]	[***]
January 1, 2004	[***]	[***]
each year thereafter	[***]	[***]

ARTICLE V
REPORTING

- 5.1 Prior to signing this Agreement, LICENSEE has provided to HARVARD a written business plan under which LICENSEE intends to bring the subject matter of the licenses

granted hereunder into commercial use upon execution of this Agreement. Such plan includes proposed marketing efforts.

- 5.2 No later than sixty (60) days after June 30 of each calendar year, LICENSEE shall provide to HARVARD a written annual Progress Report describing progress on research and development, regulatory approvals, manufacturing, sublicensing, marketing and sales during the most recent twelve (12) month period ending June 30 and plans for the forthcoming year. If multiple technologies are covered by the license granted hereunder, the Progress Report shall provide the information set forth above for each technology. If progress differs from that anticipated in the plan required under Section 5.1, LICENSEE shall explain the reasons for the difference and propose a modified plan for HARVARD's review. LICENSEE shall also provide any reasonable additional data HARVARD requires to evaluate LICENSEE's performance.
- 5.3 LICENSEE shall report to HARVARD the date of first sale of LICENSED PRODUCTS (or results of LICENSED PROCESSES) in each country within thirty (30) days of occurrence.
- 5.4 (a) LICENSEE shall submit to HARVARD within sixty (60) days after each calendar half year ending June 30 and December 31, a Royalty Report setting forth for such half year at least the following information:
- (i) the number of LICENSED PRODUCTS sold by LICENSEE in each country;
 - (ii) total billings and amounts actually received for such LICENSED PRODUCTS;
 - (iii) an accounting for all LICENSED PROCESSES used or sold;
 - (iv) deductions applicable to determine the NET SALES thereof;
 - (v) the amount of SERVICE INCOME received by LICENSEE and an accounting of all deductions to yield NET SERVICE INCOME;
 - (vi) the amount of SUBLICENSE INCOME received by LICENSEE; and
 - (vii) the amount of royalty due thereon, or, if no royalties are due to HARVARD for any reporting period, the statement that no royalties are due.

Such report shall be certified as correct by an officer of LICENSEE and shall include a detailed listing of all deductions from royalties.

- (b) LICENSEE shall pay to HARVARD with each such Royalty Report the amount of royalty due with respect to such half year. If multiple technologies are covered by the license granted hereunder, LICENSEE shall specify which PATENT RIGHTS are utilized for each LICENSED PRODUCT and LICENSED PROCESS included in the Royalty Report.

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- (c) All payments due hereunder shall be deemed received when funds are credited to HARVARD's bank account and shall be payable by check or wire transfer in United States dollars. Conversion of foreign currency to U.S. dollars shall be made at the conversion rate existing in the United States (as reported in the New York Times or the Wall Street Journal) on the last working day of each royalty period. No transfer, exchange, collection or other charges shall be deducted from such payments.
- (d) All such reports shall be maintained in confidence by HARVARD except as required by law; however, HARVARD may include in its usual reports annual amounts of royalties paid.
- (e) Late payments shall be subject to a charge of one and one-half percent (1.5%) per month, or \$250, whichever is greater.

5.5 In the event of acquisition, merger, change of corporate name or change in make-up, organization, or identity, LICENSEE shall notify HARVARD in writing within thirty (30) days of such event.

5.6 If by law, regulation or fiscal policy of a particular country, conversion into United States dollars or transfer of funds of a convertible currency to the United States is restricted or forbidden, LICENSEE shall give HARVARD prompt notice in writing and shall pay the royalty and other amounts due through such means or methods as are lawful in such country as HARVARD may reasonably designate. Failing the designation by HARVARD of such lawful means or methods within thirty (30) days after such notice is given to HARVARD, LICENSEE shall deposit such royalty or other payment in local currency to the credit of HARVARD in a recognized banking institution designated by HARVARD, or if none is designated by HARVARD within the thirty (30) day period described above, in a recognized banking institution selected by LICENSEE and identified in a written notice to HARVARD by LICENSEE, and such deposit shall fulfill all obligations of LICENSEE to HARVARD with respect to such royalties. When in any country in which the law or regulations prohibit both the transmittal and deposit of royalties on sales in such country, royalty payments shall be suspended for as long as such prohibition is in effect, and as soon as such prohibition ceases to be in effect, all royalties which LICENSEE would have been under obligation to transmit or deposit, but for the prohibition, shall be deposited or transmitted promptly to the extent allowable.

ARTICLE VI RECORD KEEPING

6.1 LICENSEE shall keep, and shall require its SUBLICENSEES to keep, accurate records (together with supporting documentation) of LICENSED PRODUCTS made, used or sold under this Agreement, and SERVICE INCOME and SUBLICENSE INCOME received by LICENSEE under this Agreement, appropriate to determine the amount of royalties due to HARVARD hereunder. Such records shall be retained for three (3) years following the end of the reporting period to which they relate. For such three year period, they shall be

available during normal business hours upon reasonable advance notice for examination by a certified public accountant selected by HARVARD, and reasonably acceptable to LICENSEE, for the sole purpose of verifying reports and payments hereunder. In conducting examinations pursuant to this Section 6.1, HARVARD's accountant shall have access to all records which HARVARD reasonably believes to be relevant to the calculation of royalties under Article IV. HARVARD agrees to maintain any information contained in such records in confidence, except as otherwise required by law and except information in regarding the amount of royalties due.

- 6.2 HARVARD's accountant shall not disclose to HARVARD any information other than information relating to the accuracy of reports and payments made hereunder.
- 6.3 Such examination by HARVARD's accountant shall be at HARVARD's expense, except that if such examination shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then LICENSEE shall pay the cost of such examination as well as any additional sum that would have been payable to HARVARD had the LICENSEE reported correctly, plus interest on said sum at the rate of one and one-half percent (1.5%) per month.

ARTICLE VII
DOMESTIC AND FOREIGN PATENT FILING AND MAINTENANCE

- 7.1 Upon execution of this Agreement, LICENSEE shall reimburse HARVARD for fifty percent (50%) of all reasonable expenses HARVARD has incurred for the preparation, filing, prosecution, maintenance and counseling with respect to PATENT RIGHTS. Such expenses total [***] as of October 1, 2000. Thereafter, LICENSEE shall reimburse HARVARD for [***] of all such future reasonable expenses prior to termination of this Agreement upon receipt of invoices from HARVARD.
- 7.2 HARVARD shall be responsible for the preparation, filing, prosecution and maintenance of any and all patent applications and patents included in PATENT RIGHTS. HARVARD will instruct counsel to directly notify HARVARD and LICENSEE and provide them copies of any official communications from the United States and foreign patent offices relating to said prosecution, and to provide LICENSEE with advance draft copies of all relevant communications to the various patent offices, so that LICENSEE may be informed and apprised of the continuing prosecution of patent applications in PATENT RIGHTS. LICENSEE shall have reasonable opportunities to participate in decision making on all key decisions affecting filing, prosecution and maintenance of patents and patent applications in PATENT RIGHTS. HARVARD will use reasonable efforts to incorporate LICENSEE's reasonable suggestions regarding said prosecution. HARVARD shall use all reasonable efforts to amend any patent application to include claims reasonably requested by LICENSEE to protect LICENSED PRODUCTS.
- 7.3 HARVARD and LICENSEE shall cooperate fully in the preparation, filing, prosecution and maintenance of PATENT RIGHTS and of all patents and patent applications licensed to LICENSEE hereunder, executing all papers and instruments or requiring members of

HARVARD to execute such papers and instruments so as to enable HARVARD to apply for, to prosecute and to maintain patent applications and patents in HARVARD's name in any country. Each party shall provide to the other prompt notice as to all matters which come to its attention and which may affect the preparation, filing, prosecution or maintenance of any such patent applications or patents.

- 7.4 LICENSEE may elect to surrender its PATENT RIGHTS in any country upon sixty (60) days written notice to HARVARD. Such notice shall not relieve LICENSEE from responsibility to reimburse HARVARD for patent-related expenses incurred prior to the expiration of the (60) day notice period.
- 7.5 If HARVARD elects not to prosecute or maintain any of the patents or patent applications relating to PATENT RIGHTS or any portion thereof in any country, LICENSEE shall be given sufficient notice of HARVARD's decision so that LICENSEE may request that HARVARD continue prosecuting or maintaining such patents or patent applications, at LICENSEE's expense. If HARVARD elects not to prosecute or maintain such patents or patent applications after such request by LICENSEE, then LICENSEE shall have the right, but not the obligation, at its own expense to prosecute and maintain such patents and patent applications or portion thereof in such country and in HARVARD's name. If LICENSEE assumes 100% of the costs to file, prosecute, and maintain certain patents and patent applications relating to the PATENT RIGHTS pursuant to this Section 7.5, and, if HARVARD licenses the PATENT RIGHTS to one or more co-exclusive licensees designated in Section 3.1 after such time, then HARVARD will credit LICENSEE with the costs LICENSEE has paid in excess of [***] if one other licensee, due for the preparation, filing, prosecution and maintenance of patents and patent applications relating to PATENT RIGHTS pursuant to Section 7.1 above.
- 7.6 If LICENSEE can demonstrate that it is not being adequately informed or apprised of the continuing prosecution of patents or patent applications in PATENT RIGHTS, or that it is not being provided with reasonable opportunities to participate in decision making or that its interests are not being adequately protected, LICENSEE shall be entitled to engage, at LICENSEE's expense, independent patent counsel to review and evaluate patent prosecution and filing of patents and patent applications included in PATENT RIGHTS.

ARTICLE VIII INFRINGEMENT

- 8.1 With respect to any PATENT RIGHTS that are licensed to LICENSEE pursuant to this Agreement, LICENSEE shall have the right to prosecute in its own name and at its own expense any infringement of such patent. HARVARD agrees to notify LICENSEE promptly of each infringement of such patents of which HARVARD, as applicable, is or becomes aware. Before LICENSEE commences an action with respect to any infringement of such patents, LICENSEE shall give careful consideration to the views of HARVARD and to potential effects on the public interest in making its decision whether or not to sue.

8.2 LICENSEE acknowledges that other co-exclusive licensees of PATENT RIGHTS designated in Section 3.1 shall have rights identical to LICENSEE to prosecute infringers and that co-exclusive licensees will be bound by the identical terms of this Section 8.2. In any prosecution instigated by LICENSEE and in which HARVARD, as necessary, is also named plaintiff as owner of the PATENT RIGHTS, LICENSEE must notify other co-exclusive licensees of the existence of such legal action and allow other co-exclusive licensees to join as a plaintiff upon co-exclusive licensees' request. In addition, in the event other co-exclusive licensees instigate an infringement prosecution, LICENSEE hereby consents to being joined as a plaintiff in such suit solely for the purpose of procuring standing to bring the action and at the sole expense of the instigating co-exclusive licensee. To the extent that LICENSEE desires to participate in any strategic decisions affecting the prosecution of the action brought by other co-exclusive licensees, LICENSEE acknowledges that it and co-exclusive licensees will necessarily have to reach a mutual agreement concerning litigation expenses and strategy. In no event shall HARVARD incur any liability or expense in connection with any action of co-exclusive licensees, joint or otherwise.

During any such litigation, HARVARD will agree to not license any defendant or accused infringer of the PATENT RIGHTS in the litigation, without LICENSEE's prior written consent.

- 8.3 (a) If LICENSEE elects to commence an action as described above, HARVARD may, to the extent permitted by law, elect to join as parties in that action. Regardless of whether HARVARD elects to join as parties, HARVARD shall cooperate fully with LICENSEE in connection with any such action.
- (b) HARVARD agrees to join as a party in any action if required by law to do so in order to bring an action under the PATENT RIGHTS.
- (c) LICENSEE shall reimburse HARVARD for any costs incurs with LICENSEE's approval, including reasonable attorneys' fees, as part of an action brought by LICENSEE, irrespective of whether HARVARD becomes a co-plaintiff.
- 8.4 If LICENSEE elects to commence an action as described above, LICENSEE may deduct from its royalty payments to HARVARD with respect to the patent(s) subject to suit an amount not exceeding [***] of LICENSEE's expenses and costs of such action, including reasonable attorneys' fees; provided, however, that such reduction shall not exceed [***] of the total royalty due to HARVARD with respect to the patent(s) subject to suit for each calendar year. If such [***] of LICENSEE's expenses and costs exceeds the amount of royalties deducted by LICENSEE for any calendar year, LICENSEE may to that extent reduce the royalties due to HARVARD from LICENSEE in succeeding calendar years, but never by more than [***] of the total royalty due in any one year with respect to the patent(s) subject to suit.

- 8.5 No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the prior written consent of HARVARD which consent shall not be unreasonably withheld.
- 8.6 Recoveries or reimbursements from actions commenced by LICENSEE pursuant to this Article shall first be applied to reimburse LICENSEE, HARVARD for litigation costs not paid from royalties and then to reimburse HARVARD for royalties deducted by LICENSEE pursuant to Section 8.4. Any remaining recoveries or reimbursements shall be shared as follows:
- (a) If the amount is lost profits or lost royalties, LICENSEE shall receive an amount equal to the damages the court determines LICENSEE has suffered as a result of the infringement less the amount of any royalties that would have been due HARVARD on sales of LICENSED PRODUCTS lost by LICENSEE as a result of the infringement had LICENSEE made such sales, and HARVARD shall receive an amount equal to the royalties it would have received if such sales had been made by LICENSEE, and
 - (b) As to awards other than lost profits or lost royalties, [***] to LICENSEE and fifty percent (50%) to HARVARD.
 - (c) If two or more co-exclusive licensees undertake the suit, the provision of this Section 8.6 will be modified to take into account each co-exclusive licensee's expenses and lost profits.
- 8.7 If LICENSEE elects not to exercise its right to prosecute an infringement of the PATENT RIGHTS pursuant to this Article, HARVARD may do so at its own expense, controlling such action and retaining all recoveries therefrom. LICENSEE shall cooperate fully with HARVARD in connection with any such action.
- 8.8 If a declaratory judgment action is brought naming LICENSEE as a defendant and alleging invalidity of any of the PATENT RIGHTS, HARVARD may elect to take over the sole defense of the action at its own expense. LICENSEE shall cooperate fully with HARVARD in connection with any such action. HARVARD shall consult with LICENSEE regarding such defense.

ARTICLE IX
TERMINATION OF AGREEMENT

- 9.1 This Agreement, unless terminated as provided herein, shall remain in effect until the last patent or patent application in PATENT RIGHTS has expired or been abandoned.
- 9.2 HARVARD may terminate this Agreement as follows:
- (a) If LICENSEE does not make a payment due hereunder and fails to cure such non-payment (including the payment of interest in accordance with Section 5.4(e)) within

thirty (30) days after the date of notice in writing of such non-payment by HARVARD.

- (b) If LICENSEE defaults in its obligations under Sections 10.3(c) and 10.3(d) to procure and maintain insurance.
- (c) If LICENSEE shall become insolvent, shall make an assignment for the benefit of creditors, or shall have a petition in bankruptcy filed for or against it. Such termination shall be effective immediately upon HARVARD giving written notice to LICENSEE.
- (d) If an examination by HARVARD's accountant pursuant to Article V shows an underreporting or underpayment by LICENSEE in excess of twenty percent (20%) for any twelve (12) month period, provided that such underreporting or underpayment is not determined to be inadvertent or the result of an honest mistake.
- (e) If LICENSEE is convicted of a felony relating to the manufacture, use, or sale of LICENSED PRODUCTS.
- (f) Except as provided in Subsections (a), (b), and (c) above, if LICENSEE defaults in the performance of any material obligations under this Agreement and the default has not been remedied within forty-five (45) days after the date of notice in writing of such default by HARVARD.

