
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2019 OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from ____ to ____
Commission File: Number 001-35980

NANOSTRING TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

20-0094687
(I.R.S. Employer
Identification No.)

530 Fairview Avenue North
Seattle, Washington 98109
(Address of principal executive offices)
(206) 378-6266
(Registrant's telephone number, including area code)

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, \$0.0001 par value per share	NSTG	The NASDAQ Stock Market LLC (The NASDAQ Global Market)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T 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 type="checkbox"/>	Accelerated filer	<input checked="" 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 31, 2019 there were 35,738,089 shares of registrant's common stock outstanding.

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FOR THE QUARTER ENDED SEPTEMBER 30, 2019
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PART 1. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

NanoString Technologies, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except par value)
(Unaudited)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 23,442	\$ 24,356
Short-term investments	105,423	69,641
Accounts receivable, net	19,542	17,279
Inventory, net	19,040	13,173
Prepaid expenses and other	10,877	7,258
Total current assets	178,324	131,707
Property and equipment, net	14,863	15,171
Operating lease right-of-use assets	25,344	—
Other assets	2,228	680
Total assets	<u>\$ 220,759</u>	<u>\$ 147,558</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 6,724	\$ 8,636
Accrued liabilities	5,632	3,705
Accrued compensation and other employee benefits	10,774	12,060
Customer deposits	6,462	8,167
Deferred revenue, current portion	4,389	9,890
Deferred rent, current portion	—	657
Operating lease liabilities, current portion	3,690	—
Total current liabilities	37,671	43,115
Deferred revenue, net of current portion	876	1,620
Deferred rent and other long-term liabilities, net of current portion	246	7,558
Long-term debt, net of discounts	79,194	58,396
Operating lease liabilities, net of current portion	30,183	—
Total liabilities	148,170	110,689
Commitment and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 15,000 shares authorized; none issued	—	—
Common stock, \$0.0001 par value, 150,000 shares authorized; 35,736 and 30,913 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	4	3
Additional paid-in capital	528,307	428,162
Accumulated other comprehensive income (loss)	217	(40)
Accumulated deficit	(455,939)	(391,256)
Total stockholders' equity	72,589	36,869
Total liabilities and stockholders' equity	<u>\$ 220,759</u>	<u>\$ 147,558</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

NanoString Technologies, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
Product and service	\$ 26,349	\$ 21,453	\$ 70,069	\$ 59,882
Collaboration	4,255	7,163	18,568	16,818
Total revenue	30,604	28,616	88,637	76,700
Costs and expenses:				
Cost of product and service revenue	10,925	9,291	29,239	25,538
Research and development	17,007	16,651	50,063	45,068
Selling, general and administrative	23,382	17,810	69,317	57,897
Total costs and expenses	51,314	43,752	148,619	128,503
Loss from operations	(20,710)	(15,136)	(59,982)	(51,803)
Other income (expense):				
Interest income	763	384	2,114	826
Interest expense	(2,415)	(1,631)	(6,052)	(4,798)
Other expense, net	(322)	(46)	(552)	(330)
Total other expense, net	(1,974)	(1,293)	(4,490)	(4,302)
Net loss before provision for income tax	(22,684)	(16,429)	(64,472)	(56,105)
Provision for income tax	(64)	(57)	(211)	(185)
Net loss	\$ (22,748)	\$ (16,486)	\$ (64,683)	\$ (56,290)
Net loss per share - basic and diluted	\$ (0.64)	\$ (0.56)	\$ (1.90)	\$ (2.09)
Weighted average shares used in computing basic and diluted net loss per share	35,576	29,366	34,121	26,882

The accompanying notes are an integral part of these condensed consolidated financial statements.

NanoString Technologies, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(in thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss	\$ (22,748)	\$ (16,486)	\$ (64,683)	\$ (56,290)
Change in unrealized gain on short-term investments	13	12	257	45
Comprehensive loss	\$ (22,735)	\$ (16,474)	\$ (64,426)	\$ (56,245)

The accompanying notes are an integral part of these condensed consolidated financial statements.

NanoString Technologies, Inc.
Condensed Consolidated Statements of Changes in Stockholders' Equity
(in thousands)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2018	25,421	\$ 2	\$ 353,308	\$ (99)	\$ (313,102)	\$ 40,109
Cumulative effect of a change in accounting policy ⁽¹⁾	—	—	—	—	(755)	(755)
Warrants issued for common stock	—	—	749	—	—	749
Common stock issued for stock options and restricted stock units	139	1	411	—	—	412
Common stock issued for employee stock purchase plan	136	—	767	—	—	767
Stock-based compensation	—	—	2,945	—	—	2,945
Net loss	—	—	—	—	(19,202)	(19,202)
Other comprehensive loss	—	—	—	(13)	—	(13)
Balance at March 31, 2018	<u>25,696</u>	<u>\$ 3</u>	<u>\$ 358,180</u>	<u>\$ (112)</u>	<u>\$ (333,059)</u>	<u>\$ 25,012</u>
Warrants issued for common stock	—	—	674	—	—	674
Common stock issued for stock options and restricted stock units	89	—	583	—	—	583
Stock-based compensation	—	—	2,903	—	—	2,903
Net loss	—	—	—	—	(20,601)	(20,601)
Other comprehensive income	—	—	—	46	—	46
Balance at June 30, 2018	<u>25,785</u>	<u>\$ 3</u>	<u>\$ 362,340</u>	<u>\$ (66)</u>	<u>\$ (353,660)</u>	<u>\$ 8,617</u>
Common stock issued in public offering, net of \$3.7 million of issuance costs	4,600	—	53,847	—	—	53,847
Warrants issued for common stock	—	—	843	—	—	843
Common stock issued for stock options and restricted stock units	163	—	1,733	—	—	1,733
Common stock issued for employee stock purchase plan	121	—	684	—	—	684
Exercise of common stock warrants, net	100	—	—	—	—	—
Stock-based compensation	—	—	2,835	—	—	2,835
Net loss	—	—	—	—	(16,486)	(16,486)
Other comprehensive income	—	—	—	12	—	12
Balance at September 30, 2018	<u>30,769</u>	<u>\$ 3</u>	<u>\$ 422,282</u>	<u>\$ (54)</u>	<u>\$ (370,146)</u>	<u>\$ 52,085</u>

⁽¹⁾ Effective January 1, 2018, we adopted Accounting Standard Update No. 2014-09, Revenue from Contracts with Customers. See Note 2. Significant Accounting Policies and Note 3. Revenue from Contracts with Customers for more information.

NanoString Technologies, Inc.
Condensed Consolidated Statements of Changes in Stockholders' Equity (continued)
(in thousands)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2019	30,913	\$ 3	\$ 428,162	\$ (40)	\$ (391,256)	\$ 36,869
Common stock issued in public offering, net of \$4.7 million of issuance costs	3,175	—	68,273	—	—	68,273
Warrants issued for common stock	—	—	698	—	—	698
Common stock issued for stock options and restricted stock units	805	—	8,075	—	—	8,075
Common stock issued for employee stock purchase plan	151	—	939	—	—	939
Tax payments from shares withheld for equity awards	—	—	(1,299)	—	—	(1,299)
Stock-based compensation	—	—	2,882	—	—	2,882
Net loss	—	—	—	—	(21,898)	(21,898)
Other comprehensive income	—	—	—	61	—	61
Balance at March 31, 2019	<u>35,044</u>	<u>\$ 3</u>	<u>\$ 507,730</u>	<u>\$ 21</u>	<u>\$ (413,154)</u>	<u>\$ 94,600</u>
Warrants issued for common stock	—	—	1,575	—	—	1,575
Common stock issued for stock options and restricted stock units	323	1	4,590	—	—	4,591
Stock-based compensation	—	—	5,076	—	—	5,076
Net loss	—	—	—	—	(20,037)	(20,037)
Other comprehensive income	—	—	—	183	—	183
Balance at June 30, 2019	<u>35,367</u>	<u>\$ 4</u>	<u>\$ 518,971</u>	<u>\$ 204</u>	<u>\$ (433,191)</u>	<u>\$ 85,988</u>
Warrants issued for common stock	—	—	516	—	—	516
Common stock issued for stock options and restricted stock units	317	—	3,234	—	—	3,234
Common stock issued for employee stock purchase plan	52	—	1,013	—	—	1,013
Tax payments from shares withheld for equity awards	—	—	(175)	—	—	(175)
Stock-based compensation	—	—	4,748	—	—	4,748
Net loss	—	—	—	—	(22,748)	(22,748)
Other comprehensive income	—	—	—	13	—	13
Balance at September 30, 2019	<u>35,736</u>	<u>\$ 4</u>	<u>\$ 528,307</u>	<u>\$ 217</u>	<u>\$ (455,939)</u>	<u>\$ 72,589</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