9.3 LICENSEE shall provide, in all sublicenses granted by it under this Agreement, that LICENSEE's interest in such sublicenses shall at HARVARD's option terminate or be assigned to HARVARD upon termination of this Agreement; however, LICENSEE shall have the option to nominate one of its sublicensees as a substitute for LICENSEE. The proposed substitute must (i) have a net worth of at least equivalent to the net worth LICENSEE had as of the date of this Agreement and (ii) have available resources and sufficient scientific, business and other expertise comparable to LICENSEE in order to satisfy its obligations under this Agreement. At least sixty (60) days prior to termination of this Agreement, LICENSEE shall provide HARVARD with written notice of LICENSEE's nominee together with documentation sufficient to demonstrate the requirements set forth in subparagraphs (i) and (ii) above for HARVARD's approval, which shall not be unreasonably withheld. HARVARD shall notify LICENSEE in writing of its decision prior to termination of this Agreement. If HARVARD approves LICENSEE's nominee, LICENSEE shall assign this Agreement to its nominee and its nominee shall accept the assignment no later than thirty (30) days after the termination date of this Agreement.

In the event that HARVARD disapproved LICENSEE's first nominee, prior to the termination date of this Agreement, LICENSEE shall have the option to nominate one of its other sublicensees for HARVARD's approval which shall not be unreasonably withheld.

9.4 LICENSEE may terminate this Agreement by giving ninety (90) days advance written notice of termination to HARVARD. Upon termination, LICENSEE shall submit a final Royalty Report to HARVARD and any royalty payments and unreimbursed patent expenses invoiced by HARVARD shall become immediately payable.

9.5 Sections 6.1, 6.2, 6.3, 7.1, 9.4, 9.5, 10.2, 10.3, 10.4, and 10.7 of this Agreement shall survive termination.

ARTICLE X
GENERAL

10.1 HARVARD does not warrant the validity of the PATENT RIGHTS licensed hereunder and make no representations whatsoever with regard to the scope of the licensed PATENT RIGHTS or that such PATENT RIGHTS may be exploited by LICENSEE, an AFFILIATE, or SUBLICENSEE without infringing other patents, provided, however, HARVARD represents that it has no knowledge of any facts or circumstances as of the execution date of this Agreement that would render any of the PATENT RIGHTS invalid or unenforceable. HARVARD represents and warrants, to the best of its knowledge, that HARVARD owns all right, title and interest in and to the PATENT RIGHTS.

10.2 HARVARD EXPRESSLY DISCLAIMS ANY AND ALL IMPLIED WARRANTIES AND MAKES NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OF THE PATENT RIGHTS OR INFORMATION SUPPLIED BY HARVARD, LICENSED PROCESSES OR LICENSED PRODUCTS CONTEMPLATED BY THIS AGREEMENT.

10.3 (a) LICENSEE shall indemnify, defend and hold harmless HARVARD and its current or former directors, governing board members, trustees, officers, faculty, medical and professional staff, employees, students, and agents and their respective successors, heirs and assigns (collectively, the "INDEMNITEES"), from and against any claim, liability, cost, expense, damage, deficiency, loss or obligation of any kind or nature (including, without limitation, reasonable attorney's fees and other costs and expenses of litigation) (collectively, "Claims"), based upon, arising out of, or otherwise relating to this Agreement, including without limitation any cause of action relating to product liability concerning any product, process, or service made, used or sold pursuant to any right or license granted under this Agreement, provided, however, that such indemnification shall not apply to any liability, damage, loss, or expense to the extent directly attributable to the negligent activities, reckless misconduct or intentional misconduct of Indemnitees.

(b) Each Indemnitee that intends to claim indemnification under Section 10.3(a) shall promptly notify LICENSEE of any claim or action in respect of which the Indemnitee intends to claim such indemnification, and LICENSEE shall assume the defense thereof with counsel mutually satisfactory to LICENSEE and HARVARD. The failure to deliver notice to LICENSEE within a reasonable time after the

commencement of any such claim or action, if materially prejudicial to its ability to defend such action, shall relieve LICENSEE of any liability to the Indemnitee under Section 10.3(a) with respect to such action, but the omission so to deliver notice to LICENSEE will not relieve it of any liability that it may have to any Indemnitee otherwise than under Section 10.3(a). HARVARD and any other Indemnitee, and their respective employees and agents, shall cooperate fully with LICENSEE and its legal representatives in the investigation of any claim or action covered by the indemnification under Section 10.3(a).

- (c) Beginning at the time any such product, process or service is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by LICENSEE or by a SUBLICENSEE, AFFILIATE or agent of LICENSEE, LICENSEE shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than [***] per incident and [***] annual aggregate and naming the Indemnitees as additional insureds. During clinical trials of any such product, process or service, LICENSEE shall, at its sole cost and expense, procure and maintain commercial general liability insurance in such equal or lesser amount as HARVARD shall require, naming the Indemnitees as additional insureds. Such commercial general liability insurance shall provide: (i) product liability coverage; and (ii) broad form contractual liability coverage for LICENSEE's indemnification under this Agreement. If LICENSEE elects to self-insure all or part of the limits described above (including deductibles or retentions which are in excess of [***] annual aggregate) such self-insurance program must be acceptable to HARVARD and the Risk Management Foundation of the Harvard Medical Institutions, Inc. in their sole discretion. The minimum amounts of insurance coverage required shall not be construed to create a limit of LICENSEE's liability with respect to its indemnification under this Agreement.
- (d) LICENSEE shall provide HARVARD with written evidence of such insurance upon request of HARVARD. LICENSEE shall provide HARVARD with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance; if LICENSEE does not obtain replacement insurance providing comparable coverage within such fifteen (15) day period, HARVARD shall have the right to terminate this Agreement effective at the end of such fifteen (15) day period without notice or any additional waiting periods.
- (e) LICENSEE shall maintain such commercial general liability insurance beyond the expiration or termination of this Agreement during: (i) the period that any product, process, or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold by LICENSEE or by a SUBLICENSEE, AFFILIATE or agent of LICENSEE; and (ii) a reasonable period after the period referred to in Subsection (e)(i) above which in no event shall be less than fifteen (15) years.

Certain identified information marked with [*] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.**

- 10.4 LICENSEE shall not use HARVARD's name or insignia, or any adaptation of them, or the name of any of HARVARD's inventors in any advertising, promotional or sales literature without the prior written approval of HARVARD.
- 10.5 Without the prior written approval of HARVARD in each instance, neither this Agreement nor the rights granted hereunder shall be transferred or assigned in whole or in part by LICENSEE to any person whether voluntarily or involuntarily, by operation of law or otherwise, except that each of LICENSEE and its AFFILIATES may assign this Agreement in connection with a merger, consolidation or sale or transfer of all or substantially all of its assets. This Agreement shall be binding upon the respective successors, legal representatives and assignees of HARVARD and LICENSEE.
- 10.6 The interpretation and application of the provisions of this Agreement shall be governed by the laws of the Commonwealth of Massachusetts.
- 10.7 LICENSEE shall comply with all applicable laws and regulations. In particular, it is understood and acknowledged that the transfer of certain commodities and technical data is subject to United States laws and regulations controlling the export of such commodities and technical data, including all Export Administration Regulations of the United States Department of Commerce. These laws and regulations among other things, prohibit or require a license for the export of certain types of technical data to certain specified countries. LICENSEE hereby agrees and gives written assurance that it will comply with all United States laws and regulations controlling the export of commodities and technical data, that it will be solely responsible for any violation of such by LICENSEE or its AFFILIATES or SUBLICENSEES, and that it will defend and hold HARVARD, CHILDREN, and MIT harmless in the event of any legal action of any nature occasioned by such violation.
- 10.8 LICENSEE agrees: (i) to obtain all regulatory approvals required for the manufacture and sale of LICENSED PRODUCTS and LICENSED PROCESSES; and (ii) to utilize appropriate patent marking on such LICENSED PRODUCTS. LICENSEE also agrees to register or record this Agreement as is required by law or regulation in any country where the license is in effect.
- 10.9 Any notices to be given hereunder shall be sufficient if signed by the party (or party's attorney) giving same and either: (i) delivered in person; (ii) mailed certified mail return receipt requested; or (iii) faxed to other party if the sender has evidence of successful transmission and if the sender promptly sends the original by ordinary mail, in any event to the following addresses:

If to LICENSEE:

Mycometrix Corporation
213 E. Grand Ave.
South San Francisco, CA 94080
Attention:
Fax: (650)-

If to HARVARD:

Office for Technology and Trademark Licensing
Harvard University
Holyoke Center, Suite 727
1350 Massachusetts Avenue
Cambridge, MA 02138
Fax: (617) 495-9568

By such notice either party may change their address for future notices.

Notices delivered in person shall be deemed given on the date delivered. Notices sent by fax shall be deemed given on the date faxed. Notices mailed shall be deemed given on the date postmarked on the envelope.

- 10.10 Should a court of competent jurisdiction later hold any provision of this Agreement to be invalid, illegal, or unenforceable, and such holding is not reversed on appeal, it shall be considered severed from this Agreement. All other provisions, rights and obligations shall continue without regard to the severed provision, provided that the remaining provisions of this Agreement are in accordance with the intention of the parties.
- 10.11 In the event of any controversy or claim arising out of or relating to any provision of this Agreement or the breach thereof, the parties shall try to settle such conflict amicably between themselves. Subject to the limitation stated in the final sentence of this Section 10.11, any such conflict which the parties are unable to resolve promptly shall be settled through arbitration conducted in accordance with the rules of the American Arbitration Association. The demand for arbitration shall be filed within a reasonable time after the controversy or claim has arisen, and in no event after the date upon which institution of legal proceedings based on such controversy or claim would be barred by the applicable statute of limitation. Such arbitration shall be held in Boston, Massachusetts. The award through arbitration shall be final and binding. Either party may enter any such award in a court having jurisdiction or may make application to such court for judicial acceptance of the award and an order of enforcement, as the case may be. Notwithstanding the foregoing, either party may, without recourse to arbitration, assert against the other party a third-party claim or cross-claim in any action brought by a third party, to which the subject matter of this Agreement may be relevant.
- 10.12 This Agreement constitutes the entire understanding between the parties and neither party shall be obligated by any condition or representation other than those expressly stated herein or as may be subsequently agreed to by the parties hereto in writing.

[The remainder of this page is intentionally blank.]

Certain identified information marked with [*] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.**

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives.

PRESIDENT AND FELLOWS
OF HARVARD COLLEGE

MYCOMETRIX CORPORATION

/s/ Joyce Brinton

/s/ Gajus Worthington

Joyce Brinton, Director
Office for Technology and
Trademark Licensing

President

12/7/00

12/10/00

Date

Date

Certain identified information marked with [*] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.**

APPENDIX A

The following comprise PATENT RIGHTS:

[***].

[***]

First Amendment
To
Co-Exclusive License Agreement

Between
PRESIDENT AND FELLOWS OF HARVARD COLLEGE
And
MYCOMETRIX CORPORATION (now Fluidigm Corporation)
Re: Harvard Case #[*]**

This is the first amendment to a co-exclusive license agreement effective October 15, 2000, by and between the President and Fellows of Harvard College, with offices at 1350 Massachusetts Avenue, Suite 727, Cambridge, MA 02138 (“Harvard”) and Mycometrix Corporation, a California Corporation, with offices at 213 East Grand Avenue, South San Francisco, CA 94080 (“Licensee”).

WHEREAS, Licensee has changed its name to Fluidigm Corporation, and moved to a new address at 7100 Shoreline Court, South San Francisco, California 94080; and

WHEREAS, both parties desire to clarify the definition of NET SALES and to make various minor changes to the Agreement.

NOW THEREFORE, Harvard and Licensee agree as follows:

1. Change Paragraph 1.5 to:

LICENSED PROCESSES: the processes claimed, in whole or in part, by at least one VALID CLAIM included within PATENT RIGHTS.

2. Change Paragraph 1.6 to:

LICENSED PRODUCTS: the products which are claimed, or the use of which is claimed, by at least one VALID CLAIM included within

PATENT RIGHTS or products made or services provided in accordance with or by means of LICENSED PROCESSES.

3. Change Paragraph 1.7 to:

LICENSEE: Fluidigm Corporation, a corporation organized under the laws of California, having its principal offices at 7100 Shoreline Court, South San Francisco, California 94080.

4. Change the second full paragraph of Paragraph 1.9 to:

In the event that a LICENSED PRODUCT is sold or leased as a combination product containing the LICENSED PRODUCT and one or more other components, NET SALES shall be calculated by multiplying the gross amount invoiced for the sale of the combination product by the fraction $A/A+B$, where A is the average gross selling price of the LICENSED PRODUCT sold separately by LICENSEE, and B is the average gross selling price of such other components of the combination products sold separately by LICENSEE during the relevant royalty payment period. In the event a substantial number of such separate sales were not made during the relevant royalty period, then NET SALES shall be reasonably allocated by LICENSEE between such LICENSED PRODUCT and such other components of the combination based on their relative importance or value. If LICENSEE does so allocate, LICENSEE shall promptly deliver to HARVARD a written report providing a detailed explanation of how LICENSEE determined said relative importance or value. In the event that HARVARD disagrees with the determination made by LICENSEE of said allocation of importance or value, HARVARD shall so notify LICENSEE in writing, and a representative of LICENSEE and a representative of HARVARD shall meet in order to discuss and resolve such disagreement. If such disagreement cannot be resolved within sixty (60) days, such disagreement shall be subject to resolution in accordance with Section 10.11.

5. Add the following sentence to the end of Paragraph 1.10:

In addition, SERVICE INCOME shall be subject to the following deductions:

- i) customary trade, quantity or cash discounts and non-affiliated broker's or agents' commissions actually allowed and taken;
- ii) amounts repaid or credited by reason of rejection; and
- iii) to the extent separately stated on purchase orders, invoices, or other documents of sale, taxes levied on and/or other governmental

charges made as to performance, production, sale or use and paid by or on behalf of LICENSEE.

6. Change Paragraph 1.15 to:

VALID CLAIM: either (i) a claim of an issued patent that has not been held unenforceable or invalid by an agency or a court of competent jurisdiction in any unappealable or unappealed decision or (ii) a claim of a pending patent application that has not been abandoned or finally rejected without the possibility of appeal or refiling and that has been pending for less than six (6) years from the earlier of a) the first priority date of such patent application or b) the effective date of this Agreement.

7. Change Paragraph 3.2(c) to:

LICENSEE shall use commercially reasonable efforts to effect introduction of the LICENSED PRODUCTS into the commercial market as soon as practicable, consistent with sound and reasonable business practice and judgment; thereafter, until the expiration of this Agreement, LICENSEE shall endeavor to keep LICENSED PRODUCTS reasonably available to the public, in each case consistent with industry practices for similar companies and similar products.

8. Replace the last two sentences of Paragraph 3.2(e) with:

“Copies of all sublicense agreements shall be promptly provided to HARVARD. If a sublicense agreement is part of a larger agreement (i.e., one that includes a business relationship in addition to a sublicense agreement), LICENSEE need only send the part of said larger agreement that is the sublicense agreement. HARVARD agrees to maintain any information contained in such sublicensing agreements in confidence, except as otherwise required by law, however, HARVARD may include in its usual reports annual amounts of royalties paid.”

9. In Paragraph 5.3 delete “in each country”, so LICENSEE needs to report the date of first sale in the first country to have a sale, but LICENSEE still needs to report the date of first sale for each LICENSED PRODUCT.

10. Replace Paragraph 6.2 with:

“HARVARD’s accountant shall not disclose to HARVARD any information other than whether the reports are correct or not, the reasons for any incorrectness and the amount of any discrepancies.”

11. Add new Paragraph 6.4:

“Such examination by HARVARD’s accountant shall take place not more than once in each calendar year.”

12. Change Paragraph 9.2(d) to:

“If an examination by HARVARD’s accountant pursuant to Article V shows an underreporting or underpayment by LICENSEE in excess of twenty (20%) percent for any twelve (12) month period and HARVARD’s accountant determines said underreporting or underpayment was not inadvertent or not the result of an honest mistake on LICENSEE’s part. In that event, LICENSEE may promptly request HARVARD to have its accountant’s findings reviewed by another independent certified public accounting firm of nationally recognized standing reasonably acceptable to LICENSEE, the total cost of which will be invoiced to LICENSEE and paid within thirty (30) days. If said review indicates said underreporting or underpayment by LICENSEE was inadvertent or the result of an honest mistake then HARVARD will not terminate this Agreement.

13. In Paragraph 10.9, change lines 6-11 to:

If to LICENSEE:

Fluidigm Corporation
7100 Shoreline Court
South San Francisco, CA 94080
Attention: General Counsel
Fax: 650-871-7195

In all other respects the co-exclusive License Agreement, effective October 15, 2000, shall remain the same. This amendment shall become effective upon both parties signing below, and have an effective date of January 1, 2005.

IN WITNESS WHEREOF, the parties hereto have caused this second amendment to be executed by their duly authorized representatives.

**PRESIDENT AND FELLOWS
OF HARVARD COLLEGE:**

**FLUIDIGM
CORPORATION:**

/s/ Joyce Brinton

/s/ Gajus Worthington

Joyce Brinton

Director
Office for Technology and
Trademark Licensing

Printed: Gajus Worthington

Title: President & CEO

Date: 12/22/04

Date: 12/23/04

4060.LICI.008 Harvard

CO-EXCLUSIVE LICENSE AGREEMENT

Between

President and Fellows of Harvard College

And

Mycometrix Corporation

Effective as of October 15, 2000

Re: Harvard Case #[***]

In consideration of the mutual promises and covenants set forth below, the parties hereto agree as follows:

ARTICLE I
DEFINITIONS

As used in this Agreement, the following terms shall have the following meanings:

- 1.1 ACADEMIC RESEARCH PURPOSES: use of PATENT RIGHTS for academic research or other not-for-profit scholarly purposes which are undertaken at a non-profit or governmental institution that does not use the PATENT RIGHTS in the production or manufacture of products for sale or the performance of services for a fee.
- 1.2 AFFILIATE: any entity which controls, is controlled by, or is under common control with a party by ownership or control of at least fifty percent (50%) of the voting stock or other ownership. Unless otherwise specified, the term LICENSEE includes AFFILIATES.
- 1.3 FIELD: use of PATENT RIGHTS to develop, manufacture, use, offer for sale, sell, or import components and products in FIELD I and/or FIELD II:

FIELD I: [***]

FIELD II: [***]

Certain identified information marked with [*] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.**

- 1.4 HARVARD: President and Fellows of Harvard College, a nonprofit Massachusetts educational corporation having offices at the Office for Technology and Trademark Licensing, Holyoke Center, Suite 727, 1350 Massachusetts Avenue, Cambridge, Massachusetts 02138.
- 1.5 LICENSED PROCESSES: the processes covered by at least one VALID CLAIM included within the PATENT RIGHTS.
- 1.6 LICENSED PRODUCTS: products covered by at least one VALID CLAIM included within the PATENT RIGHTS or products made or services provided in accordance with or by means of LICENSED PROCESSES.
- 1.7 LICENSEE: Mycometrix Corporation, a corporation organized under the laws of California having its principal offices at 213 East Grand Avenue, South San Francisco, CA 94080.
- 1.8 NET SERVICE INCOME: SERVICE INCOME less LICENSEE'S actual direct and indirect cost for research, development and/or services provided.
- 1.9 NET SALES: the amount actually received for sales, leases, or other transfers of LICENSED PRODUCTS, less:
 - (i) customary trade, quantity or cash discounts and non-affiliated brokers' or agents' commissions actually allowed and taken;
 - (ii) amounts repaid or credited by reason of rejection or return;
 - (iii) to the extent separately stated on purchase orders, invoices, or other documents of sale, taxes levied on and/or other governmental charges made as to production, sale, transportation, delivery or use and paid by or on behalf of LICENSEE; and
 - (iv) reasonable charges for delivery or transportation provided by third parties and cost of insurance in transit, if separately stated.

NET SALES also includes the fair market value of any non-cash consideration received by LICENSEE for the sale, lease, or transfer of LICENSED PRODUCTS.

If a LICENSED PRODUCT is sold as a combination product containing the LICENSED PRODUCT and one or more other components, NET SALES shall be calculated by multiplying the gross amount invoiced for the sale of the combination product by the fraction $A/A+B$ where A is the average gross selling price of the LICENSED PRODUCT sold separately by LICENSEE and B is the average gross selling price of such other components of the combination products sold separately by LICENSEE during the relevant royalty payment period.

In the event that LICENSEE grants a sublicensee hereunder, and receives payments based upon SUBLICENSEE's sales of LICENSED PRODUCTS, LICENSEE may upon approval from HARVARD (which shall not be unreasonably withheld) modify the definition of NET SALES for the purposes of calculating royalties payable to HARVARD on such SUBLICENSEE's sales to be the same as the definition of NET SALES on which such royalties to LICENSEE are calculated.

- 1.10 SERVICE INCOME: the total financial consideration received by LICENSEE for commercial services performed on a fee-for-service basis using the LICENSED PRODUCTS or LICENSED PROCESSES by LICENSEE under a contract with a third party, where such services are based primarily on the use of fully functional LICENSED PRODUCTS or LICENSED PROCESSES (as applicable) for their intended commercial use (such as, for example, where LICENSEE performs commercial-scale genotyping services for a pharmaceutical company on a fee-for-service basis using fully developed microfluidics chips comprising LICENSED PRODUCTS). SERVICE INCOME shall not include amounts received in connection with research and/or development of LICENSED PRODUCTS or LICENSED PROCESSES themselves.
- 1.11 PATENT RIGHTS: The applications and patents filed on the basis of the disclosure attached in Appendix A of this Agreement, the allowed claims of such applications, the inventions described and claimed therein, and any divisions or continuations of the applications and patents, and specific claims of any continuations-in-part of such applications to the extent the specific claims are directed to subject matter described in the applications and patents in a manner sufficient to support such specific claims under 35 U.S.C., patents issuing thereon or reissues thereof, and any and all foreign patents and patent applications corresponding thereto, all to the extent owned or controlled by HARVARD.
- 1.12 SUBLICENSE INCOME: the amount paid to LICENSEE by a third party (other than an AFFILIATE of LICENSEE) (a) for the sublicensing of PATENT RIGHTS to a third party as well as (b) for the related licensing of LICENSEE's own patent rights or know-how or LICENSEE's in-licensed non-HARVARD technologies, including but not limited to (i) license fees, (ii) milestone payments, (iii) royalties, (iv) the fair market value in cash of any non-cash consideration for such sublicense, and (v) in the event that LICENSEE receives any payment for equity in consideration for the grant of sublicense rights that included a premium over the fair market value of such equity, the amount of such premium. LICENSEE shall be responsible for determining such fair market value with reasonable business judgment.
- 1.13 SUBLICENSEE: any non-AFFILIATE granted a sublicense of any of the rights HARVARD has granted to LICENSEE under Section 3.1.
- 1.14 TERRITORY: Worldwide.

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- 1.15 VALID CLAIM: either (i) a claim of an issued patent that has not been held unenforceable or invalid by an agency or a court of competent jurisdiction in any unappealable or unappealed decision or (ii) a claim of a published, pending patent application, which claim is substantially identical to a corresponding claim in a subsequently issued patent having priority to the patent application.
- 1.16 The terms “Public Law 96-517” and “Public Law 98-620” include all amendments to those statutes.
- 1.17 The terms “sold” and “sell” include, without limitation, leases and other transfers and similar transactions.

ARTICLE II REPRESENTATIONS

- 2.1 HARVARD is or will be owner by assignment from [***] in the US and foreign patent applications corresponding thereto, and in the inventions described and claimed therein. Inventorship will be finalized at the time of the US utility filing or in the near future when it is necessary.
- 2.2 HARVARD has authority to issue licenses under PATENT RIGHTS.
- 2.3 HARVARD is committed to the policy that ideas or creative works produced at HARVARD should be used for the greatest possible public benefit, and believes that every reasonable incentive should be provided for the prompt introduction of such ideas into public use, all in a manner consistent with the public interest.
- 2.4 LICENSEE is prepared and intends to diligently develop the invention and to bring products to market which are subject to this Agreement, specifically including one or more products in the FIELD selected from a [***].
- 2.5 LICENSEE is desirous of obtaining a co-exclusive license in the FIELD and in the TERRITORY in order to practice the PATENT RIGHTS in the United States and in certain foreign countries, and to manufacture, use and sell in the commercial market the products made in accordance therewith, and HARVARD is desirous of granting such a license to LICENSEE in accordance with the terms of this Agreement.

ARTICLE III GRANT OF RIGHTS

- 3.1 HARVARD hereby grants to LICENSEE and LICENSEE accepts, subject to the terms and conditions hereof, in the TERRITORY a co-exclusive commercial license under PATENT

RIGHTS in FIELD I and in FIELD II to make and have made, to use and have used, to sell and have sold, and to offer for sale and have offered for sale the LICENSED PRODUCTS, and to practice the LICENSED PROCESSES, for the life of the PATENT RIGHTS. HARVARD will grant no more than two commercial licenses in FIELD I at any time and will grant no more than two commercial licenses in FIELD II at any time and HARVARD will not grant other licenses in the FIELD except as required by HARVARD's obligations in Section 3.2(a) or as permitted Section 3.2(b). Such co-exclusive license shall include the right to grant sublicenses under the following circumstances: (i) LICENSEE can demonstrate that it has added significant value to the PATENT RIGHTS to be sublicensed, and that such a sublicense also contains a substantial and essentially simultaneous license of LICENSEE owned intellectual property, or (ii) LICENSEE grants a sublicense under other HARVARD patent rights licensed exclusively to LICENSEE which are dominated by PATENT RIGHTS, and such sublicense under PATENT RIGHTS is necessary to practice such other HARVARD patent rights.

3.2 The granting and exercise of this license is subject to the following conditions:

- (a) HARVARD's "Statement of Policy in Regard to Inventions, Patents and Copyrights," dated August 10, 1998, Public Law 96-517, Public Law 98-620. In addition, this Agreement is subject to HARVARD's obligations under agreements with other sponsors of research, provided that such obligations are not in conflict with the rights granted hereunder. Any right granted in this Agreement greater than that permitted under Public Law 96-517, or Public Law 98-620, shall be subject to modification as may be required to conform to the provisions of those statutes.
- (b) HARVARD reserves the right to make and use, and grant to others non-exclusive licenses to make and use solely for ACADEMIC RESEARCH PURPOSES the subject matter described and claimed in PATENT RIGHTS.
- (c) LICENSEE shall use commercially reasonable efforts to effect introduction of the LICENSED PRODUCTS into the commercial market as soon as practicable, consistent with sound and reasonable business practice and judgment; thereafter, until the expiration of this Agreement, LICENSEE shall endeavor to keep LICENSED PRODUCTS reasonably available to the public.
- (d) At any time after three years from the effective date of this Agreement and as HARVARD's sole remedy for such non-performance, HARVARD may increase the license maintenance royalty under Section 4.4 to [***] dollars each in FIELD I and in FIELD II in year 2004 and [***] dollars each in FIELD I and in FIELD II per year each year beginning in 2005, if in HARVARD's reasonable judgment, the Progress Reports furnished by LICENSEE do not demonstrate that LICENSEE has satisfied at least one of the following conditions, which non-performance is not cured within ninety (90) days following the written notification of such by HARVARD to LICENSEE:

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- (i) has put the licensed subject matter into commercial use in at least one of the countries hereby licensed, directly or through a sublicense, and is keeping the licensed subject matter reasonably available to the public; or
 - (ii) is engaged in research, development, manufacturing, marketing or sublicensing activity appropriate to achieving 3.2(d)(i).
- (e) In all sublicenses granted by LICENSEE hereunder, LICENSEE shall include a requirement that the SUBLICENSEE use commercially reasonable efforts to bring the subject matter of the sublicense into commercial use. LICENSEE shall further provide in such sublicenses that such sublicenses are subject and subordinate to the terms and conditions of this Agreement, except: (i) the SUBLICENSEE may not further sublicense; and (ii) the rate of royalty on NET SALES paid by the SUBLICENSEE to the LICENSEE. Copies of the relevant provisions of all sublicense agreements shall be provided promptly to HARVARD. HARVARD agrees to maintain any information contained in such provisions in confidence, except as otherwise required by law, however, HARVARD may include in its usual reports annual amounts of royalties paid.
- (f) A license in any other field of use in addition to the FIELD shall be the subject of a separate agreement and shall require LICENSEE's submission of evidence, satisfactory to HARVARD, demonstrating LICENSEE's willingness and ability to develop and commercialize in such other field of use the kinds of products or processes likely to be encompassed in such other fields.
- (g) To the extent that federal funds are used to support research leading to a patent or patent application in the PATENT RIGHTS, LICENSEE shall cause any LICENSED PRODUCT produced for sale by LICENSEE or SUBLICENSEES in the United States to be manufactured substantially in the United States during the period of exclusivity of this license in the United States.
- 3.4 All rights reserved to the United States Government and others under Public Law 96-517, and Public Law 98-620, shall remain and shall in no way be affected by this Agreement.

ARTICLE IV ROYALTIES

- 4.1 LICENSEE shall pay to HARVARD a non-refundable license royalty fee in the sum of [***] payable within thirty (30) days of the execution date of this Agreement.
- 4.2 (a) In consideration of the right and license granted herein, LICENSEE shall pay to HARVARD during the term of this Agreement a royalty of [***] on NET SALES of LICENSED PRODUCTS sold by LICENSEE.

Certain identified information marked with [*] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.**

(b) In the event that a single LICENSED PRODUCT or LICENSED PROCESS is covered by HARVARD intellectual property in addition to PATENT RIGHTS, which is licensed to LICENSEE under other agreements as of the date of this Agreement, then the total royalty payment due HARVARD under all such agreements including this Agreement shall be [***] of NET SALES. LICENSEE shall notify HARVARD of the identity of each license agreement that includes patent rights covering the product or process, and HARVARD shall distribute the royalties evenly among such agreements.

(c) As consideration for the rights granted hereunder, LICENSEE shall pay to HARVARD during the term of this Agreement a royalty in the form of stock of LICENSEE as follows:

- (i) LICENSEE shall issue to HARVARD [***] shares of the Common Stock of LICENSEE (“Shares”) pursuant to the terms of a mutually acceptable Stock Subscription Agreement, provided, however, that HARVARD shall be subject to and enter into appropriate agreements and related documents as required of other stockholders of LICENSEE.
- (ii) HARVARD represents and warrants to LICENSEE that:
 - (1) HARVARD is acquiring the Shares for its own account for investment and not with a view to, or for sale in connection with any distribution thereof, nor with any present intention of distributing or selling the same; and HARVARD has no present or contemplated agreement, undertaking, arrangement, obligation, indebtedness or commitment providing for the disposition thereof.
 - (2) HARVARD has full power and authority to enter into and to perform this Agreement in accordance with its terms.
 - (3) HARVARD has sufficient knowledge and experience in investing in companies similar to LICENSEE so as to be able to evaluate the risks and merits of its investment in LICENSEE and is able financially to bear the risks thereof.
- (iii) Each certificate representing the Shares shall bear a legend substantially in the following form:

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“The shares represented by this certificate have not been registered under the Securities Act of 1933 or any state securities law and they may not be sold or otherwise transferred by any person, including a pledgee, unless (1) either (a) a registration statement with respect to such shares shall be effective under the Securities Act of 1933, as amended, or (b) the Corporation shall have received an opinion of counsel satisfactory to the Corporation that an exemption from registration under such Act is then available, and (2) there shall have been compliance with all applicable securities laws.”

“The shares represented by this certificate are subject to a mutually agree-upon Stock Purchase and Right of First Refusal Agreement with this Corporation, a copy of which Stock Purchase and Right of First Refusal Agreement is available for inspection at the offices of the Corporation or may be made available upon request.”

The foregoing legend shall be removed from the certificates representing any Shares, at the request of the holder thereof, at such time as they become eligible for resale pursuant to the Securities Act of 1933, as amended.

If at any time prior to the time the Shares are eligible for resale pursuant to an exemption from registration under the Securities Act of 1933, as amended, LICENSEE proposes to register any of its Common Stock, under the Securities Act of 1933, except at LICENSEE's initial public offering or any offering pursuant to Forms S-4 or S-8, LICENSEE shall offer HARVARD the opportunity to have its Shares registered under the registration statement to be filed at such time. HARVARD will be offered the right to register its Shares under the same terms, conditions and restrictions as other shareholders with piggyback registration rights and the inclusion of any Shares in such registration statement shall be subject to the approval of the underwriters of such offering

(iv) HARVARD's ownership rights to Shares shall not be affected should the license pursuant to this Agreement be converted to a nonexclusive one.