NanoString Technologies, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2019	2018
Operating activities		
Net loss	\$ (64,683)	\$ (56,290)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	12,706	8,683
Depreciation and amortization	3,625	2,975
Non-cash operating lease cost	2,069	—
Amortization of premium on short-term investments	(11)	373
Amortization of deferred financing costs	575	276
Conversion of accrued interest to long-term debt	1,565	1,130
Provision for bad debts	(62)	467
Provision for inventory obsolescence	784	629
Changes in operating assets and liabilities:		
Accounts receivable	(2,224)	562
Inventory	(7,161)	3,468
Prepaid expenses and other assets	(5,292)	(2,418)
Accounts payable	(2,027)	1,261
Accrued liabilities	1,133	(1,388)
Accrued compensation and other employee benefits	(1,232)	532
Customer deposits	(1,705)	1,263
Deferred revenue	(6,244)	(789)
Operating lease liabilities	(1,701)	—
Deferred rent and other liabilities	—	(384)
Net cash used in operating activities	<u>(69,885)</u>	<u>(39,650)</u>
Investing activities		
Purchases of property and equipment	(1,832)	(2,855)
Proceeds from sale of short-term investments	2,500	5,410
Proceeds from maturity of short-term investments	84,070	34,100
Purchases of short-term investments	(122,084)	(62,150)
Net cash used in investing activities	<u>(37,346)</u>	<u>(25,495)</u>
Financing activities		
Borrowings under long-term debt agreement	20,000	—
Deferred costs related to long-term debt	(100)	—
Proceeds from sale of common stock, net	68,273	53,847
Proceeds from issuance of common stock warrants	1,821	2,266
Tax withholdings related to net share settlements of restricted stock units	(1,474)	(197)
Proceeds from issuance of common stock for employee stock purchase plan	1,952	1,451
Proceeds from exercise of stock options	15,899	2,727
Net cash provided by financing activities	<u>106,371</u>	<u>60,094</u>
Net decrease in cash and cash equivalents	(860)	(5,051)
Effect of exchange rate changes on cash and cash equivalents	(54)	(29)
Cash and cash equivalents		
Beginning of period	24,356	26,279
End of period	<u>\$ 23,442</u>	<u>\$ 21,199</u>
Supplemental disclosures		
Operating lease right-of-use assets obtained in exchange for lease obligations	\$ 27,364	\$ —

The accompanying notes are an integral part of these condensed consolidated financial statements.

NanoString Technologies, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Description of the Business

NanoString Technologies, Inc. (the “Company”) was incorporated in the state of Delaware on June 20, 2003. The Company’s headquarters is located in Seattle, Washington. The Company’s proprietary optical barcoding chemistry enables direct detection, identification and quantification of individual target molecules in a biological sample by attaching a unique color coded fluorescent reporter to each target molecule of interest. The Company currently markets and sells two platforms based on its proprietary technology, its nCounter Analysis System and its GeoMx Digital Spatial Profiler, or GeoMx DSP system, both consisting of instruments and consumables, to academic, government, biopharmaceutical and clinical laboratory customers.

The Company has incurred losses to date and expects to incur additional losses for the foreseeable future. The Company continues to invest the majority of its resources in the development and growth of its business, including significant investments in new product development and sales and marketing efforts. The Company’s activities have been financed to date primarily through the sale of equity securities and incurrence of indebtedness and cash received by the Company pursuant to certain product development collaborations.

In March 2019, the Company completed an underwritten public offering of 3,175,000 shares of its common stock, including the exercise in full by the underwriters of their option to purchase 675,000 additional shares of common stock. An additional 2,000,000 shares were sold by a related party stockholder. The Company’s total gross proceeds were \$73.0 million. The Company did not receive any proceeds from the sale of shares of common stock by the related party stockholder. After underwriter’s commissions and other expenses of the offering, the Company’s aggregate net proceeds were approximately \$68.3 million.

In July 2018, the Company completed an underwritten public offering of 4,600,000 shares of common stock, including the exercise in full by the underwriters of their option to purchase 600,000 additional shares of common stock in August 2018, for total gross proceeds of \$57.5 million. After underwriter’s commissions and other expenses of the offering, the Company’s aggregate net proceeds were approximately \$53.8 million.

In January 2018, the Company entered into a Sales Agreement with a sales agent to sell shares of the Company’s common stock through an “at the market” equity offering program for up to \$40.0 million in gross cash proceeds. In March 2019, the Company terminated this agreement and there were no shares of common stock sold under this agreement.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements reflect the accounts of the Company and its wholly-owned subsidiaries. The unaudited condensed consolidated balance sheet at December 31, 2018 has been derived from the audited consolidated financial statements at that date but does not include all information and disclosures required by generally accepted accounting principles in the United States of America (“U.S. GAAP”) for annual financial statements. These unaudited condensed consolidated financial statements and notes should be read in conjunction with the Company’s audited consolidated financial statements and accompanying notes included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2018. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (“SEC”) and U.S. GAAP for unaudited condensed consolidated financial information. Accordingly, they do not include all information and footnotes required by U.S. GAAP for complete financial statements. The accompanying unaudited condensed consolidated financial statements reflect all adjustments consisting of normal recurring adjustments which, in the opinion of management, are necessary for a fair statement of the Company’s financial position and results of its operations as of and for the periods presented.

Unless indicated otherwise, all amounts presented in financial tables are presented in thousands, except for per share and par value amounts.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ from those estimates. The results of the Company’s operations for the three and nine month periods ended September 30, 2019 are not necessarily indicative of the results to be expected for the full year or for any other period.

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Revenue Recognition

The Company recognizes revenue when control of the promised goods or services is transferred to its customers, in an amount that reflects the consideration expected to be received in exchange for those products and services. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. Performance obligations are considered satisfied once the Company has transferred control of a product or service to the customer, meaning the customer has the ability to use and obtain the benefit of the product or service. The Company recognizes revenue for satisfied performance obligations only when there are no uncertainties regarding payment terms or transfer of control.

The Company generates the majority of its revenue from the sale of products and services. The Company's commercial products consist of its proprietary nCounter Analysis System and GeoMx DSP System, and related consumables. Services consist of instrument service contracts and service fees for assay processing.