(d) In the case of sublicenses, LICENSEE shall also pay to HARVARD a royalty of [***] of SUBLICENSE INCOME. If compensation for such a sublicense of PATENT RIGHTS is bundled with compensation received for the sublicensing of the other HARVARD patent rights licensed to LICENSEE under other agreements as of the date of this Agreement, LICENSEE shall pay HARVARD only [***] of the total compensation received no matter how many license agreements from HARVARD are involved. In such a case, LICENSEE shall notify HARVARD of the identity of each license agreement involved and HARVARD shall distribute its [***] of

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compensation equally among those license agreements, including this Agreement.

(e) LICENSEE shall pay HARVARD [***] of NET SERVICE INCOME. If SERVICE INCOME is bundled with service income under another license to LICENSEE as of the date of this Agreement, LICENSEE shall pay a royalty of [***] of NET SERVICE INCOME received from each and every third party ("Third Party") to which services are provided. LICENSEE shall notify HARVARD of the identity of each license agreement involved in the services and HARVARD shall distribute its [***] of compensation equally among those license agreements, including this Agreement.

(f) If other co-exclusive licenses in the same FIELD and TERRITORY are granted after the date this Agreement is executed, the above financial compensation shall not exceed the financial compensation to be paid by other licensees in the same FIELD and TERRITORY during the term of the co-exclusive license provided LICENSEE accepts any less favorable terms included in such other license.

If stock is part of the financial compensation to be paid by other licensees in the same FIELD and TERRITORY, the fair market value of the stock shall be the same as the price per share which other investors paid in the last round of financing unless the stock is publicly traded.

- 4.3 On sales between LICENSEE and its AFFILIATES for resale or incorporation into products, the royalty shall be paid on the NET SALES of the AFFILIATE. On sales between LICENSEE and sublicensees for resale, the royalty shall be paid on the SUBLICENSE INCOME.
- 4.4 No later than January 1 of each calendar year indicated below, LICENSEE shall pay to HARVARD the following non-refundable license maintenance royalty and/or advance on royalties. Such payments shall be credited against running royalties due for that calendar year and Royalty Reports shall reflect such a credit. Such payments shall not be credited against milestone payments (if any) nor against royalties due for any subsequent calendar year nor against such payments due under any other agreements with HARVARD.

	FIELD I	FIELD II
January 1, 2002	[***]	[***]
January 1, 2003	[***]	[***]
January 1, 2004	[***]	[***]
each year thereafter	[***]	[***]

ARTICLE V REPORTING

- 5.1 Prior to signing this Agreement, LICENSEE has provided to HARVARD a written business plan under which LICENSEE intends to bring the subject matter of the licenses

granted hereunder into commercial use upon execution of this Agreement. Such plan includes proposed marketing efforts.

- 5.2 No later than sixty (60) days after June 30 of each calendar year, LICENSEE shall provide to HARVARD a written annual Progress Report describing progress on research and development, regulatory approvals, manufacturing, sublicensing, marketing and sales during the most recent twelve (12) month period ending June 30 and plans for the forthcoming year. If multiple technologies are covered by the license granted hereunder, the Progress Report shall provide the information set forth above for each technology. If progress differs from that anticipated in the plan required under Section 5.1, LICENSEE shall explain the reasons for the difference and propose a modified plan for HARVARD's review. LICENSEE shall also provide any reasonable additional data HARVARD requires to evaluate LICENSEE's performance.
- 5.3 LICENSEE shall report to HARVARD the date of first sale of LICENSED PRODUCTS (or results of LICENSED PROCESSES) in each country within thirty (30) days of occurrence.
- 5.4 (a) LICENSEE shall submit to HARVARD within sixty (60) days after each calendar half year ending June 30 and December 31, a Royalty Report setting forth for such half year at least the following information:
- (i) the number of LICENSED PRODUCTS sold by LICENSEE in each country;
 - (ii) total billings and amounts actually received for such LICENSED PRODUCTS;
 - (iii) an accounting for all LICENSED PROCESSES used or sold;
 - (iv) deductions applicable to determine the NET SALES thereof;
 - (v) the amount of SERVICE INCOME received by LICENSEE and an accounting of all deductions to yield NET SERVICE INCOME;
 - (vi) the amount of SUBLICENSE INCOME received by LICENSEE; and
 - (vii) the amount of royalty due thereon, or, if no royalties are due to HARVARD for any reporting period, the statement that no royalties are due.

Such report shall be certified as correct by an officer of LICENSEE and shall include a detailed listing of all deductions from royalties.

- (b) LICENSEE shall pay to HARVARD with each such Royalty Report the amount of royalty due with respect to such half year. If multiple technologies are covered by the license granted hereunder, LICENSEE shall specify which PATENT RIGHTS are utilized for each LICENSED PRODUCT and LICENSED PROCESS included in the Royalty Report.

- (c) All payments due hereunder shall be deemed received when funds are credited to HARVARD's bank account and shall be payable by check or wire transfer in United States dollars. Conversion of foreign currency to U.S. dollars shall be made at the conversion rate existing in the United States (as reported in the New York Times or the Wall Street Journal) on the last working day of each royalty period. No transfer, exchange, collection or other charges shall be deducted from such payments.
 - (d) All such reports shall be maintained in confidence by HARVARD except as required by law; however, HARVARD may include in its usual reports annual amounts of royalties paid.
 - (e) Late payments shall be subject to a charge of one and one-half percent (1.5%) per month, or \$250, whichever is greater.
- 5.5 In the event of acquisition, merger, change of corporate name or change in make-up, organization, or identity, LICENSEE shall notify HARVARD in writing within thirty (30) days of such event.
- 5.6 If by law, regulation or fiscal policy of a particular country, conversion into United States dollars or transfer of funds of a convertible currency to the United States is restricted or forbidden, LICENSEE shall give HARVARD prompt notice in writing and shall pay the royalty and other amounts due through such means or methods as are lawful in such country as HARVARD may reasonably designate. Failing the designation by HARVARD of such lawful means or methods within thirty (30) days after such notice is given to HARVARD, LICENSEE shall deposit such royalty or other payment in local currency to the credit of HARVARD in a recognized banking institution designated by HARVARD, or if none is designated by HARVARD within the thirty (30) day period described above, in a recognized banking institution selected by LICENSEE and identified in a written notice to HARVARD by LICENSEE, and such deposit shall fulfill all obligations of LICENSEE to HARVARD with respect to such royalties. When in any country in which the law or regulations prohibit both the transmittal and deposit of royalties on sales in such country, royalty payments shall be suspended for as long as such prohibition is in effect, and as soon as such prohibition ceases to be in effect, all royalties which LICENSEE would have been under obligation to transmit or deposit, but for the prohibition, shall be deposited or transmitted promptly to the extent allowable.

ARTICLE VI
RECORD KEEPING

- 6.1 LICENSEE shall keep, and shall require its SUBLICENSEES to keep, accurate records (together with supporting documentation) of LICENSED PRODUCTS made, used or sold under this Agreement, and SERVICE INCOME and SUBLICENSE INCOME received by LICENSEE under this Agreement, appropriate to determine the amount of royalties due to HARVARD hereunder. Such records shall be retained for three (3) years following the end of the reporting period to which they relate. For such three year period, they shall be

available during normal business hours upon reasonable advance notice for examination by a certified public accountant selected by HARVARD, and reasonably acceptable to LICENSEE, for the sole purpose of verifying reports and payments hereunder. In conducting examinations pursuant to this Section 6.1, HARVARD's accountant shall have access to all records which HARVARD reasonably believes to be relevant to the calculation of royalties under Article IV. HARVARD agrees to maintain any information contained in such records in confidence, except as otherwise required by law and except information in regarding the amount of royalties due.

- 6.2 HARVARD's accountant shall not disclose to HARVARD any information other than information relating to the accuracy of reports and payments made hereunder.
- 6.3 Such examination by HARVARD's accountant shall be at HARVARD's expense, except that if such examination shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then LICENSEE shall pay the cost of such examination as well as any additional sum that would have been payable to HARVARD had the LICENSEE reported correctly, plus interest on said sum at the rate of one and one-half percent (1.5%) per month.

ARTICLE VII DOMESTIC AND FOREIGN PATENT FILING AND MAINTENANCE

- 7.1 Upon execution of this Agreement, LICENSEE shall reimburse HARVARD for fifty percent (50%) of all reasonable expenses HARVARD has incurred for the preparation, filing, prosecution, maintenance and counseling with respect to PATENT RIGHTS. Such expenses total [***] as of October 1, 2000. Thereafter, LICENSEE shall reimburse HARVARD for fifty percent (50%) of all such future reasonable expenses prior to the termination of this Agreement upon receipt of invoices from HARVARD.
- 7.2 HARVARD shall be responsible for the preparation, filing, prosecution and maintenance of any and all patent applications and patents included in PATENT RIGHTS. HARVARD will instruct counsel to directly notify HARVARD and LICENSEE and provide them copies of any official communications from the United States and foreign patent offices relating to said prosecution, and to provide LICENSEE with advance draft copies of all relevant communications to the various patent offices, so that LICENSEE may be informed and apprised of the continuing prosecution of patent applications in PATENT RIGHTS. LICENSEE shall have reasonable opportunities to participate in decision making on all key decisions affecting filing, prosecution and maintenance of patents and patent applications in PATENT RIGHTS. HARVARD will use reasonable efforts to incorporate LICENSEE's reasonable suggestions regarding said prosecution. HARVARD shall use all reasonable efforts to amend any patent application to include claims reasonably requested by LICENSEE to protect LICENSED PRODUCTS.
- 7.3 HARVARD and LICENSEE shall cooperate fully in the preparation, filing, prosecution and maintenance of PATENT RIGHTS and of all patents and patent applications licensed to LICENSEE hereunder, executing all papers and instruments or requiring members of

HARVARD to execute such papers and instruments so as to enable HARVARD to apply for, to prosecute and to maintain patent applications and patents in HARVARD's name in any country. Each party shall provide to the other prompt notice as to all matters which come to its attention and which may affect the preparation, filing, prosecution or maintenance of any such patent applications or patents.

- 7.4 LICENSEE may elect to surrender its PATENT RIGHTS in any country upon sixty (60) days written notice to HARVARD. Such notice shall not relieve LICENSEE from responsibility to reimburse HARVARD for patent-related expenses incurred prior to the expiration of the (60) day notice period.
- 7.5 If HARVARD elects not to prosecute or maintain any of the patents or patent applications relating to PATENT RIGHTS or any portion thereof in any country, LICENSEE shall be given sufficient notice of HARVARD's decision so that LICENSEE may request that HARVARD continue prosecuting or maintaining such patents or patent applications, at LICENSEE's expense. If HARVARD elects not to prosecute or maintain such patents or patent applications after such request by LICENSEE, then LICENSEE shall have the right, but not the obligation, at its own expense to prosecute and maintain such patents and patent applications or portion thereof in such country and in HARVARD's name. If LICENSEE assumes 100% of the costs to file, prosecute, and maintain certain patents and patent applications relating to the PATENT RIGHTS pursuant to this Section 7.5, and, if HARVARD licenses the PATENT RIGHTS to one or more co-exclusive licensees designated in Section 3.1 after such time, then HARVARD will credit LICENSEE with the costs LICENSEE has paid in excess of 50% if one other licensee, due for the preparation, filing, prosecution and maintenance of patents and patent applications relating to PATENT RIGHTS pursuant to Section 7.1 above.
- 7.6 If LICENSEE can demonstrate that it is not being adequately informed or apprised of the continuing prosecution of patents or patent applications in PATENT RIGHTS, or that it is not being provided with reasonable opportunities to participate in decision making or that its interests are not being adequately protected, LICENSEE shall be entitled to engage, at LICENSEE's expense, independent patent counsel to review and evaluate patent prosecution and filing of patents and patent applications included in PATENT RIGHTS.

ARTICLE VIII INFRINGEMENT

- 8.1 With respect to any PATENT RIGHTS that are licensed to LICENSEE pursuant to this Agreement, LICENSEE shall have the right to prosecute in its own name and at its own expense any infringement of such patent. HARVARD agrees to notify LICENSEE promptly of each infringement of such patents of which HARVARD, as applicable, is or becomes aware. Before LICENSEE commences an action with respect to any infringement of such patents, LICENSEE shall give careful consideration to the views of HARVARD and to potential effects on the public interest in making its decision whether or not to sue.

8.2 LICENSEE acknowledges that other co-exclusive licensees of PATENT RIGHTS designated in Section 3.1 shall have rights identical to LICENSEE to prosecute infringers and that co-exclusive licensees will be bound by the identical terms of this Section 8.2. In any prosecution instigated by LICENSEE and in which HARVARD, as necessary, is also named plaintiff as owner of the PATENT RIGHTS, LICENSEE must notify other co-exclusive licensees of the existence of such legal action and allow other co-exclusive licensees to join as a plaintiff upon co-exclusive licensees' request. In addition, in the event other co-exclusive licensees instigate an infringement prosecution, LICENSEE hereby consents to being joined as a plaintiff in such suit solely for the purpose of procuring standing to bring the action and at the sole expense of the instigating co-exclusive licensee. To the extent that LICENSEE desires to participate in any strategic decisions affecting the prosecution of the action brought by other co-exclusive licensees, LICENSEE acknowledges that it and co-exclusive licensees will necessarily have to reach a mutual agreement concerning litigation expenses and strategy. In no event shall HARVARD incur any liability or expense in connection with any action of co-exclusive licensees, joint or otherwise.

During any such litigation, HARVARD will agree to not license any defendant or accused infringer of the PATENT RIGHTS in the litigation, without LICENSEE'S prior written consent.

- 8.3 (a) If LICENSEE elects to commence an action as described above, HARVARD may, to the extent permitted by law, elect to join as parties in that action. Regardless of whether HARVARD elects to join as parties, HARVARD shall cooperate fully with LICENSEE in connection with any such action.
- (b) HARVARD agrees to join as a party in any action if required by law to do so in order to bring an action under the PATENT RIGHTS.
- (c) LICENSEE shall reimburse HARVARD for any costs incurs with LICENSEE's approval, including reasonable attorneys' fees, as part of an action brought by LICENSEE, irrespective of whether HARVARD becomes a co-plaintiff.

8.4 If LICENSEE elects to commence an action as described above, LICENSEE may deduct from its royalty payments to HARVARD with respect to the patent(s) subject to suit an amount not exceeding fifty percent (50%) of LICENSEE's expenses and costs of such action, including reasonable attorneys' fees; provided, however, that such reduction shall not exceed fifty percent (50%) of the total royalty due to HARVARD with respect to the patent(s) subject to suit for each calendar year. If such fifty percent (50%) of LICENSEE's expenses and costs exceeds the amount of royalties deducted by LICENSEE for any calendar year, LICENSEE may to that extent reduce the royalties due to HARVARD from LICENSEE in succeeding calendar years, but never by more than fifty percent (50%) of the total royalty due in any one year with respect to the patent(s) subject to suit.

- 8.5 No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the prior written consent of HARVARD which consent shall not be unreasonably withheld.
- 8.6 Recoveries or reimbursements from actions commenced by LICENSEE pursuant to this Article shall first be applied to reimburse LICENSEE, HARVARD for litigation costs not paid from royalties and then to reimburse HARVARD for royalties deducted by LICENSEE pursuant to Section 8.4. Any remaining recoveries or reimbursements shall be shared as follows:
- (a) If the amount is lost profits or lost royalties, LICENSEE shall receive an amount equal to the damages the court determines LICENSEE has suffered as a result of the infringement less the amount of any royalties that would have been due HARVARD on sales of LICENSED PRODUCTS lost by LICENSEE as a result of the infringement had LICENSEE made such sales, and HARVARD shall receive an amount equal to the royalties it would have received if such sales had been made by LICENSEE, and
 - (b) As to awards other than lost profits or lost royalties, fifty percent (50%) to LICENSEE and fifty percent (50%) to HARVARD.
 - (c) If two or more co-exclusive licensees undertake the suit, the provision of this Section 8.6 will be modified to take into account each co-exclusive licensee's expenses and lost profits.
- 8.7 If LICENSEE elects not to exercise its right to prosecute an infringement of the PATENT RIGHTS pursuant to this Article, HARVARD may do so at its own expense, controlling such action and retaining all recoveries therefrom. LICENSEE shall cooperate fully with HARVARD in connection with any such action.
- 8.8 If a declaratory judgment action is brought naming LICENSEE as a defendant and alleging invalidity of any of the PATENT RIGHTS, HARVARD may elect to take over the sole defense of the action at its own expense. LICENSEE shall cooperate fully with HARVARD in connection with any such action. HARVARD shall consult with LICENSEE regarding such defense.

ARTICLE IX
TERMINATION OF AGREEMENT

- 9.1 This Agreement, unless terminated as provided herein, shall remain in effect until the last patent or patent application in PATENT RIGHTS has expired or been abandoned.
- 9.2 HARVARD may terminate this Agreement as follows:
- (a) If LICENSEE does not make a payment due hereunder and fails to cure such non-payment (including the payment of interest in accordance with Section 5.4(e)) within

thirty (30) days after the date of notice in writing of such non-payment by HARVARD.

- (b) If LICENSEE defaults in its obligations under Sections 10.3(c) and 10.3(d) to procure and maintain insurance.
- (c) If LICENSEE shall become insolvent, shall make an assignment for the benefit of creditors, or shall have a petition in bankruptcy filed for or against it. Such termination shall be effective immediately upon HARVARD giving written notice to LICENSEE.
- (d) If an examination by HARVARD's accountant pursuant to Article V shows an underreporting or underpayment by LICENSEE in excess of twenty percent (20%) for any twelve (12) month period, provided that such underreporting or underpayment is not determined to be inadvertent or the result of an honest mistake.
- (e) If LICENSEE is convicted of a felony relating to the manufacture, use, or sale of LICENSED PRODUCTS.
- (f) Except as provided in Subsections (a), (b), and (c) above, if LICENSEE defaults in the performance of any material obligations under this Agreement and the default has not been remedied within forty-five (45) days after the date of notice in writing of such default by HARVARD.

9.3 LICENSEE shall provide, in all sublicenses granted by it under this Agreement, that LICENSEE's interest in such sublicenses shall at HARVARD's option terminate or be assigned to HARVARD upon termination of this Agreement; however, LICENSEE shall have the option to nominate one of its sublicensees as a substitute for LICENSEE. The proposed substitute must (i) have a net worth of at least equivalent to the net worth LICENSEE had as of the date of this Agreement and (ii) have available resources and sufficient scientific, business and other expertise comparable to LICENSEE in order to satisfy its obligations under this Agreement. At least sixty (60) days prior to termination of this Agreement, LICENSEE shall provide HARVARD with written notice of LICENSEE's nominee together with documentation sufficient to demonstrate the requirements set forth in subparagraphs (i) and (ii) above for HARVARD's approval, which shall not be unreasonably withheld. HARVARD shall notify LICENSEE in writing of its decision prior to termination of this Agreement. If HARVARD approves LICENSEE's nominee, LICENSEE shall assign this Agreement to its nominee and its nominee shall accept the assignment no later than thirty (30) days after the termination date of this Agreement.

In the event that HARVARD disapproved LICENSEE's first nominee, prior to the termination date of this Agreement, LICENSEE shall have the option to nominate one of its other sublicensees for HARVARD's approval which shall not be unreasonably withheld.

9.4 LICENSEE may terminate this Agreement by giving ninety (90) days advance written notice of termination to HARVARD. Upon termination, LICENSEE shall submit a final Royalty Report to HARVARD and any royalty payments and unreimbursed patent expenses invoiced by HARVARD shall become immediately payable.

9.5 Sections 6.1, 6.2, 6.3, 7.1, 9.4, 9.5, 10.2, 10.3, 10.4, and 10.7 of this Agreement shall survive termination.

ARTICLE X
GENERAL

10.1 HARVARD does not warrant the validity of the PATENT RIGHTS licensed hereunder and make no representations whatsoever with regard to the scope of the licensed PATENT RIGHTS or that such PATENT RIGHTS may be exploited by LICENSEE, an AFFILIATE, or SUBLICENSEE without infringing other patents, provided, however, HARVARD represents that it has no knowledge of any facts or circumstances as of the execution date of this Agreement that would render any of the PATENT RIGHTS invalid or unenforceable. HARVARD represents and warrants, to the best of its knowledge, that HARVARD will own all right, title and interest in and to the PATENT RIGHTS.

10.2 HARVARD EXPRESSLY DISCLAIMS ANY AND ALL IMPLIED WARRANTIES AND MAKES NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OF THE PATENT RIGHTS OR INFORMATION SUPPLIED BY HARVARD, LICENSED PROCESSES OR LICENSED PRODUCTS CONTEMPLATED BY THIS AGREEMENT.

10.3 (a) LICENSEE shall indemnify, defend and hold harmless HARVARD and its current or former directors, governing board members, trustees, officers, faculty, medical and professional staff, employees, students, and agents and their respective successors, heirs and assigns (collectively, the "INDEMNITEES"), from and against any claim, liability, cost, expense, damage, deficiency, loss or obligation of any kind or nature (including, without limitation, reasonable attorney's fees and other costs and expenses of litigation) (collectively, "Claims"), based upon, arising out of, or otherwise relating to this Agreement, including without limitation any cause of action relating to product liability concerning any product, process, or service made, used or sold pursuant to any right or license granted under this Agreement, provided, however, that such indemnification shall not apply to any liability, damage, loss, or expense to the extent directly attributable to the negligent activities, reckless misconduct or intentional misconduct of Indemnitees.

(b) Each Indemnitee that intends to claim indemnification under Section 10.3(a) shall promptly notify LICENSEE of any claim or action in respect of which the Indemnitee intends to claim such indemnification, and LICENSEE shall assume the defense thereof with counsel mutually satisfactory to LICENSEE and HARVARD. The failure to deliver notice to LICENSEE within a reasonable time after the commencement of any such claim or action, if materially prejudicial to its ability to

defend such action, shall relieve LICENSEE of any liability to the Indemnitee under Section 10.3(a) with respect to such action, but the omission so to deliver notice to LICENSEE will not relieve it of any liability that it may have to any Indemnitee otherwise than under Section 10.3(a). HARVARD and any other Indemnitee, and their respective employees and agents, shall cooperate fully with LICENSEE and its legal representatives in the investigation of any claim or action covered by the indemnification under Section 10.3(a).

- (c) Beginning at the time any such product, process or service is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by LICENSEE or by a SUBLICENSEE, AFFILIATE or agent of LICENSEE, LICENSEE shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than \$2,000,000 per incident and \$2,000,000 annual aggregate and naming the Indemnitees as additional insureds. During clinical trials of any such product, process or service, LICENSEE shall, at its sole cost and expense, procure and maintain commercial general liability insurance in such equal or lesser amount as HARVARD shall require, naming the Indemnitees as additional insureds. Such commercial general liability insurance shall provide: (i) product liability coverage; and (ii) broad form contractual liability coverage for LICENSEE's indemnification under this Agreement. If LICENSEE elects to self-insure all or part of the limits described above (including deductibles or retentions which are in excess of \$250,000 annual aggregate) such self-insurance program must be acceptable to HARVARD and the Risk Management Foundation of the Harvard Medical Institutions, Inc. in their sole discretion. The minimum amounts of insurance coverage required shall not be construed to create a limit of LICENSEE's liability with respect to its indemnification under this Agreement.
 - (d) LICENSEE shall provide HARVARD with written evidence of such insurance upon request of HARVARD. LICENSEE shall provide HARVARD with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance; if LICENSEE does not obtain replacement insurance providing comparable coverage within such fifteen (15) day period, HARVARD shall have the right to terminate this Agreement effective at the end of such fifteen (15) day period without notice or any additional waiting periods.
 - (e) LICENSEE shall maintain such commercial general liability insurance beyond the expiration or termination of this Agreement during: (i) the period that any product, process, or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold by LICENSEE or by a SUBLICENSEE, AFFILIATE or agent of LICENSEE; and (ii) a reasonable period after the period referred to in Subsection (e)(i) above which in no event shall be less than fifteen (15) years.
- 10.4 LICENSEE shall not use HARVARD's name or insignia, or any adaptation of them, or the name of any of HARVARD's inventors in any advertising, promotional or sales literature without the prior written approval of HARVARD.

- 10.5 Without the prior written approval of HARVARD in each instance, neither this Agreement nor the rights granted hereunder shall be transferred or assigned in whole or in part by LICENSEE to any person whether voluntarily or involuntarily, by operation of law or otherwise, except that each of LICENSEE and its AFFILIATES may assign this Agreement in connection with a merger, consolidation or sale or transfer of all or substantially all of its assets. This Agreement shall be binding upon the respective successors, legal representatives and assignees of HARVARD and LICENSEE.
- 10.6 The interpretation and application of the provisions of this Agreement shall be governed by the laws of the Commonwealth of Massachusetts.
- 10.7 LICENSEE shall comply with all applicable laws and regulations. In particular, it is understood and acknowledged that the transfer of certain commodities and technical data is subject to United States laws and regulations controlling the export of such commodities and technical data, including all Export Administration Regulations of the United States Department of Commerce. These laws and regulations among other things, prohibit or require a license for the export of certain types of technical data to certain specified countries. LICENSEE hereby agrees and gives written assurance that it will comply with all United States laws and regulations controlling the export of commodities and technical data, that it will be solely responsible for any violation of such by LICENSEE or its AFFILIATES or SUBLICENSEES, and that it will defend and hold HARVARD, CHILDREN, and MIT harmless in the event of any legal action of any nature occasioned by such violation.
- 10.8 LICENSEE agrees: (i) to obtain all regulatory approvals required for the manufacture and sale of LICENSED PRODUCTS and LICENSED PROCESSES; and (ii) to utilize appropriate patent marking on such LICENSED PRODUCTS. LICENSEE also agrees to register or record this Agreement as is required by law or regulation in any country where the license is in effect.
- 10.9 Any notices to be given hereunder shall be sufficient if signed by the party (or party's attorney) giving same and either: (i) delivered in person; (ii) mailed certified mail return receipt requested; or (iii) faxed to other party if the sender has evidence of successful transmission and if the sender promptly sends the original by ordinary mail, in any event to the following addresses:

If to LICENSEE:

Mycometrix Corporation
213 E. Grand Ave.
South San Francisco, CA 94080
Attention:
Fax: (650)-

If to HARVARD:

Office for Technology and Trademark Licensing

Harvard University
Holyoke Center, Suite 727
1350 Massachusetts Avenue
Cambridge, MA 02138
Fax: (617) 495-9568

By such notice either party may change their address for future notices.

Notices delivered in person shall be deemed given on the date delivered. Notices sent by fax shall be deemed given on the date faxed. Notices mailed shall be deemed given on the date postmarked on the envelope.

- 10.10 Should a court of competent jurisdiction later hold any provision of this Agreement to be invalid, illegal, or unenforceable, and such holding is not reversed on appeal, it shall be considered severed from this Agreement. All other provisions, rights and obligations shall continue without regard to the severed provision, provided that the remaining provisions of this Agreement are in accordance with the intention of the parties.
- 10.11 In the event of any controversy or claim arising out of or relating to any provision of this Agreement or the breach thereof, the parties shall try to settle such conflict amicably between themselves. Subject to the limitation stated in the final sentence of this Section 10.11, any such conflict which the parties are unable to resolve promptly shall be settled through arbitration conducted in accordance with the rules of the American Arbitration Association. The demand for arbitration shall be filed within a reasonable time after the controversy or claim has arisen, and in no event after the date upon which institution of legal proceedings based on such controversy or claim would be barred by the applicable statute of limitation. Such arbitration shall be held in Boston, Massachusetts. The award through arbitration shall be final and binding. Either party may enter any such award in a court having jurisdiction or may make application to such court for judicial acceptance of the award and an order of enforcement, as the case may be. Notwithstanding the foregoing, either party may, without recourse to arbitration, assert against the other party a third-party claim or cross-claim in any action brought by a third party, to which the subject matter of this Agreement may be relevant.
- 10.12 This Agreement constitutes the entire understanding between the parties and neither party shall be obligated by any condition or representation other than those expressly stated herein or as may be subsequently agreed to by the parties hereto in writing.

[The remainder of this page is intentionally blank.]

Certain identified information marked with [*] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.**

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives.

PRESIDENT AND FELLOWS
OF HARVARD COLLEGE

 /s/ Joyce Brinton

Joyce Brinton, Director
Office for Technology and
Trademark Licensing

 12/7/00

Date

MYCOMETRIX CORPORATION

 /s/ Gajus Worthington

President

 12/18/00

Date

Certain identified information marked with [*] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.**

APPENDIX A

The following comprise PATENT RIGHTS:

[***]

4060.LICI.010 Harvard

CO-EXCLUSIVE LICENSE AGREEMENT

Between

President and Fellows of Harvard College

And

Mycometrix Corporation

Effective as of October 15, 2000

Re: Harvard Case #[***]

In consideration of the mutual promises and covenants set forth below, the parties hereto agree as follows:

ARTICLE I
DEFINITIONS

As used in this Agreement, the following terms shall have the following meanings:

- 1.1 **ACADEMIC RESEARCH PURPOSES:** use of PATENT RIGHTS for academic research or other not-for-profit scholarly purposes which are undertaken at a non-profit or governmental institution that does not use the PATENT RIGHTS in the production or manufacture of products for sale or the performance of services for a fee.
- 1.2 **AFFILIATE:** any entity which controls, is controlled by, or is under common control with a party by ownership or control of at least fifty percent (50%) of the voting stock or other ownership. Unless otherwise specified, the term LICENSEE includes AFFILIATES.
- 1.3 **FIELD :** use of PATENT RIGHTS to develop, manufacture, use, offer for sale, sell, or import components and products in FIELD I and/or FIELD II:

FIELD I: [***]

FIELD II: [***]

Certain identified information marked with [*] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.**

- 1.4 HARVARD: President and Fellows of Harvard College, a nonprofit Massachusetts educational corporation having offices at the Office for Technology and Trademark Licensing, Holyoke Center, Suite 727, 1350 Massachusetts Avenue, Cambridge, Massachusetts 02138.
- 1.5 LICENSED PROCESSES: the processes covered by at least one VALID CLAIM included within the PATENT RIGHTS.
- 1.6 LICENSED PRODUCTS: products covered by at least one VALID CLAIM included within the PATENT RIGHTS or products made or services provided in accordance with or by means of LICENSED PROCESSES.
- 1.7 LICENSEE: Mycometrix Corporation, a corporation organized under the laws of California having its principal offices at 213 East Grand Avenue, South San Francisco, CA 94080.
- 1.8 NET SERVICE INCOME: SERVICE INCOME less LICENSEE's actual direct and indirect cost for research, development and/or services provided.
- 1.9 NET SALES: the amount actually received for sales, leases, or other transfers of LICENSED PRODUCTS, less:
- (i) customary trade, quantity or cash discounts and non-affiliated brokers' or agents' commissions actually allowed and taken;
 - (ii) amounts repaid or credited by reason of rejection or return;
 - (iii) to the extent separately stated on purchase orders, invoices, or other documents of sale, taxes levied on and/or other governmental charges made as to production, sale, transportation, delivery or use and paid by or on behalf of LICENSEE; and
 - (iv) reasonable charges for delivery or transportation provided by third parties and cost of insurance in transit, if separately stated.

NET SALES also includes the fair market value of any non-cash consideration received by LICENSEE for the sale, lease, or transfer of LICENSED PRODUCTS.

If a LICENSED PRODUCT is sold as a combination product containing the LICENSED PRODUCT and one or more other components, NET SALES shall be calculated by multiplying the gross amount invoiced for the sale of the combination product by the fraction $A/A+B$ where A is the average gross selling price of the LICENSED PRODUCT sold separately by LICENSEE and B is the average gross selling price of such other components of the combination products sold separately by LICENSEE during the relevant royalty payment period.

In the event that LICENSEE grants a sublicensee hereunder, and receives payments based upon SUBLICENSEE's sales of LICENSED PRODUCTS, LICENSEE may upon approval from HARVARD (which shall not be unreasonably withheld) modify the definition of NET SALES for the purposes of calculating royalties payable to HARVARD on such SUBLICENSEE's sales to be the same as the definition of NET SALES on which such royalties to LICENSEE are calculated.