Revenue from instruments and consumables, including *in vitro* diagnostic kits, is recognized generally upon shipment to the end customer, which is when title of the product has been transferred to the customer. Performance obligations related to instrument sales are reviewed on a contract-by-contract basis, as individual contract terms may vary, and may include installation and calibration services. Performance obligations for consumable products are generally completed upon shipment to the customer. Instrument revenue related to installation and calibration services is recognized when the customer has possession of the instrument and the services have been performed. Such services can also be provided by the Company's distribution partners and other third parties. For instruments sold solely to run *in vitro* diagnostic assays, such as our Prosigna assay, training the customer is a required performance obligation that must be provided by the Company prior to any revenue recognition related to the instrument sale.

Instrument service contracts are sold with contract terms ranging from 12–36 months and cover periods after the end of the initial 12-month warranty. These contracts include services to maintain performance within the Company's designed specifications and a minimum of one preventative maintenance service procedure during the contract term. Revenue from services to maintain designed specifications is considered a stand-ready obligation and recognized evenly over the contract term and service revenue related to preventative maintenance of instruments is recognized when the procedure is completed. Revenue from service fees for assay processing is recognized upon the rendering of the related performance obligation.

For arrangements with multiple performance obligations, the Company allocates the contract price in proportion to its stand-alone selling price. The Company uses its best estimate of stand-alone selling price for its products and services based on average selling prices over a 12-month period and reviews its stand-alone prices annually.

Product and service revenues from sales to customers through distributors are recognized consistent with the policies and practices for direct sales to customers, as described above.

The Company at times may enter into collaboration agreements that may generate upfront fees, and in some cases subsequent milestone payments that may be earned upon completion of certain product development milestones or other designated activities. The Company estimates the expected total cost of product development and other services under these arrangements and recognizes collaboration revenue using a contingency-adjusted proportional performance model. Costs incurred to date compared to total expected costs are used to determine proportional performance, as this is considered to be representative of the delivery of outputs under the arrangements. Revenue recognized at any point in time is limited to cash received, amounts contractually due, or the amounts of any product development or other contractual milestone payments when achievement of a milestone is deemed to be probable. Changes in estimates of total expected collaboration product development or other costs are accounted for prospectively as a change in estimate. From period to period, collaboration revenue can fluctuate substantially based on the achievement or probable achievement of product development or other milestones, or as estimates of total expected collaboration product development or other costs are changed or updated. The Company may recognize revenue from collaboration agreements that do not include upfront or milestone-based payments. Amounts due to collaboration partners are recognized when the related activities have occurred and are classified in the statement of operations, generally as research and development expense, based on the nature of the related activities.

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Reclassifications

Certain reclassifications have been made to prior year financial statements to conform to current year presentation.

Recently Adopted Accounting Pronouncements

In February 2018, FASB issued “ASU 2018-02, Income Statement — Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income.” The new guidance permits companies to reclassify the stranded tax effects of the Tax Cuts and Jobs Act (the “Act”) on items within accumulated other comprehensive income to retained earnings. The standard became effective for the Company beginning January 1, 2019, and did not have a material impact on its results of operations, financial condition, cash flows or financial statement disclosures, as the Company has not historically recorded the tax effects within accumulated other comprehensive income. The Company maintains a full valuation allowance for its net deferred tax assets.

Leases

In February 2016, FASB issued “ASU 2016-02, Leases – Recognition and Measurement of Financial Assets and Financial Liabilities.” The standard requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition. In August 2018, FASB issued “ASU 2018-11, Leases (Topic 842): Targeted Improvements,” which allows the cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption.

On January 1, 2019, the Company adopted ASU 2016-02 and has elected the optional modified transition method. Accordingly, all periods prior to January 1, 2019 were presented in accordance with the previous ASC Topic 840, Leases, and no retrospective adjustments were made to the comparative periods presented. The adoption of the standard had a material impact on the Company’s condensed consolidated balance sheet as of March 31, 2019, but did not have a material impact on the Company’s condensed consolidated statements of operations or condensed consolidated statements of cash flows. Upon adoption, the Company recognized operating lease right-of-use assets, current and non-current operating lease liabilities, and derecognized current and non-current deferred rent liabilities, with no cumulative-effect adjustment to the opening balance of retained earnings.

The Company elected the package of practical expedients permitted under the transition guidance within the new standard which, among other things, allowed the carry forward of the historical lease classification and assessment of prior conclusions about lease identification. In addition, the Company elected, as an accounting policy election, to use the short-term lease recognition exemption on all classes of assets. Leases with an initial term of 12 months or less are not recorded on the balance sheet and the Company recognizes lease expense for these leases on a straight-line basis over the lease term.

The Company determines if an arrangement is a lease at inception of a contract. The Company’s leasing portfolio is comprised of operating leases primarily for general office, manufacturing, and research and development purposes. Operating lease liabilities and the corresponding right-of-use assets are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. The operating lease right-of-use asset is reduced by lease incentives included in the agreement. As the existing leases do not contain an implicit interest rate, the Company estimates its incremental borrowing rate based on information available at commencement date in determining the present value of future payments. The Company includes options to extend the lease in the lease liability and right-of-use asset when it is reasonably certain that the option will be exercised. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. For our short-term leases, we recognize lease payments as an expense on a straight-line basis over the lease term. See Note 4. Operating Leases for additional information regarding lease agreements.

Recent Accounting Pronouncements

In June 2016, FASB issued “ASU 2016-13, Financial Instruments: Credit Losses.” The standard requires disclosure regarding expected credit losses on financial instruments at each reporting date, and changes how other than temporary impairments on investment securities are recorded. The standard will become effective for the Company beginning January 1, 2020 with early adoption permitted. The Company is currently assessing the impact adoption of this standard will have on its consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

In August 2018, FASB issued “ASU 2018-15, Intangibles — Goodwill and other — Internal-use software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract.” The standard aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The Company has had a practice of expensing the implementation costs related to cloud computing arrangements. Upon adoption of the standard, the Company may capitalize certain implementation costs for new cloud computing arrangements in other assets, and amortize the costs over the related service contract period for the hosted arrangement. The

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amortization of the implementation costs and the related service contract costs will be presented in its results of operations. The impact to the Company's consolidated financial statements will depend on multiple factors, including the timing, scope and cost of future cloud-based implementation projects. The Company will adopt the standard, on a prospective basis, on January 1, 2020, the effective date of the standard.

In November 2018, the FASB issued "ASU 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606." The new guidance clarifies when certain transactions between collaborative arrangement participants which should be accounted for as revenue under Topic 606. The Company will adopt the standard on January 1, 2020, the effective date of the standard. The Company has assessed its collaborative arrangements and had concluded no adjustment is necessary, based on guidance in the standard.

3. Revenue from Contracts with Customers

Disaggregated Revenues

The following table provides information about disaggregated revenue by major product line and primary geographic market (in thousands):

	Three Months Ended September 30, 2019				Nine Months Ended September 30, 2019			
	Americas	Europe and Middle East	Asia Pacific	Total	Americas	Europe and Middle East	Asia Pacific	Total
Product revenue:								
Instruments	\$ 5,823	\$ 1,577	\$ 637	\$ 8,037	\$ 11,609	\$ 4,066	\$ 1,620	\$ 17,295
Consumables	8,872	3,040	824	12,736	25,241	9,084	2,331	36,656
<i>In vitro</i> diagnostic kits	776	1,670	71	2,517	1,852	5,350	243	7,445
Total product revenue	15,471	6,287	1,532	23,290	38,702	18,500	4,194	61,396
Service revenue	2,004	841	214	3,059	5,965	2,136	572	8,673
Total product and service revenue	17,475	7,128	1,746	26,349	44,667	20,636	4,766	70,069
Collaboration revenue	4,255	—	—	4,255	18,568	—	—	18,568
Total revenues	\$ 21,730	\$ 7,128	\$ 1,746	\$ 30,604	\$ 63,235	\$ 20,636	\$ 4,766	\$ 88,637

	Three Months Ended September 30, 2018				Nine Months Ended September 30, 2018			
	Americas	Europe and Middle East	Asia Pacific	Total	Americas	Europe and Middle East	Asia Pacific	Total
Product revenue:								
Instruments	\$ 3,696	\$ 1,149	\$ 584	\$ 5,429	\$ 9,512	\$ 4,189	\$ 1,890	\$ 15,591
Consumables	7,808	2,633	699	11,140	20,770	7,882	2,126	30,778
<i>In vitro</i> diagnostic kits	783	1,687	77	2,547	2,382	4,600	252	7,234
Total product revenue	12,287	5,469	1,360	19,116	32,664	16,671	4,268	53,603
Service revenue	1,582	641	114	2,337	4,383	1,589	307	6,279
Total product and service revenue	13,869	6,110	1,474	21,453	37,047	18,260	4,575	59,882
Collaboration revenue	7,163	—	—	7,163	16,818	—	—	16,818
Total revenues	\$ 21,032	\$ 6,110	\$ 1,474	\$ 28,616	\$ 53,865	\$ 18,260	\$ 4,575	\$ 76,700

Contract balances and remaining performance obligations

Contract liabilities are comprised of the current and long-term portions of deferred revenue of \$5.3 million and \$11.5 million as of September 30, 2019 and December 31, 2018, respectively, and customer deposits of \$6.5 million and \$8.2 million as of September 30, 2019 and December 31, 2018, respectively, included within the condensed consolidated balance sheets. Total contract liabilities decreased by \$8.0 million for the nine months ended September 30, 2019 as a result of the recognition of previously deferred revenue and customer deposits of \$23.9 million for the completion of certain performance obligations

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during the period, partially offset by cash payments received of \$16.0 million related to our collaborations and service contracts. The Company did not record any contract assets as of September 30, 2019.

As of September 30, 2019, unsatisfied or partially unsatisfied performance obligations related to the collaboration agreement with Lam Research Corporation ("Lam") were \$6.0 million and are expected to be completed by the first half of 2020. Performance obligations related to undelivered products and service contracts as of September 30, 2019 were \$5.7 million and are expected to be completed over the term of the related contract or as products are delivered.

4. Operating Leases

The Company maintains operating leases for its manufacturing, research and development and general operations with terms that expire from 2020 to 2030 and include renewal options to extend the lease term at the then current fair market rental for each of the lease agreements. None of the options to extend the rental term of existing leases were considered reasonably certain as of September 30, 2019. The Company's lease agreements do not contain any material variable lease payments, material residual value guarantees or any material restrictive covenants.

The components of lease expense were as follows (in thousands):

	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
Operating lease cost	\$ 1,540	\$ 4,404

Other information related to leases were as follows (in thousands):

	Nine Months Ended September 30, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	\$ 4,134

The lease term and discount rate was as follows:

	September 30, 2019
Weighted Average Remaining Lease Term (years)	6.9
Weighted Average Discount Rate	7.1%

Future minimum lease payments under the lease agreements as of September 30, 2019 were as follows (in thousands):

Remainder of 2019	\$ 1,398
2020	6,159
2021	6,266
2022	6,327
2023	6,506
Thereafter	17,676
Total future minimum lease payments	\$ 44,332
Less: imputed interest	(10,459)
Total	\$ 33,873

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Disclosures related to periods prior to adoption

Future minimum lease payments under non-cancellable leases as of December 31, 2018 were as follows (in thousands):

2019	\$	5,526
2020		5,560
2021		5,593
2022		5,708
2023		5,869
Thereafter		13,458
Total future minimum lease payments	\$	<u>41,714</u>

5. Net Loss Per Share

Net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding. Outstanding stock options, restricted stock units and warrants have not been included in the calculation of diluted net loss per share because to do so would be anti-dilutive. Accordingly, the numerator and the denominator used in computing both basic and diluted net loss per share for each period are the same.

The following shares underlying outstanding options, restricted stock units and warrants were excluded from the computation of basic and diluted net loss per share for the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Options to purchase common stock	4,448	5,302	4,682	5,496
Restricted stock units	1,864	1,194	1,675	1,135
Common stock warrants	1,231	551	1,052	460

6. Concentration of Risks

Financial instruments that potentially expose the Company to concentrations of credit risk consist principally of cash and cash equivalents, short-term investments and accounts receivable. Cash is invested in accordance with the Company's investment policy, which includes guidelines intended to minimize and diversify credit risk. Most of the Company's investments are not federally insured. The Company has credit risk related to the collectability of its accounts receivable. The Company performs initial and ongoing evaluations of its customers' credit history or financial position and generally extends credit on account without collateral. The Company has not experienced significant credit losses to date.

During the three and nine months ended September 30, 2019, the Company had one collaborator, Lam, that individually represented 13% and 15% of total revenue, respectively. The Company had one collaborator, Lam, that individually represented 18% of total revenue during the three and nine months ended September 30, 2018, respectively. The Company had no customers or collaborators that represented more than 10% of total product and service revenue for the three and nine months ended September 30, 2019 and 2018, respectively. The Company had no customers or collaborators that represented more than 10% of total accounts receivable as of September 30, 2019 or December 31, 2018.

The Company is also subject to supply chain risks related to the outsourcing of the manufacturing and production of its instruments to sole suppliers. Although there are a limited number of manufacturers for instruments of this type, the Company believes that other suppliers could provide similar products on comparable terms. Similarly, the Company sources certain raw materials used in the manufacture of consumables from certain sole suppliers. A change in suppliers could cause a delay in manufacturing and a possible loss of sales, which would adversely affect operating results.

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7. Short-term Investments

Short-term investments consisted of available-for-sale securities as follows (in thousands):

Type of securities as of September 30, 2019	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Corporate debt securities	\$ 66,299	\$ 148	\$ —	\$ 66,447
U.S. government-related debt securities	28,431	48	—	28,479
Asset-backed securities	10,476	21	—	10,497
Total available-for-sale securities	<u>\$ 105,206</u>	<u>\$ 217</u>	<u>\$ —</u>	<u>\$ 105,423</u>

Type of securities as of December 31, 2018	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Corporate debt securities	\$ 47,299	\$ 1	\$ (21)	\$ 47,279
U.S. government-related debt securities	14,972	—	(11)	14,961
Asset-backed securities	7,410	—	(9)	7,401
Total available-for-sale securities	<u>\$ 69,681</u>	<u>\$ 1</u>	<u>\$ (41)</u>	<u>\$ 69,641</u>

The fair values of available-for-sale securities by contractual maturity were as follows (in thousands):

	September 30, 2019	December 31, 2018
Maturing in one year or less	\$ 97,894	\$ 69,641
Maturing in one to three years	7,529	—
Total available-for-sale securities	<u>\$ 105,423</u>	<u>\$ 69,641</u>

The Company has both the intent and ability to sell its available-for-sale investments maturing greater than one year within 12 months from the balance sheet date and, accordingly, has classified these securities as current in the condensed consolidated balance sheets.

8. Fair Value Measurements

The Company establishes the fair value of its assets and liabilities using the price that would be received to sell an asset or paid to transfer a financial liability in an orderly transaction between market participants at the measurement date. A fair value hierarchy is used to measure fair value. The three levels of the fair value hierarchy are as follows:

- Level 1 — Quoted prices in active markets for identical assets and liabilities.
- Level 2 — Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.
- Level 3 — Valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

The recorded amounts of certain financial instruments, including cash, accounts receivable, prepaid expenses and other, accounts payable and accrued liabilities, approximate fair value due to their relatively short-term maturities. The recorded amount of the Company's long-term debt approximates fair value because the related interest rates approximate rates currently available to the Company.