- 1.10 SERVICE INCOME: the total financial consideration received by LICENSEE for commercial services performed on a fee-for-service basis using the LICENSED PRODUCTS or LICENSED PROCESSES by LICENSEE under a contract with a third party, where such services are based primarily on the use of fully functional LICENSED PRODUCTS or LICENSED PROCESSES (as applicable) for their intended commercial use (such as, for example, where LICENSEE performs commercial-scale genotyping services for a pharmaceutical company on a fee-for-service basis using fully developed microfluidics chips comprising LICENSED PRODUCTS). SERVICE INCOME shall not include amounts received in connection with research and/or development of LICENSED PRODUCTS or LICENSED PROCESSES themselves.
- 1.11 PATENT RIGHTS: The applications and patents as listed in Appendix A of this Agreement, the allowed claims of such applications, the inventions described and claimed therein, and any divisions or continuations of the applications and patents as listed in Appendix A, and specific claims of any continuations-in-part of such applications to the extent the specific claims are directed to subject matter described in the applications and patents listed in Appendix A in a manner sufficient to support such specific claims under 35 U.S.C., patents issuing thereon or reissues thereof, and any and all foreign patents and patent applications corresponding thereto, all to the extent owned or controlled by HARVARD.
- 1.12 SUBLICENSE INCOME: the amount paid to LICENSEE by a third party (other than an AFFILIATE of LICENSEE) (a) for the sublicensing of PATENT RIGHTS to a third party as well as (b) for the related licensing of LICENSEE's own patent rights or know-how or LICENSEE's in-licensed non-HARVARD technologies, including but not limited to (i) license fees, (ii) milestone payments, (iii) royalties, (iv) the fair market value in cash of any non-cash consideration for such sublicense, and (v) in the event that LICENSEE receives any payment for equity in consideration for the grant of sublicense rights that included a premium over the fair market value of such equity, the amount of such premium. LICENSEE shall be responsible for determining such fair market value with reasonable business judgment.
- 1.13 SUBLICENSEE: any non-AFFILIATE granted a sublicense of any of the rights HARVARD has granted to LICENSEE under Section 3.1.
- 1.14 TERRITORY: Worldwide.
- 1.15 VALID CLAIM: either (i) a claim of an issued patent that has not been held unenforceable or invalid by an agency or a court of competent jurisdiction in any

unappealable or unappealed decision or (ii) a claim of a published, pending patent application, which claim is substantially identical to a corresponding claim in a subsequently issued patent having priority to the patent application.

1.16 The terms “Public Law 96-517” and “Public Law 98-620” include all amendments to those statutes.

1.17 The terms “sold” and “sell” include, without limitation, leases and other transfers and similar transactions.

ARTICLE II REPRESENTATIONS

2.1 HARVARD is owner by assignment from [***], in the foreign patent applications corresponding thereto, and in the inventions described and claimed therein.

2.2 HARVARD has authority to issue licenses under PATENT RIGHTS.

2.3 HARVARD is committed to the policy that ideas or creative works produced at HARVARD should be used for the greatest possible public benefit, and believes that every reasonable incentive should be provided for the prompt introduction of such ideas into public use, all in a manner consistent with the public interest.

2.4 LICENSEE is prepared and intends to diligently develop the invention and to bring products to market which are subject to this Agreement, specifically including one or more products in the FIELD selected from a [***].

2.5 LICENSEE is desirous of obtaining a co-exclusive license in the FIELD and in the TERRITORY in order to practice the PATENT RIGHTS in the United States and in certain foreign countries, and to manufacture, use and sell in the commercial market the products made in accordance therewith, and HARVARD is desirous of granting such a license to LICENSEE in accordance with the terms of this Agreement.

ARTICLE III GRANT OF RIGHTS

3.1 HARVARD hereby grants to LICENSEE and LICENSEE accepts, subject to the terms and conditions hereof, in the TERRITORY a co-exclusive commercial license under PATENT RIGHTS in FIELD I and in FIELD II to make and have made, to use and have used, to sell

and have sold, and to offer for sale and have offered for sale the LICENSED PRODUCTS, and to practice the LICENSED PROCESSES, for the life of the PATENT RIGHTS. HARVARD will grant no more than two commercial licenses in FIELD I at any time and will grant no more than two commercial licenses in FIELD II at any time and HARVARD will not grant other licenses in the FIELD except as required by HARVARD's obligations in Section 3.2(a) or as permitted Section 3.2(b). Such co-exclusive license shall include the right to grant sublicenses under the following circumstances: (i) LICENSEE can demonstrate that it has added significant value to the PATENT RIGHTS to be sublicensed, and that such a sublicense also contains a substantial and essentially simultaneous license of LICENSEE owned intellectual property, or (ii) LICENSEE grants a sublicense under other HARVARD patent rights licensed exclusively to LICENSEE which are dominated by PATENT RIGHTS, and such sublicense under PATENT RIGHTS is necessary to practice such other HARVARD patent rights.

3.2 The granting and exercise of this license is subject to the following conditions:

- (a) HARVARD's "Statement of Policy in Regard to Inventions, Patents and Copyrights," dated August 10, 1998, Public Law 96-517, Public Law 98-620. In addition, this Agreement is subject to HARVARD's obligations under agreements with other sponsors of research, provided that such obligations are not in conflict with the rights granted hereunder. Any right granted in this Agreement greater than that permitted under Public Law 96-517, or Public Law 98-620, shall be subject to modification as may be required to conform to the provisions of those statutes.
- (b) HARVARD reserves the right to make and use, and grant to others non-exclusive licenses to make and use solely for ACADEMIC RESEARCH PURPOSES the subject matter described and claimed in PATENT RIGHTS.
- (c) LICENSEE shall use commercially reasonable efforts to effect introduction of the LICENSED PRODUCTS into the commercial market as soon as practicable, consistent with sound and reasonable business practice and judgment; thereafter, until the expiration of this Agreement, LICENSEE shall endeavor to keep LICENSED PRODUCTS reasonably available to the public.
- (d) At any time after three years from the effective date of this Agreement and as HARVARD's sole remedy for such non-performance, HARVARD may increase the license maintenance royalty under Section 4.4 to [***] dollars each in FIELD I and in FIELD II in year 2004 and [***] dollars each in FIELD I and in FIELD II per year each year beginning in 2005, if in HARVARD's reasonable judgment, the Progress Reports furnished by LICENSEE do not demonstrate that LICENSEE has satisfied at least one of the following conditions, which non-performance is not cured within ninety (90) days following the written notification of such by HARVARD to LICENSEE:

Certain identified information marked with [*] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.**

- (i) has put the licensed subject matter into commercial use in at least one of the countries hereby licensed, directly or through a sublicense, and is keeping the licensed subject matter reasonably available to the public; or
 - (ii) is engaged in research, development, manufacturing, marketing or sublicensing activity appropriate to achieving 3.2(d)(i).
- (e) In all sublicenses granted by LICENSEE hereunder, LICENSEE shall include a requirement that the SUBLICENSEE use commercially reasonable efforts to bring the subject matter of the sublicense into commercial use. LICENSEE shall further provide in such sublicenses that such sublicenses are subject and subordinate to the terms and conditions of this Agreement, except: (i) the SUBLICENSEE may not further sublicense; and (ii) the rate of royalty on NET SALES paid by the SUBLICENSEE to the LICENSEE. Copies of the relevant provisions of all sublicense agreements shall be provided promptly to HARVARD. HARVARD agrees to maintain any information contained in such provisions in confidence, except as otherwise required by law, however, HARVARD may include in its usual reports annual amounts of royalties paid.
- (f) A license in any other field of use in addition to the FIELD shall be the subject of a separate agreement and shall require LICENSEE's submission of evidence, satisfactory to HARVARD, demonstrating LICENSEE's willingness and ability to develop and commercialize in such other field of use the kinds of products or processes likely to be encompassed in such other fields.
- (g) To the extent that federal funds are used to support research leading to a patent or patent application in the PATENT RIGHTS, LICENSEE shall cause any LICENSED PRODUCT produced for sale by LICENSEE or SUBLICENSEES in the United States to be manufactured substantially in the United States during the period of exclusivity of this license in the United States.

3.4 All rights reserved to the United States Government and others under Public Law 96-517, and Public Law 98-620, shall remain and shall in no way be affected by this Agreement.

ARTICLE IV ROYALTIES

4.1 LICENSEE shall pay to HARVARD a non-refundable license royalty fee in the sum of [***] payable within thirty (30) days of the execution date of this Agreement.

4.2 (a) In consideration of the right and license granted herein, LICENSEE shall pay to HARVARD during the term of this Agreement a royalty of [***] on NET SALES of LICENSED PRODUCTS sold by LICENSEE.

Certain identified information marked with [*] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.**

(b) In the event that a single LICENSED PRODUCT or LICENSED PROCESS is covered by HARVARD intellectual property in addition to PATENT RIGHTS, which is licensed to LICENSEE under other agreements as of the date of this Agreement, then the total royalty payment due HARVARD under all such agreements including this Agreement shall be [***] of NET SALES. LICENSEE shall notify HARVARD of the identity of each license agreement that includes patent rights covering the product or process, and HARVARD shall distribute the royalties evenly among such agreements.

(c) As consideration for the rights granted hereunder, LICENSEE shall pay to HARVARD during the term of this Agreement a royalty in the form of stock of LICENSEE as follows:

- (i) LICENSEE shall issue to HARVARD [***] shares of the Common Stock of LICENSEE (“Shares”) pursuant to the terms of a mutually acceptable Stock Subscription Agreement, provided, however, that HARVARD shall be subject to and enter into appropriate agreements and related documents as required of other stockholders of LICENSEE.
- (ii) HARVARD represents and warrants to LICENSEE that:
 - (1) HARVARD is acquiring the Shares for its own account for investment and not with a view to, or for sale in connection with any distribution thereof, nor with any present intention of distributing or selling the same; and HARVARD has no present or contemplated agreement, undertaking, arrangement, obligation, indebtedness or commitment providing for the disposition thereof.
 - (2) HARVARD has full power and authority to enter into and to perform this Agreement in accordance with its terms.
 - (3) HARVARD has sufficient knowledge and experience in investing in companies similar to LICENSEE so as to be able to evaluate the risks and merits of its investment in LICENSEE and is able financially to bear the risks thereof.
- (iii) Each certificate representing the Shares shall bear a legend substantially in the following form:

Certain identified information marked with [*] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.**

“The shares represented by this certificate have not been registered under the Securities Act of 1933 or any state securities law and they may not be sold or otherwise transferred by any person, including a pledgee, unless (1) either (a) a registration statement with respect to such shares shall be effective under the Securities Act of 1933, as amended, or (b) the Corporation shall have received an opinion of counsel satisfactory to the Corporation that an exemption from registration under such Act is then available, and (2) there shall have been compliance with all applicable securities laws.”

“The shares represented by this certificate are subject to a mutually agree-upon Stock Purchase and Right of First Refusal Agreement with this Corporation, a copy of which Stock Purchase and Right of First Refusal Agreement is available for inspection at the offices of the Corporation or may be made available upon request.”

The foregoing legend shall be removed from the certificates representing any Shares, at the request of the holder thereof, at such time as they become eligible for resale pursuant to the Securities Act of 1933, as amended.

If at any time prior to the time the Shares are eligible for resale pursuant to an exemption from registration under the Securities Act of 1933, as amended, LICENSEE proposes to register any of its Common Stock, under the Securities Act of 1933, except at LICENSEE’s initial public offering or any offering pursuant to Forms S-4 or S-8, LICENSEE shall offer HARVARD the opportunity to have its Shares registered under the registration statement to be filed at such time. HARVARD will be offered the right to register its Shares under the same terms, conditions and restrictions as other shareholders with piggyback registration rights and the inclusion of any Shares in such registration statement shall be subject to the approval of the underwriters of such offering

- (iv) HARVARD’s ownership rights to Shares shall not be affected should the license pursuant to this Agreement be converted to a nonexclusive one.

(d) In the case of sublicenses, LICENSEE shall also pay to HARVARD a royalty of [***] of SUBLICENSE INCOME. If compensation for such a sublicense of PATENT RIGHTS is bundled with compensation received for the sublicensing of the other HARVARD patent rights licensed to LICENSEE under other agreements as of the date of this Agreement, LICENSEE shall pay HARVARD only [***] of the total compensation received no matter how many license agreements from HARVARD are involved. In such a case, LICENSEE shall notify HARVARD of the identity of each license agreement involved and HARVARD shall distribute its [***] of

compensation equally among those license agreements, including this Agreement.

(e) LICENSEE shall pay HARVARD [***] of NET SERVICE INCOME. If SERVICE INCOME is bundled with service income under another license to LICENSEE as of the date of this Agreement, LICENSEE shall pay a royalty of [***] of NET SERVICE INCOME received from each and every third party ("Third Party") to which services are provided. LICENSEE shall notify HARVARD of the identity of each license agreement involved in the services and HARVARD shall distribute its [***] of compensation equally among those license agreements, including this Agreement.

(f) If other co-exclusive licenses in the same FIELD and TERRITORY are granted after the date this Agreement is executed, the above financial compensation shall not exceed the financial compensation to be paid by other licensees in the same FIELD and TERRITORY during the term of the co-exclusive license provided LICENSEE accepts any less favorable terms included in such other license.

If stock is part of the financial compensation to be paid by other licensees in the same FIELD and TERRITORY, the fair market value of the stock shall be the same as the price per share which other investors paid in the last round of financing unless the stock is publicly traded.

- 4.3 On sales between LICENSEE and its AFFILIATES for resale or incorporation into products, the royalty shall be paid on the NET SALES of the AFFILIATE. On sales between LICENSEE and sublicensees for resale, the royalty shall be paid on the SUBLICENSE INCOME.
- 4.4 No later than January 1 of each calendar year indicated below, LICENSEE shall pay to HARVARD the following non-refundable license maintenance royalty and/or advance on royalties. Such payments shall be credited against running royalties due for that calendar year and Royalty Reports shall reflect such a credit. Such payments shall not be credited against milestone payments (if any) nor against royalties due for any subsequent calendar year nor against such payments due under any other agreements with HARVARD.

	FIELD I	FIELD II
January 1, 2002	[***]	[***]
January 1, 2003	[***]	[***]
January 1, 2004	[***]	[***]
each year thereafter	[***]	[***]

ARTICLE V REPORTING

- 5.1 Prior to signing this Agreement, LICENSEE has provided to HARVARD a written business plan under which LICENSEE intends to bring the subject matter of the licenses

granted hereunder into commercial use upon execution of this Agreement. Such plan includes proposed marketing efforts.

- 5.2 No later than sixty (60) days after June 30 of each calendar year, LICENSEE shall provide to HARVARD a written annual Progress Report describing progress on research and development, regulatory approvals, manufacturing, sublicensing, marketing and sales during the most recent twelve (12) month period ending June 30 and plans for the forthcoming year. If multiple technologies are covered by the license granted hereunder, the Progress Report shall provide the information set forth above for each technology. If progress differs from that anticipated in the plan required under Section 5.1, LICENSEE shall explain the reasons for the difference and propose a modified plan for HARVARD's review. LICENSEE shall also provide any reasonable additional data HARVARD requires to evaluate LICENSEE's performance.
- 5.3 LICENSEE shall report to HARVARD the date of first sale of LICENSED PRODUCTS (or results of LICENSED PROCESSES) in each country within thirty (30) days of occurrence.
- 5.4 (a) LICENSEE shall submit to HARVARD within sixty (60) days after each calendar half year ending June 30 and December 31, a Royalty Report setting forth for such half year at least the following information:
- (i) the number of LICENSED PRODUCTS sold by LICENSEE in each country;
 - (ii) total billings and amounts actually received for such LICENSED PRODUCTS;
 - (iii) an accounting for all LICENSED PROCESSES used or sold;
 - (iv) deductions applicable to determine the NET SALES thereof;
 - (v) the amount of SERVICE INCOME received by LICENSEE and an accounting of all deductions to yield NET SERVICE INCOME;
 - (vi) the amount of SUBLICENSE INCOME received by LICENSEE; and
 - (vii) the amount of royalty due thereon, or, if no royalties are due to HARVARD for any reporting period, the statement that no royalties are due.