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The Company's available-for-sale securities by level within the fair value hierarchy were as follows (in thousands):

As of September 30, 2019	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market fund	\$ 15,687	\$ —	\$ —	\$ 15,687
Short-term investments:				
Corporate debt securities	—	66,447	—	66,447
U.S. government-related debt securities	—	28,479	—	28,479
Asset-backed securities	—	10,497	—	10,497
Total	\$ 15,687	\$ 105,423	\$ —	\$ 121,110

As of December 31, 2018	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market fund	\$ 16,293	\$ —	\$ —	\$ 16,293
Short-term investments:				
Corporate debt securities	—	47,279	—	47,279
U.S. government-related debt securities	—	14,961	—	14,961
Asset-backed securities	—	7,401	—	7,401
Total	\$ 16,293	\$ 69,641	\$ —	\$ 85,934

9. Inventory

Inventory consisted of the following as of the date indicated (in thousands):

	September 30, 2019	December 31, 2018
Raw materials	\$ 4,610	\$ 3,408
Work in process	4,800	4,054
Finished goods	9,630	5,711
Total inventory	\$ 19,040	\$ 13,173

10. Long-term Debt

Term Loan Agreements

In April 2014, the Company entered into a term loan agreement ("2014 Term Loan"), under which it borrowed \$45.0 million. Interest on the 2014 Term Loan accrued at an annual rate of 12.0%, payable quarterly, of which 3.0% can be deferred during the first six years of the term at the Company's option and paid together with the principal at maturity. The 2014 Term Loan had an interest-only period through March 2021 and a final maturity date of March 2022.

In October 2018, the Company entered into an amended and restated term loan agreement ("2018 Term Loan"), under which it may borrow up to \$100.0 million, which is due and payable in September 2024. At closing, the Company received net proceeds of approximately \$7.8 million, pursuant to borrowings of \$60.0 million under the new facility, net of repayment of the Company's 2014 Term Loan of \$50.4 million, including deferred interest and transaction-related fees and expenses. In June 2019, the Company borrowed an additional \$20.0 million under the 2018 Term Loan and has the option to borrow the remaining \$20.0 million until March 2020, which is subject to the achievement of annual revenue thresholds on or prior to December 31, 2019.

The term loan agreements involved multiple lenders who were considered members of a loan syndicate. In determining whether the most recent amendment was to be accounted for as a debt extinguishment or a debt modification, the Company considered whether lenders remained the same or changed. As all the lenders who were members of the loan syndicate changed as part of the amended and restated loan agreement, the 2014 Term Loan was extinguished, and the 2018 Term Loan was treated as a new borrowing. The extinguishment resulted in a loss of approximately \$0.8 million for the year ended December 31, 2018, which was included in interest expense during the fourth quarter of 2018.

The 2018 Term Loan accrues interest at a rate of 10.5%, payable quarterly, of which 3.0% may be deferred during the six-year term at the Company's option and repaid at maturity together with the principal. The Company paid an upfront fee of 0.5% of the aggregate principal amount of the initial borrowing under the 2018 Term Loan, and will pay a facility fee equal to

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2.0% of the total amount borrowed including any deferred interest at the time the principal is repaid. A long-term liability of \$1.9 million is being accreted using the effective interest method for the facility fee over the term of the 2018 Term Loan. Additional borrowings under the 2018 Term Loan will bear the same upfront and facility fees as the initial borrowing.

In connection with entry into the 2018 Term Loan, warrants to purchase an aggregate of 341,578 shares of common stock with an exercise price per share of \$21.12 were issued to the lenders. In June 2019, in connection with the borrowing of an additional \$20.0 million principal amount, warrants to purchase an aggregate of 128,932 shares of common stock with an exercise price per share of \$34.20 were issued to the lenders. If additional amounts are borrowed under the 2018 Term Loan, additional warrants will be issued on each subsequent draw date for 0.3% of the fully-diluted shares then outstanding. The exercise price for additional warrants will be set at a 25.0% premium to the average closing trading price for the 30-day trading period as of the date immediately before the applicable draw date. The warrants issued in conjunction under the 2018 Term Loan were determined to be closely linked to the Company's stock, and as such, were recorded as an equity security in additional paid-in capital at their relative fair value of \$1.6 million and \$1.0 million, in October 2018 and June 2019, respectively, with a corresponding debt discount recorded against the 2018 Term Loan balance outstanding.

Total borrowings and deferred interest under the 2018 Term Loan were \$82.0 million and \$60.4 million as of September 30, 2019 and December 31, 2018, respectively. The balance of the 2018 Term Loan as of September 30, 2019 and December 31, 2018 is net of discounts related to the warrants, debt issuance costs and other upfront fees of \$2.8 million and \$2.0 million, respectively.

The Company has the option to prepay the 2018 Term Loan, in whole or part, at any time subject to payment of a redemption fee of up to 4.0% during the first year of the term, 3.0% during the second year of the term and with no redemption fee payable if prepayment occurs after the second year of the loan.

Obligations under the 2018 Term Loan are collateralized by substantially all of the Company's assets. The 2018 Term Loan contains customary conditions to borrowings, events of default and covenants, including negative covenants that could limit the Company's ability to, among other things, incur additional indebtedness, liens or other encumbrances; make dividends or other distributions; buy, sell or transfer assets; engage in any new line of business; and enter into certain transactions with affiliates. The 2018 Term Loan also includes a \$2.0 million minimum liquidity covenant and minimum annual revenue-based financial covenants. If the Company's actual revenue is below the minimum annual revenue requirement for any given year, it may avoid a related default by generating proceeds from an equity or subordinated debt issuance equal to the shortfall between its actual revenues and the minimum revenue requirement.

The Company incurred \$2.4 million and \$1.6 million of interest expense under the term loan agreements for the three months ended September 30, 2019 and 2018, respectively, and \$6.1 million and \$4.8 million for the nine months ended September 30, 2019 and 2018, respectively. The Company was in compliance with its financial covenants under the term loan agreement as of September 30, 2019.

2018 Revolving Loan Facility

In January 2018, the Company entered into a \$15.0 million secured revolving loan facility, with availability subject to a borrowing base consisting of eligible accounts receivable. In November 2018, the Company entered into an amended and restated loan and security agreement to increase the borrowing capacity under the facility to \$20.0 million, amend the borrowing base to include finished goods inventory, and extend the final maturity under the facility to November 2021. As of September 30, 2019 and December 31, 2018, no amounts had been drawn on the facility.

Interest on borrowings is payable monthly and accrues at a yearly rate equal to the greater of (i) the prime rate as reported in the Wall Street Journal plus 0.50% and (ii) 4.75%. During an event of default, amounts drawn accrue interest at a yearly rate equal to 8.75%. Obligations under the agreement are secured by the Company's cash and cash equivalents, accounts receivable and proceeds thereof, and inventory and proceeds from the sale thereof. The lender's interest in the collateral under the loan facility is senior to the lender's interest in such collateral under the term loan agreement. The loan facility contains various customary representations and warranties, conditions to borrowing, events of default, including cross default provisions with respect to the loan facility, and covenants, including financial covenants requiring the maintenance of minimum annual revenue and liquidity. The Company was in compliance with its financial covenants under the secured revolving loan facility as of September 30, 2019.

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Long-term debt consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Borrowings under term loan agreements	\$ 80,000	\$ 60,000
Paid-in-kind interest on term loan agreements	1,965	400
Unamortized debt discounts	(2,771)	(2,004)
Long-term debt, net of discounts	<u>\$ 79,194</u>	<u>\$ 58,396</u>

Scheduled future principal payments for outstanding debt were as follows at September 30, 2019 (in thousands):

Years Ending December 31,

Remainder of 2019	\$ —
2020	—
2021	—
2022	—
2023	—
Thereafter	81,965
	<u>\$ 81,965</u>

11. Collaboration Agreements

At the time of entering into collaboration agreements, the Company evaluates the appropriate presentation and classification of payments within its consolidated financial statements based on the nature of the arrangement, the nature of its business operations and the contractual terms of the arrangement. The Company has determined that amounts to be received from collaborators in connection with its collaboration agreements entered into through September 30, 2019 are related to revenue generating activities.

The Company uses a contingency-adjusted proportional performance model to recognize revenue over the Company's performance period for each collaboration agreement that includes up front, or milestone-based or other contractual payments. Costs incurred to date compared to total expected costs are used to determine proportional performance, as this is considered to be representative of the delivery of outputs under the arrangement. Revenue recognized at any point in time is a factor of and limited to cash received and amounts contractually due. Changes in estimates of total expected costs are accounted for prospectively in the period of change.

The Company recognizes revenue from collaboration agreements that do not include up front, milestone-based or other contractual payments when earned, which is generally in the same period that related costs are incurred. Amounts due to collaboration partners are recognized when the related activities have occurred and are classified in the statement of operations, generally as research and development expense, based on the nature of the related activities.

Lam Research Corporation

In August 2017, the Company entered into a collaboration agreement with Lam with respect to the development of the Company's Hyb & Seq platform product candidate. Pursuant to the terms of the collaboration agreement, Lam will contribute up to an aggregate of \$50.0 million, with amounts thereunder payable quarterly, to be applied to the research and development of the Company's Hyb & Seq platform, based on allowable development costs. Lam is eligible to receive certain single-digit percentage royalty payments from the Company on net sales of certain products and technologies developed under the collaboration agreement, if any such net sales are ever achieved. The maximum amount of royalties payable to Lam will be capped at an amount up to three times the amount of development funding actually provided by Lam. The Company retains exclusive rights to obtain regulatory approval, manufacture and commercialize the Hyb & Seq products. Lam participates in research and product development through a joint steering committee. The Company will reimburse Lam for the cost of up to 10 full-time Lam employees each year in accordance with the product development plan.

In connection with the execution of the collaboration agreement, the Company issued Lam a warrant to purchase up to 1.0 million shares of the Company's common stock with the number of underlying shares exercisable at any time proportionate to the amount of the \$50.0 million commitment that has been provided by Lam. The exercise price of the warrant is \$16.75 per share, and the warrant will expire on the seventh anniversary of the issuance date. The warrant was determined to have a fair value of \$6.7 million upon issuance, and such amount will be recorded as additional paid-in capital proportionately from the quarterly collaboration payments made by Lam.

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During the three and nine months ended September 30, 2019, the Company recognized revenue related to the Lam agreement of \$4.0 million and \$13.2 million, respectively, and \$5.3 million and \$13.4 million for the three and nine months ended September 30, 2018, respectively. The Company received development funding of \$3.4 million and \$11.7 million related to the Lam collaboration for the three and nine months ended September 30, 2019, respectively, and \$7.0 million and \$18.4 million for the three and nine months ended September 30, 2018, respectively. The Company has received \$46.8 million in development funding since the inception of the agreement through September 30, 2019.

At September 30, 2019, the Company had recorded \$0.5 million of deferred revenue related to the Lam collaboration, all of which is estimated to be recognizable as revenue within one year. In addition, \$5.3 million is included in customer deposits in the condensed consolidated balance sheet as of September 30, 2019, which represents amounts received in advance. The Company incurred costs related to services provided by Lam employees under the terms of the agreement of \$0.2 million and \$0.6 million during the three and nine months ended September 30, 2019, respectively, and \$0.1 million and \$0.2 million for the three and nine months ended September 30, 2018, respectively. As of September 30, 2019, Lam had not exercised any warrants.

Celgene Corporation

In March 2014, the Company entered into a collaboration agreement with Celgene Corporation (“Celgene”) to develop, seek regulatory approval for, and commercialize a companion diagnostic using the nCounter Analysis System to identify a subset of patients with Diffuse Large B-Cell Lymphoma. In February 2018, the Company and Celgene entered into an amendment to their collaboration agreement in which Celgene agreed to provide the Company additional funding for work intended to enable a subtype and prognostic indication for the test being developed under the agreement for Celgene’s drug REVLIMID. In connection with this amendment, the Company agreed to remove the right to receive payments from Celgene in the event commercial sales of the companion diagnostic test do not exceed certain pre-specified minimum annual revenues during the first three years following regulatory approval. In addition, the amendment allows Celgene, at its election, to use trial samples with additional technologies for companion diagnostics.

Pursuant to the Company’s agreement as amended in February 2018, the Company is eligible to receive payments from Celgene totaling up to \$24.8 million, of which \$5.8 million was received as an upfront payment upon delivery of certain information to Celgene and \$19.0 million is for development funding and potential success-based development and regulatory milestones. There have been several amendments to the collaboration agreement and in return the Company has received additional payments totaling \$2.1 million.

The process of successfully developing a product candidate, obtaining regulatory approval and ultimately commercializing a product candidate is highly uncertain and the attainment of any additional milestones is therefore uncertain and difficult to predict. In addition, certain milestones are outside the Company’s control and are dependent on the performance of Celgene and the outcome of a clinical trial and related regulatory processes. Pursuant to its collaboration with Celgene, the Company has been developing an *in vitro* diagnostic test, LymphMark, as a potential companion diagnostic to aid in identifying patients with diffuse large B-cell lymphoma (DLBCL) for treatment. In April 2019, Celgene announced that the trial evaluating REVLIMID for the treatment of DLBCL did not meet its primary endpoint. In May 2019, the Company’s collaboration agreement with Celgene was terminated effective July 2019, with substantially all the remaining deferred revenue from the agreement recognized in the three months ended June 30, 2019. In addition, the Company does not intend to file a pre-market approval for LymphMark as a companion diagnostic for REVLIMID.

The Company did not recognize revenue related to the Celgene agreement during the three months ended September 30, 2019 and recognized \$4.4 million during the nine months ended September 30, 2019. During the three and nine months ended September 30, 2018, the Company recognized revenue related to the Celgene agreement of \$1.6 million and \$1.4 million, respectively. The Company received development funding of \$0.8 million and \$1.1 million related to the Celgene collaboration for the three and nine months ended September 30, 2019.

Merck & Co., Inc.

In May 2015, the Company entered into a clinical research collaboration agreement with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. (“Merck”), to develop an assay intended to optimize immune-related gene expression signatures and evaluate the potential to predict benefit from Merck’s anti-PD-1 therapy, KEYTRUDA. Under the terms of the collaboration agreement, the Company received \$3.9 million in payments during 2015. In connection with the execution of the development collaboration agreement, the Company and Merck terminated the May 2015 clinical research collaboration and moved all remaining activities under the related work plan to the new development collaboration agreement. In February 2016, the Company expanded its collaboration with Merck by entering into a new development collaboration agreement to clinically develop, seek regulatory approval for, and commercialize a companion diagnostic test to predict response to KEYTRUDA in multiple tumor types. During 2016, the Company received \$12.0 million upfront as a technology access fee and \$8.5 million of preclinical milestone payments. In October 2017, Merck notified the Company of its decision not to pursue regulatory approval

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of the companion diagnostic test for KEYTRUDA and, in August 2018, the Company and Merck agreed to mutually terminate their development collaboration agreement, effective as of September 30, 2018, following the completion of certain close-out activities. As part of the mutual termination agreement, Merck granted to the Company a non-exclusive license to certain intellectual property that relates to Merck's tumor inflammation signature. The Company recognized revenue of \$0.2 million and \$1.6 million during the three and nine months ended September 30, 2018, respectively.