Such report shall be certified as correct by an officer of LICENSEE and shall include a detailed listing of all deductions from royalties.

- (b) LICENSEE shall pay to HARVARD with each such Royalty Report the amount of royalty due with respect to such half year. If multiple technologies are covered by the license granted hereunder, LICENSEE shall specify which PATENT RIGHTS are utilized for each LICENSED PRODUCT and LICENSED PROCESS included in the Royalty Report.

- (c) All payments due hereunder shall be deemed received when funds are credited to HARVARD's bank account and shall be payable by check or wire transfer in United States dollars. Conversion of foreign currency to U.S. dollars shall be made at the conversion rate existing in the United States (as reported in the New York Times or the Wall Street Journal) on the last working day of each royalty period. No transfer, exchange, collection or other charges shall be deducted from such payments.
 - (d) All such reports shall be maintained in confidence by HARVARD except as required by law; however, HARVARD may include in its usual reports annual amounts of royalties paid.
 - (e) Late payments shall be subject to a charge of one and one-half percent (1.5%) per month, or \$250, whichever is greater.
- 5.5 In the event of acquisition, merger, change of corporate name or change in make-up, organization, or identity, LICENSEE shall notify HARVARD in writing within thirty (30) days of such event.
- 5.6 If by law, regulation or fiscal policy of a particular country, conversion into United States dollars or transfer of funds of a convertible currency to the United States is restricted or forbidden, LICENSEE shall give HARVARD prompt notice in writing and shall pay the royalty and other amounts due through such means or methods as are lawful in such country as HARVARD may reasonably designate. Failing the designation by HARVARD of such lawful means or methods within thirty (30) days after such notice is given to HARVARD, LICENSEE shall deposit such royalty or other payment in local currency to the credit of HARVARD in a recognized banking institution designated by HARVARD, or if none is designated by HARVARD within the thirty (30) day period described above, in a recognized banking institution selected by LICENSEE and identified in a written notice to HARVARD by LICENSEE, and such deposit shall fulfill all obligations of LICENSEE to HARVARD with respect to such royalties. When in any country in which the law or regulations prohibit both the transmittal and deposit of royalties on sales in such country, royalty payments shall be suspended for as long as such prohibition is in effect, and as soon as such prohibition ceases to be in effect, all royalties which LICENSEE would have been under obligation to transmit or deposit, but for the prohibition, shall be deposited or transmitted promptly to the extent allowable.

ARTICLE VI RECORD KEEPING

- 6.1 LICENSEE shall keep, and shall require its SUBLICENSEES to keep, accurate records (together with supporting documentation) of LICENSED PRODUCTS made, used or sold under this Agreement, and SERVICE INCOME and SUBLICENSE INCOME received by LICENSEE under this Agreement, appropriate to determine the amount of royalties due to HARVARD hereunder. Such records shall be retained for three (3) years following the end of the reporting period to which they relate. For such three year period, they shall be

available during normal business hours upon reasonable advance notice for examination by a certified public accountant selected by HARVARD, and reasonably acceptable to LICENSEE, for the sole purpose of verifying reports and payments hereunder. In conducting examinations pursuant to this Section 6.1, HARVARD's accountant shall have access to all records which HARVARD reasonably believes to be relevant to the calculation of royalties under Article IV. HARVARD agrees to maintain any information contained in such records in confidence, except as otherwise required by law and except information in regarding the amount of royalties due.

- 6.2 HARVARD's accountant shall not disclose to HARVARD any information other than information relating to the accuracy of reports and payments made hereunder.
- 6.3 Such examination by HARVARD's accountant shall be at HARVARD's expense, except that if such examination shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then LICENSEE shall pay the cost of such examination as well as any additional sum that would have been payable to HARVARD had the LICENSEE reported correctly, plus interest on said sum at the rate of one and one-half percent (1.5%) per month.

ARTICLE VII DOMESTIC AND FOREIGN PATENT FILING AND MAINTENANCE

- 7.1 Upon execution of this Agreement, LICENSEE shall reimburse HARVARD for fifty percent (50%) of all reasonable expenses HARVARD has incurred for the preparation, filing, prosecution, maintenance and counseling with respect to PATENT RIGHTS. Such expenses total [***] as of October 1, 2000. Thereafter, LICENSEE shall reimburse HARVARD for fifty percent (50%) of all such future reasonable expenses prior to the termination of this Agreement upon receipt of invoices from HARVARD.
- 7.2 HARVARD shall be responsible for the preparation, filing, prosecution and maintenance of any and all patent applications and patents included in PATENT RIGHTS. HARVARD will instruct counsel to directly notify HARVARD and LICENSEE and provide them copies of any official communications from the United States and foreign patent offices relating to said prosecution, and to provide LICENSEE with advance draft copies of all relevant communications to the various patent offices, so that LICENSEE may be informed and apprised of the continuing prosecution of patent applications in PATENT RIGHTS. LICENSEE shall have reasonable opportunities to participate in decision making on all key decisions affecting filing, prosecution and maintenance of patents and patent applications in PATENT RIGHTS. HARVARD will use reasonable efforts to incorporate LICENSEE's reasonable suggestions regarding said prosecution. HARVARD shall use all reasonable efforts to amend any patent application to include claims reasonably requested by LICENSEE to protect LICENSED PRODUCTS.
- 7.3 HARVARD and LICENSEE shall cooperate fully in the preparation, filing, prosecution and maintenance of PATENT RIGHTS and of all patents and patent applications licensed to LICENSEE hereunder, executing all papers and instruments or requiring members of

HARVARD to execute such papers and instruments so as to enable HARVARD to apply for, to prosecute and to maintain patent applications and patents in HARVARD's name in any country. Each party shall provide to the other prompt notice as to all matters which come to its attention and which may affect the preparation, filing, prosecution or maintenance of any such patent applications or patents.

- 7.4 LICENSEE may elect to surrender its PATENT RIGHTS in any country upon sixty (60) days written notice to HARVARD. Such notice shall not relieve LICENSEE from responsibility to reimburse HARVARD for patent-related expenses incurred prior to the expiration of the (60) day notice period.
- 7.5 If HARVARD elects not to prosecute or maintain any of the patents or patent applications relating to PATENT RIGHTS or any portion thereof in any country, LICENSEE shall be given sufficient notice of HARVARD's decision so that LICENSEE may request that HARVARD continue prosecuting or maintaining such patents or patent applications, at LICENSEE's expense. If HARVARD elects not to prosecute or maintain such patents or patent applications after such request by LICENSEE, then LICENSEE shall have the right, but not the obligation, at its own expense to prosecute and maintain such patents and patent applications or portion thereof in such country and in HARVARD's name. If LICENSEE assumes 100% of the costs to file, prosecute, and maintain certain patents and patent applications relating to the PATENT RIGHTS pursuant to this Section 7.5, and, if HARVARD licenses the PATENT RIGHTS to one or more co-exclusive licensees designated in Section 3.1 after such time, then HARVARD will credit LICENSEE with the costs LICENSEE has paid in excess of 50% if one other licensee, due for the preparation, filing, prosecution and maintenance of patents and patent applications relating to PATENT RIGHTS pursuant to Section 7.1 above.
- 7.6 If LICENSEE can demonstrate that it is not being adequately informed or apprised of the continuing prosecution of patents or patent applications in PATENT RIGHTS, or that it is not being provided with reasonable opportunities to participate in decision making or that its interests are not being adequately protected, LICENSEE shall be entitled to engage, at LICENSEE's expense, independent patent counsel to review and evaluate patent prosecution and filing of patents and patent applications included in PATENT RIGHTS.

ARTICLE VIII INFRINGEMENT

- 8.1 With respect to any PATENT RIGHTS that are licensed to LICENSEE pursuant to this Agreement, LICENSEE shall have the right to prosecute in its own name and at its own expense any infringement of such patent. HARVARD agrees to notify LICENSEE promptly of each infringement of such patents of which HARVARD, as applicable, is or becomes aware. Before LICENSEE commences an action with respect to any infringement of such patents, LICENSEE shall give careful consideration to the views of HARVARD and to potential effects on the public interest in making its decision whether or not to sue.

8.2 LICENSEE acknowledges that other co-exclusive licensees of PATENT RIGHTS designated in Section 3.1 shall have rights identical to LICENSEE to prosecute infringers and that co-exclusive licensees will be bound by the identical terms of this Section 8.2. In any prosecution instigated by LICENSEE and in which HARVARD, as necessary, is also named plaintiff as owner of the PATENT RIGHTS, LICENSEE must notify other co-exclusive licensees of the existence of such legal action and allow other co-exclusive licensees to join as a plaintiff upon co-exclusive licensees' request. In addition, in the event other co-exclusive licensees instigate an infringement prosecution, LICENSEE hereby consents to being joined as a plaintiff in such suit solely for the purpose of procuring standing to bring the action and at the sole expense of the instigating co-exclusive licensee. To the extent that LICENSEE desires to participate in any strategic decisions affecting the prosecution of the action brought by other co-exclusive licensees, LICENSEE acknowledges that it and co-exclusive licensees will necessarily have to reach a mutual agreement concerning litigation expenses and strategy. In no event shall HARVARD incur any liability or expense in connection with any action of co-exclusive licensees, joint or otherwise.

During any such litigation, HARVARD will agree to not license any defendant or accused infringer of the PATENT RIGHTS in the litigation, without LICENSEE's prior written consent.

- 8.3
- (a) If LICENSEE elects to commence an action as described above, HARVARD may, to the extent permitted by law, elect to join as parties in that action. Regardless of whether HARVARD elects to join as parties, HARVARD shall cooperate fully with LICENSEE in connection with any such action.
 - (b) HARVARD agrees to join as a party in any action if required by law to do so in order to bring an action under the PATENT RIGHTS.
 - (c) LICENSEE shall reimburse HARVARD for any costs incurs with LICENSEE's approval, including reasonable attorneys' fees, as part of an action brought by LICENSEE, irrespective of whether HARVARD becomes a co-plaintiff.
- 8.4 If LICENSEE elects to commence an action as described above, LICENSEE may deduct from its royalty payments to HARVARD with respect to the patent(s) subject to suit an amount not exceeding fifty percent (50%) of LICENSEE's expenses and costs of such action, including reasonable attorneys' fees; provided, however, that such reduction shall not exceed fifty percent (50%) of the total royalty due to HARVARD with respect to the patent(s) subject to suit for each calendar year. If such fifty percent (50%) of LICENSEE's expenses and costs exceeds the amount of royalties deducted by LICENSEE for any calendar year, LICENSEE may to that extent reduce the royalties due to HARVARD from LICENSEE in succeeding calendar years, but never by more than fifty percent (50%) of the total royalty due in any one year with respect to the patent(s) subject to suit.

- 8.5 No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the prior written consent of HARVARD which consent shall not be unreasonably withheld.
- 8.6 Recoveries or reimbursements from actions commenced by LICENSEE pursuant to this Article shall first be applied to reimburse LICENSEE, HARVARD for litigation costs not paid from royalties and then to reimburse HARVARD for royalties deducted by LICENSEE pursuant to Section 8.4. Any remaining recoveries or reimbursements shall be shared as follows:
- (a) If the amount is lost profits or lost royalties, LICENSEE shall receive an amount equal to the damages the court determines LICENSEE has suffered as a result of the infringement less the amount of any royalties that would have been due HARVARD on sales of LICENSED PRODUCTS lost by LICENSEE as a result of the infringement had LICENSEE made such sales, and HARVARD shall receive an amount equal to the royalties it would have received if such sales had been made by LICENSEE, and
 - (b) As to awards other than lost profits or lost royalties, fifty percent (50%) to LICENSEE and fifty percent (50%) to HARVARD.
 - (c) If two or more co-exclusive licensees undertake the suit, the provision of this Section 8.6 will be modified to take into account each co-exclusive licensee's expenses and lost profits.
- 8.7 If LICENSEE elects not to exercise its right to prosecute an infringement of the PATENT RIGHTS pursuant to this Article, HARVARD may do so at its own expense, controlling such action and retaining all recoveries therefrom. LICENSEE shall cooperate fully with HARVARD in connection with any such action.
- 8.8 If a declaratory judgment action is brought naming LICENSEE as a defendant and alleging invalidity of any of the PATENT RIGHTS, HARVARD may elect to take over the sole defense of the action at its own expense. LICENSEE shall cooperate fully with HARVARD in connection with any such action. HARVARD shall consult with LICENSEE regarding such defense.

ARTICLE IX
TERMINATION OF AGREEMENT

- 9.1 This Agreement, unless terminated as provided herein, shall remain in effect until the last patent or patent application in PATENT RIGHTS has expired or been abandoned.
- 9.2 HARVARD may terminate this Agreement as follows:
- (a) If LICENSEE does not make a payment due hereunder and fails to cure such non-payment (including the payment of interest in accordance with Section 5.4(e)) within

thirty (30) days after the date of notice in writing of such non-payment by HARVARD.

- (b) If LICENSEE defaults in its obligations under Sections 10.3(c) and 10.3(d) to procure and maintain insurance.
- (c) If LICENSEE shall become insolvent, shall make an assignment for the benefit of creditors, or shall have a petition in bankruptcy filed for or against it. Such termination shall be effective immediately upon HARVARD giving written notice to LICENSEE.
- (d) If an examination by HARVARD's accountant pursuant to Article V shows an underreporting or underpayment by LICENSEE in excess of twenty percent (20%) for any twelve (12) month period, provided that such underreporting or underpayment is not determined to be inadvertent or the result of an honest mistake.
- (e) If LICENSEE is convicted of a felony relating to the manufacture, use, or sale of LICENSED PRODUCTS.
- (f) Except as provided in Subsections (a), (b), and (c) above, if LICENSEE defaults in the performance of any material obligations under this Agreement and the default has not been remedied within forty-five (45) days after the date of notice in writing of such default by HARVARD.

9.3 LICENSEE shall provide, in all sublicenses granted by it under this Agreement, that LICENSEE's interest in such sublicenses shall at HARVARD's option terminate or be assigned to HARVARD upon termination of this Agreement; however, LICENSEE shall have the option to nominate one of its sublicensees as a substitute for LICENSEE. The proposed substitute must (i) have a net worth of at least equivalent to the net worth LICENSEE had as of the date of this Agreement and (ii) have available resources and sufficient scientific, business and other expertise comparable to LICENSEE in order to satisfy its obligations under this Agreement. At least sixty (60) days prior to termination of this Agreement, LICENSEE shall provide HARVARD with written notice of LICENSEE's nominee together with documentation sufficient to demonstrate the requirements set forth in subparagraphs (i) and (ii) above for HARVARD's approval, which shall not be unreasonably withheld. HARVARD shall notify LICENSEE in writing of its decision prior to termination of this Agreement. If HARVARD approves LICENSEE's nominee, LICENSEE shall assign this Agreement to its nominee and its nominee shall accept the assignment no later than thirty (30) days after the termination date of this Agreement.

In the event that HARVARD disapproved LICENSEE's first nominee, prior to the termination date of this Agreement, LICENSEE shall have the option to nominate one of its other sublicensees for HARVARD's approval which shall not be unreasonably withheld.

9.4 LICENSEE may terminate this Agreement by giving ninety (90) days advance written notice of termination to HARVARD. Upon termination, LICENSEE shall submit a final Royalty Report to HARVARD and any royalty payments and unreimbursed patent expenses invoiced by HARVARD shall become immediately payable.

9.5 Sections 6.1, 6.2, 6.3, 7.1, 9.4, 9.5, 10.2, 10.3, 10.4, and 10.7 of this Agreement shall survive termination.

ARTICLE X
GENERAL

10.1 HARVARD does not warrant the validity of the PATENT RIGHTS licensed hereunder and make no representations whatsoever with regard to the scope of the licensed PATENT RIGHTS or that such PATENT RIGHTS may be exploited by LICENSEE, an AFFILIATE, or SUBLICENSEE without infringing other patents, provided, however, HARVARD represents that it has no knowledge of any facts or circumstances as of the execution date of this Agreement that would render any of the PATENT RIGHTS invalid or unenforceable. HARVARD represents and warrants, to the best of its knowledge, that HARVARD owns all right, title and interest in and to the PATENT RIGHTS.