12. Commitments and Contingencies

From time to time, the Company may become involved in litigation relating to claims arising from the ordinary course of business. Additionally, the Company operates in various states and local jurisdictions for which sales, occupation, or franchise taxes may be payable to certain taxing authorities. Management believes that there are no claims or actions pending against the Company currently, the ultimate disposition of which would have a material adverse effect on the Company's consolidated results of operations, financial condition or cash flows.

13. Information about Geographic Areas

The Company operates as a single reportable segment and enables customers to perform both research and clinical testing on its nCounter Analysis and GeoMx DSP Systems. The Company has one sales force that sells these systems to both research and clinical testing labs, and certain of its nCounter reagents can be used for both research and diagnostic testing. GeoMx DSP reagents are sold for research use only. In addition, the Company's Prosigna Breast Cancer Assay is marketed to clinical laboratories.

The following table of total revenue is based on the geographic location of distributors or end users who purchase products and services and collaborators. For sales to distributors, their geographic location may be different from the geographic locations of the ultimate end user. For collaboration agreements, revenues are derived from partners located primarily in the United States. Americas consists of the United States, Canada, Mexico and South America; and Asia Pacific includes Japan, China, South Korea, Singapore, Malaysia, India and Australia.

Revenue by geography was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Americas	\$ 21,730	\$ 21,032	\$ 63,235	\$ 53,865
Europe & Middle East	7,128	6,110	20,636	18,260
Asia Pacific	1,746	1,474	4,766	4,575
Total revenue	\$ 30,604	\$ 28,616	\$ 88,637	\$ 76,700

Total revenue in the United States was \$21.3 million and \$20.4 million for the three months ended September 30, 2019 and 2018, respectively, and \$61.7 million and \$51.2 million for the nine months ended September 30, 2019 and 2018, respectively. The Company's assets are primarily located in the United States and not allocated to any specific geographic region. Substantially all of the Company's long-lived assets are located in the United States.

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

Special Note Regarding Forward-Looking Information

This Quarterly Report on Form 10-Q contains forward-looking statements that are based on our management’s beliefs and assumptions and on information currently available. This section should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in Part I, Item 1 of this report. The statements contained in this Quarterly Report on Form 10-Q that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended.

Forward-looking statements can be identified by words such as “believe,” “anticipate,” “could,” “continue,” “depends,” “expect,” “expand,” “forecast,” “intend,” “predict,” “plan,” “rely,” “should,” “will,” “may,” “seek,” or the negative of these terms and other similar expressions, although not all forward-looking statements contain these words. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other “forward-looking” information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements include, but are not limited to:

- our expectations regarding our future operating results and capital needs, including our expectations regarding instrument, consumable and total revenue, operating expenses, sufficiency of cash on hand and operating and net loss;
- our ability to successfully commercialize our GeoMx DSP platform;
- our ability to successfully develop our Hyb & Seq platform;
- the success, costs and timing of implementation of our business model, strategic plans for our business and future product development plans;
- the regulatory regime and our ability to secure and maintain regulatory clearance or approval or reimbursement for the clinical use of our products, domestically and internationally;
- our ability to realize the potential payments set forth in our collaboration agreements;
- our strategic relationships, including with patent holders of our technologies, manufacturers and distributors of our products, collaboration partners and third parties who conduct our clinical studies;
- our intellectual property position;
- our ability to attract and retain key scientific or management personnel;
- our expectations regarding the competitive position, market size and growth potential for our business;
- and
- our ability to sustain and manage growth, including our ability to expand our customer base, develop new products, enter new markets and hire and retain key personnel.

These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part II, Item 1A — “Risk Factors,” and elsewhere in this report. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. In this report, “we,” “our,” “us,” “NanoString,” and “the Company” refer to NanoString Technologies, Inc. and its subsidiaries.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

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Overview

We develop, manufacture and sell products that unlock scientifically valuable and clinically actionable information from minute amounts of biological material. Our core technology is a unique, proprietary optical barcoding chemistry that enables the labeling and counting of single molecules. This proprietary chemistry may reduce the number of steps required to conduct certain types of scientific experiments and allow for multiple experiments to be conducted at once. As a result, we are able to develop tools that are easier for researchers to use and that may generate faster and more consistent scientific results.

We use our technology to develop tools for scientific research, primarily in the fields of genomics and proteomics, and also to develop clinical diagnostic tests. We currently have two commercially available product platforms, our nCounter Analysis System instruments and related consumables, and our GeoMx Digital Spatial Profiler, or GeoMx DSP, system and related consumables.

Our GeoMx DSP system, for which we recorded our first revenue during third quarter of 2019, is designed to enable the field of spatial genomics. While nCounter and other existing technologies analyze gene activity as a whole throughout the totality of a biological sample, GeoMx DSP is used to analyze specifically selected regions of a biological sample in order to see how gene activity or protein levels might vary across those regions or in certain cell types.

We shipped our first 10 commercial GeoMx DSP systems during the third quarter of 2019. In addition, we continue to provide access to the GeoMx DSP's capabilities by offering selected potential customers the opportunity to send biological samples to our Seattle facility to be tested in our lab prior to purchasing a GeoMx DSP system. To date, we have completed approximately 170 projects for 110 customers pursuant to this Technology Access Program, or TAP. As a result of the TAP program and other commercial sales activities conducted this year, as of September 30, 2019 we have received more than 70 orders for GeoMx DSP systems.

We market and sell our instruments and related consumables to researchers in academic, government and biopharmaceutical laboratories for research use and to clinical laboratories and medical centers for diagnostic use, both through our direct sales force and through selected distributors in certain markets. As of September 30, 2019, we had an installed base of approximately 820 nCounter systems, which our customers have used to publish more than 2,800 peer-reviewed papers.

We derive a substantial majority of our revenue from the sale of our products, which consist of our nCounter and GeoMx DSP instruments and related proprietary consumables. Our instruments are designed to work only with our consumable products. Accordingly, as the installed base of instruments grows, we expect recurring revenue from consumable sales to become an increasingly important driver of our operating results. Our consumables include our standardized nCounter and GeoMx DSP panel products, nCounter custom codeset products that contain a specific set of targets for scientific analysis as requested by a customer, and our Prosigna breast cancer assay. We also derive revenue from processing fees related to proof-of-principle studies, including from our GeoMx DSP TAP, which we conduct for potential customers. For both our nCounter and GeoMx DSP systems, we offer extended service contracts and we continue to generate revenue through product development collaborations.

We use third-party contract manufacturers to produce the instruments comprising our nCounter and GeoMx DSP systems. We manufacture consumables at our Seattle, Washington facility.

We focus a substantial portion of our resources on developing new technologies, products and solutions. We invested \$50.1 million and \$45.1 million for the nine months ended September 30, 2019 and 2018, respectively, in research and development and intend to continue to make significant investments in research and development to support our existing instrument platforms and related consumable offerings, as well as research and development of new technologies to complement our growing instrument and consumable product portfolio.

We have discovered other novel applications that utilize our proprietary barcoding chemistry, and we continue to invest in the development of potential new product platforms. For example, our Hyb & Seq molecular profiling system is currently under development, and is designed to use a modified version of our proprietary chemistry to determine and analyze gene sequences within a biological sample, or to potentially profile the activity of an even greater number of genes as compared to our nCounter Analysis System. Following completion of product development, the Hyb & Seq platform is expected to be commercialized as a new instrument along with associated consumables.