10.2 HARVARD EXPRESSLY DISCLAIMS ANY AND ALL IMPLIED WARRANTIES AND MAKES NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OF THE PATENT RIGHTS OR INFORMATION SUPPLIED BY HARVARD, LICENSED PROCESSES OR LICENSED PRODUCTS CONTEMPLATED BY THIS AGREEMENT.

10.3 (a) LICENSEE shall indemnify, defend and hold harmless HARVARD and its current or former directors, governing board members, trustees, officers, faculty, medical and professional staff, employees, students, and agents and their respective successors, heirs and assigns (collectively, the "INDEMNITEES"), from and against any claim, liability, cost, expense, damage, deficiency, loss or obligation of any kind or nature (including, without limitation, reasonable attorney's fees and other costs and expenses of litigation) (collectively, "Claims"), based upon, arising out of, or otherwise relating to this Agreement, including without limitation any cause of action relating to product liability concerning any product, process, or service made, used or sold pursuant to any right or license granted under this Agreement, provided, however, that such indemnification shall not apply to any liability, damage, loss, or expense to the extent directly attributable to the negligent activities, reckless misconduct or intentional misconduct of Indemnitees.

(b) Each Indemnitee that intends to claim indemnification under Section 10.3(a) shall promptly notify LICENSEE of any claim or action in respect of which the Indemnitee intends to claim such indemnification, and LICENSEE shall assume the defense thereof with counsel mutually satisfactory to LICENSEE and HARVARD. The failure to deliver notice to LICENSEE within a reasonable time after the

commencement of any such claim or action, if materially prejudicial to its ability to defend such action, shall relieve LICENSEE of any liability to the Indemnitee under Section 10.3(a) with respect to such action, but the omission so to deliver notice to LICENSEE will not relieve it of any liability that it may have to any Indemnitee otherwise than under Section 10.3(a). HARVARD and any other Indemnitee, and their respective employees and agents, shall cooperate fully with LICENSEE and its legal representatives in the investigation of any claim or action covered by the indemnification under Section 10.3(a).

- (c) Beginning at the time any such product, process or service is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by LICENSEE or by a SUBLICENSEE, AFFILIATE or agent of LICENSEE, LICENSEE shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than \$2,000,000 per incident and \$2,000,000 annual aggregate and naming the Indemnitees as additional insureds. During clinical trials of any such product, process or service, LICENSEE shall, at its sole cost and expense, procure and maintain commercial general liability insurance in such equal or lesser amount as HARVARD shall require, naming the Indemnitees as additional insureds. Such commercial general liability insurance shall provide: (i) product liability coverage; and (ii) broad form contractual liability coverage for LICENSEE's indemnification under this Agreement. If LICENSEE elects to self-insure all or part of the limits described above (including deductibles or retentions which are in excess of \$250,000 annual aggregate) such self-insurance program must be acceptable to HARVARD and the Risk Management Foundation of the Harvard Medical Institutions, Inc. in their sole discretion. The minimum amounts of insurance coverage required shall not be construed to create a limit of LICENSEE's liability with respect to its indemnification under this Agreement.
- (d) LICENSEE shall provide HARVARD with written evidence of such insurance upon request of HARVARD. LICENSEE shall provide HARVARD with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance; if LICENSEE does not obtain replacement insurance providing comparable coverage within such fifteen (15) day period, HARVARD shall have the right to terminate this Agreement effective at the end of such fifteen (15) day period without notice or any additional waiting periods.
- (e) LICENSEE shall maintain such commercial general liability insurance beyond the expiration or termination of this Agreement during: (i) the period that any product, process, or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold by LICENSEE or by a SUBLICENSEE, AFFILIATE or agent of LICENSEE; and (ii) a reasonable period after the period referred to in Subsection (e)(i) above which in no event shall be less than fifteen (15) years.

Certain identified information marked with [*] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.**

- 10.4 LICENSEE shall not use HARVARD's name or insignia, or any adaptation of them, or the name of any of HARVARD's inventors in any advertising, promotional or sales literature without the prior written approval of HARVARD.
- 10.5 Without the prior written approval of HARVARD in each instance, neither this Agreement nor the rights granted hereunder shall be transferred or assigned in whole or in part by LICENSEE to any person whether voluntarily or involuntarily, by operation of law or otherwise, except that each of LICENSEE and its AFFILIATES may assign this Agreement in connection with a merger, consolidation or sale or transfer of all or substantially all of its assets. This Agreement shall be binding upon the respective successors, legal representatives and assignees of HARVARD and LICENSEE.
- 10.6 The interpretation and application of the provisions of this Agreement shall be governed by the laws of the Commonwealth of Massachusetts.
- 10.7 LICENSEE shall comply with all applicable laws and regulations. In particular, it is understood and acknowledged that the transfer of certain commodities and technical data is subject to United States laws and regulations controlling the export of such commodities and technical data, including all Export Administration Regulations of the United States Department of Commerce. These laws and regulations among other things, prohibit or require a license for the export of certain types of technical data to certain specified countries. LICENSEE hereby agrees and gives written assurance that it will comply with all United States laws and regulations controlling the export of commodities and technical data, that it will be solely responsible for any violation of such by LICENSEE or its AFFILIATES or SUBLICENSEES, and that it will defend and hold HARVARD, CHILDREN, and MIT harmless in the event of any legal action of any nature occasioned by such violation.
- 10.8 LICENSEE agrees: (i) to obtain all regulatory approvals required for the manufacture and sale of LICENSED PRODUCTS and LICENSED PROCESSES; and (ii) to utilize appropriate patent marking on such LICENSED PRODUCTS. LICENSEE also agrees to register or record this Agreement as is required by law or regulation in any country where the license is in effect.
- 10.9 Any notices to be given hereunder shall be sufficient if signed by the party (or party's attorney) giving same and either: (i) delivered in person; (ii) mailed certified mail return receipt requested; or (iii) faxed to other party if the sender has evidence of successful transmission and if the sender promptly sends the original by ordinary mail, in any event to the following addresses:

If to LICENSEE:

Mycometrix Corporation
213 E. Grand Ave.
South San Francisco, CA 94080
Attention:
Fax: (650)-

If to HARVARD:

Office for Technology and Trademark Licensing
Harvard University
Holyoke Center, Suite 727
1350 Massachusetts Avenue
Cambridge, MA 02138
Fax: (617) 495-9568

By such notice either party may change their address for future notices.

Notices delivered in person shall be deemed given on the date delivered. Notices sent by fax shall be deemed given on the date faxed. Notices mailed shall be deemed given on the date postmarked on the envelope.

- 10.10 Should a court of competent jurisdiction later hold any provision of this Agreement to be invalid, illegal, or unenforceable, and such holding is not reversed on appeal, it shall be considered severed from this Agreement. All other provisions, rights and obligations shall continue without regard to the severed provision, provided that the remaining provisions of this Agreement are in accordance with the intention of the parties.
- 10.11 In the event of any controversy or claim arising out of or relating to any provision of this Agreement or the breach thereof, the parties shall try to settle such conflict amicably between themselves. Subject to the limitation stated in the final sentence of this Section 10.11, any such conflict which the parties are unable to resolve promptly shall be settled through arbitration conducted in accordance with the rules of the American Arbitration Association. The demand for arbitration shall be filed within a reasonable time after the controversy or claim has arisen, and in no event after the date upon which institution of legal proceedings based on such controversy or claim would be barred by the applicable statute of limitation. Such arbitration shall be held in Boston, Massachusetts. The award through arbitration shall be final and binding. Either party may enter any such award in a court having jurisdiction or may make application to such court for judicial acceptance of the award and an order of enforcement, as the case may be. Notwithstanding the foregoing, either party may, without recourse to arbitration, assert against the other party a third-party claim or cross-claim in any action brought by a third party, to which the subject matter of this Agreement may be relevant.
- 10.12 This Agreement constitutes the entire understanding between the parties and neither party shall be obligated by any condition or representation other than those expressly stated herein or as may be subsequently agreed to by the parties hereto in writing.

[The remainder of this page is intentionally blank.]

Certain identified information marked with [*] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.**

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives.

PRESIDENT AND FELLOWS
OF HARVARD COLLEGE

MYCOMETRIX CORPORATION

/s/ Joyce Brinton

/s/ Gajus Worthington

Joyce Brinton, Director
Office for Technology and
Trademark Licensing

President

12/20/00

12/21/00

Date

Date

Certain identified information marked with [*] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.**

APPENDIX A

The following comprise PATENT RIGHTS:

[***]

HARVARD UNIVERSITY
Office for Technology and Trademark Licensing

Holyoke Center, Suite 727
1350 Massachusetts Avenue
Cambridge, MA 02138 USA

t. 617.495.3067
f. 617.495.9568
www.techtransfer.harvard.edu

December 22, 2004

William M. Smith
Vice President, Legal Affairs
Fluidigm Corporation
7100 Shoreline Court
South San Francisco, CA 94080

Subject: Letter Agreement between Fluidigm and Harvard Concerning Harvard Case Numbers [***]

Dear Bill,

Fluidigm Corporation (Fluidigm) has licensed a number of Harvard University (Harvard) owned patents and patent applications in the area of [***]. In particular, on October 15, 2000, Fluidigm (then known as Mycometrix Corporation) licensed Harvard Case Numbers [***], all exclusively or co- exclusively. Fluidigm has since terminated the license to Case Numbers [***], and the parties have mutually agreed in this letter to hereby terminate Fluidigm's licenses to Case Numbers [***]. Fluidigm is retaining its licenses to Case Numbers [***].

Fluidigm is concerned that Harvard or a licensee of Harvard may file claims in the previously or hereby terminated Case Numbers [***] or [***] that cover inventions that are not separately patentable (as described in 37 CFR 1.601(n)) from inventions covered, as of the date of this letter, by the pending or issued claims in Case Numbers [***]. Fluidigm further is concerned that Harvard or a licensee of Harvard may file claims in the previously or hereby terminated Case Numbers [***] that (a) cover inventions that (i) are separately patentable (as described in 37 CFR 1.601(n)) from inventions covered, as of the date of this letter, by the pending or issued claims in Case Numbers [***], and (ii) would meet the criteria of 35 USC §§102, 103 and 112 for patentability in Case Numbers [***], and (b) are not now pending in any of Case Numbers [***]. Fluidigm believes it has rights (through its co-exclusive license agreements to Case Numbers [***],) to the not separately patentable inventions and the separately patentable inventions, each as described above. Harvard is willing to address Fluidigm's concerns through this letter agreement.

Therefore, Harvard and Fluidigm agree as follows:

- A) Harvard agrees not to file, or to permit any other to file, claims in the previously or hereby terminated Case Numbers [***], that cover inventions that are not

Certain identified information marked with [*] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.**

separately patentable (as described in 37 CFR 1.601(n)) from inventions covered, as of the date of this letter, by the pending or issued claims in Case Numbers [***], without the prior express written consent of Fluidigm given after the date of this letter.

- B) Harvard agrees to first offer to Fluidigm for licensing any claims, filed after the date of this letter, in Case Number [***] that (a) cover inventions that (i) are separately patentable (as described in 37 CFR 1.601(n)) from inventions covered, as of the date of this letter, by the pending or issued claims in Case Numbers [***], and (ii) would meet the criteria of 35 USC §§102, 103 and 112 for patentability in Case Numbers [***], and (b) are not now pending in any of Case Numbers [***]. Fluidigm agrees to inform Harvard within one month after Fluidigm receives express written notice from Harvard of the existence of said claims (together with a copy of such claims) whether it desires a license to said claims, or else Harvard shall be free to license them to other parties. Any license agreement between Fluidigm and Harvard for said claims shall be negotiated in good faith by the parties, have a field no broader than that now pending in Fluidigm's license to Case [***], have commercially reasonable royalties and be substantially like Harvard's then current license agreement with diligence requirements based on an acceptable development plan provided by Fluidigm; provided, however, if the parties have not entered into such license agreement within [***] after Fluidigm receives express written notice from Harvard of the existence of the applicable claims (together with a copy of such claims), then any license agreement between Fluidigm and Harvard for said claims shall be on the same terms and conditions, and in the same form, as the parties' license agreements with respect to Case Numbers [***], (as in effect as of the date of this letter), except that the license will be a non-exclusive license.
- C) Harvard represents that all patent applications in Case Numbers [***] have been abandoned as of the date of this letter. Harvard agrees not to revive any such patent application or to file any other patent application under Case Number [***].
- D) Fluidigm agrees to pay [***] of Harvard's reasonable out-of-pocket patent expenses, incurred after the date of this letter agreement, in Case Number [***], and within [***] of receiving an invoice from Harvard, up to a maximum aggregate amount of [***]. Harvard agrees to inform Fluidigm if any US patent or patent application in Case Number [***] becomes involved in an interference proceeding in the US Patent and Trademark Office before Harvard has incurred any expense to allow Fluidigm to terminate this letter agreement.
- E) The parties mutually agree that the license to Case Numbers [***] hereby are terminated, and in connection therewith, promptly following the first meeting of the Board of Directors of Fluidigm after such date, Fluidigm shall issue to Harvard [***] of Common Stock of Fluidigm. Fluidigm represents that, in its last institutional round of financing, Fluidigm sold shares of its Series D Preferred Stock at a price of \$2.80 per share. Harvard makes to Fluidigm, as of the date of the issuance of such [***], the same representations and warranties with respect to such shares as those representations and warranties set forth in Paragraph 4.2(c)(ii)(1), (2) and (3) of the

license for Case Number [***] regarding the Shares. Paragraphs 4.2(c)(iii) and (iv) of the license for Case Number [***] shall apply as well to such [***].

Fluidigm may terminate this Letter Agreement in writing with thirty (30) days written notice to Harvard and owe no patent expenses incurred by Harvard in Case Number [***] after said thirty day notice period.

- F) Harvard may terminate this Letter Agreement for any material breach by Fluidigm of its obligations under Paragraphs (D) or (E) of this letter if Harvard gives express written notice to Fluidigm of such breach and such breach is not cured within thirty (30) days after Fluidigm's receipt of such notice.
- G) Any disputes between the parties regarding this letter shall be resolved in the same manner as disputes are resolved under Fluidigm's licenses to Case Numbers [***].
- H) The parties acknowledge that each party may currently have a different interpretation of certain aspects of the three remaining license agreements. With respect to the three remaining license agreements, the provisions of this letter are intended by the parties solely to provide specific protective mechanisms regarding the subject matter licensed by Harvard to Fluidigm. This letter shall not prejudice either parties' interpretation or intent of the three remaining license agreements, and is not intended to constitute the parties' interpretation of the three remaining license agreements (including the original intent thereof).

Sincerely,

/s/ Robert Benson

Robert Benson, PhD
Associate Director

Agreed to:

PRESIDENT AND FELLOWS
OF HARVARD COLLEGE:

/s/ Robert Benson for

Joyce Brinton
Director
Office for Technology and Trademark
Licensing

Date: Dec. 23, 2004

Fluidigm Corporation:

/s/ Gajus Worthington

Signature

President and CEO
Title

Date: 12/23/04

**CERTIFICATION OF THE PRESIDENT AND CHIEF EXECUTIVE OFFICER
PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a),
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Stephen Christopher Linthwaite, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Fluidigm Corporation;
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 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 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.

Date: November 6, 2020

By: /s/ Stephen Christopher Linthwaite
Stephen Christopher Linthwaite
President and Chief Executive Officer

**CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a),
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Vikram Jog, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Fluidigm Corporation;
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 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 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.

Date: November 6, 2020

By: /s/ Vikram Jog
Vikram Jog
Chief Financial Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

I, Stephen Christopher Linthwaite, the chief executive officer of Fluidigm Corporation (the "Company"), certify for the purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge,

1. the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 (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 results of operations of the Company.

Date: November 6, 2020

By: /s/ Stephen Christopher Linthwaite
Stephen Christopher Linthwaite
President and Chief Executive Officer

**CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

I, Vikram Jog, the chief financial officer of Fluidigm Corporation (the "Company"), certify for the purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge,

1. the Company's Quarterly Report on Form 10-Q for the quarter year ended September 30, 2020 (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 results of operations of the Company.

Date: November 6, 2020

By: /s/ Vikram Jog
Vikram Jog
Chief Financial Officer