Our product and service revenue increased 17.0% to \$70.1 million for the nine months ended September 30, 2019, compared to \$59.9 million for the first nine months of 2018. Our total revenue was \$88.6 million for the nine months ended September 30, 2019, compared to \$76.7 million for the first nine months of 2018. We have never been profitable and had net losses of \$64.7 million and \$56.3 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, our accumulated deficit was \$455.9 million.

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Results of Operations

Revenue

Our product revenue consists of sales of our nCounter Analysis Systems, including their related consumables and Prosigna *in vitro* diagnostic kits, and our GeoMx DSP systems and their related consumables. Service revenue consists of fees associated with service contracts and conducting proof-of-principle studies, including programs in which we offer customers early access to technologies under development for which we generate data and perform analysis services on their behalf. Our customer base is primarily comprised of academic institutions, government laboratories, biopharmaceutical companies and clinical laboratories that perform analyses or testing using our nCounter and GeoMx DSP systems and purchase related consumables. Collaboration revenue is derived primarily from our collaboration with Lam and, historically, our terminated collaboration with Celgene.

The following table reflects total revenue by geography based on the geographic location of our customers, distributors and collaborators. For sales to distributors, their geographic location may be different from the geographic locations of the ultimate end customer.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	% Change	2019	2018	% Change
	(In thousands)			(In thousands)		
Americas	\$ 21,730	\$ 21,032	3%	\$ 63,235	\$ 53,865	17%
Europe & Middle East	7,128	6,110	17%	20,636	18,260	13%
Asia Pacific	1,746	1,474	18%	4,766	4,575	4%
Total revenue	\$ 30,604	\$ 28,616	7%	\$ 88,637	\$ 76,700	16%

The following table reflects the breakdown of our revenue into the primary components of our products, services, and collaborations.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	% Change	2019	2018	% Change
	(In thousands)			(In thousands)		
Product revenue:						
Instruments	\$ 8,037	\$ 5,429	48%	\$ 17,295	\$ 15,591	11%
Consumables	12,736	11,140	14%	36,656	30,778	19%
<i>In vitro</i> diagnostic kits	2,517	2,547	(1)%	7,445	7,234	3%
Total product revenue	23,290	19,116	22%	61,396	53,603	15%
Service revenue	3,059	2,337	31%	8,673	6,279	38%
Total product and service revenue	26,349	21,453	23%	70,069	59,882	17%
Collaboration revenue	4,255	7,163	(41)%	18,568	16,818	10%
Total revenue	\$ 30,604	\$ 28,616	7%	\$ 88,637	\$ 76,700	16%

Instrument revenue during the three months ended September 30, 2019 increased as compared to the same period in 2018, due primarily to the first commercial shipments of our new GeoMx DSP system, which contributed \$2.2 million of revenue during the period. In addition, we experienced an increase in the number of nCounter FLEX instruments sold, which generally have higher average selling prices, as compared to the number of nCounter SPRINT instruments sold during the period. Instrument revenue for the nine months ended September 30, 2019 also benefited from the first commercial shipments of GeoMx DSP system during the third quarter and a favorable mix shift to an increased number of our nCounter MAX and FLEX instruments sold year to date as a percentage of our total nCounter instruments sold, partially offset by a decrease in the number of SPRINT instruments sold during the nine months ended September 30, 2019 compared to same period in 2018.

Consumables revenue increased for the three and nine months ended September 30, 2019, primarily as a result of our growing installed base of nCounter Analysis Systems, as well as growth in sales of our standardized panel consumable products.

In vitro diagnostic kit revenue represents sales of our Prosigna assay. Prosigna sales were approximately flat for the three and nine months ended September 30, 2019 as compared to the same periods last year. Prosigna sales grew in territories

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outside of North America during the periods, in particular in certain territories within the European Union, while sales were stable in the United States, and declined in Canada.

The increase in service revenue for the three and nine months ended September 30, 2019 was related primarily to increases in revenue generated from technology access fees, particularly fees related to services offered pursuant to our GeoMx DSP TAP and, to a lesser extent, increases in the number of installed instruments covered by service contracts.

Our product and service revenue may continue to increase in future periods as a result of the growth in sales of our GeoMx DSP instruments, the growth in sales of our nCounter and GeoMx DSP consumable products as driven by our increasing installed base of these instruments, continued growth in sales of our standardized panel consumable products and the introduction of new nCounter and GeoMx DSP consumable products.

Collaboration revenue decreased for the three months ended September 30, 2019 as compared to the same period in 2018, due primarily to changes in activity levels relating to our collaboration with Lam and, historically, our terminated collaboration with Celgene. For the nine months ended September 30, 2019, collaboration revenue increased as compared to the same period in 2018 as a result of the acceleration of revenue related to our terminated Celgene collaboration. In April 2019, Celgene announced that its clinical trial evaluating REVLIMID for the treatment of DLBCL, which was conducted using our companion diagnostic product candidate LymphMark, did not meet its primary endpoint. As a result of this outcome, our collaboration agreement with Celgene was terminated in July 2019, with substantially all the remaining deferred collaboration revenue recognized during the three months ended June 30, 2019. Our collaboration agreement with Lam represented \$4.0 million and \$13.2 million of our collaboration revenue for the three and nine months ended September 30, 2019, respectively, and \$5.3 million and \$13.4 million for the three and nine months ended September 30, 2018, respectively. Lam has committed to provide up to \$50.0 million in funding to support the research and development activities relating to Hyb & Seq, of which \$46.8 million has been received as of September 30, 2019.

Cost of Product and Service Revenue; Gross Profit; and Gross Margin

Cost of product and service revenue consists primarily of costs incurred in the production process, including costs of purchasing instruments from third-party contract manufacturers, consumable component materials and assembly labor and overhead, installation, warranty, service and packaging and delivery costs. In addition, cost of product and service revenue includes royalty costs for licensed technologies included in our products, provisions for slow-moving and obsolete inventory and stock-based compensation expense. We provide a one-year warranty on each nCounter Analysis System sold and establish a reserve for warranty repairs based on historical warranty repair costs incurred.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	% Change	2019	2018	% Change
	(Dollars in thousands)			(Dollars in thousands)		
Cost of product and service revenue	\$ 10,925	\$ 9,291	18%	\$ 29,239	\$ 25,538	14%
Product and service gross profit	\$ 15,424	\$ 12,162	27%	\$ 40,830	\$ 34,344	19%
Product and service gross margin	59%	57%		58%	57%	

For the three and nine months ended September 30, 2019, cost of product and service revenue increased as compared to the same periods in 2018, due primarily to higher volumes of consumables sold during the periods, as well as increased costs associated with the first commercial shipments of GeoMx DSP systems. In addition, cost of product and service revenue increased as a result of a higher volume of service contracts associated with our growing installed base of nCounter instruments and investments made to support the growth, installation and service of our product lines, including our new GeoMx DSP systems. Our gross margin on product and service revenue for the three months ended September 30, 2019 increased as compared to the same period in 2018 due primarily to a mix shift towards our higher margin MAX and FLEX nCounter instruments, as well as due to sales of our new GeoMx DSP instruments, which commenced shipping during the quarter and contributed a higher average gross margin as compared to our nCounter instrument platforms. In addition, we continue to see increases in our TAP service revenue as a percentage of total revenue, which has a favorable impact on our gross margins. Gross margin for the nine months ended September 30, 2019 increased modestly, as a result of higher sales of consumables as a percentage of our sales mix and due to our sales of GeoMx DSP instruments, partially offset by investments made in our operations to support the growth of our business. In addition, increasing revenue from our GeoMx TAP service favorably impacted our overall margins for both the three and nine month periods compared to the same periods in 2018.

We expect our cost of product and service revenue to increase in future periods, primarily due to our expected growth in product and service revenue. We expect our gross margin on product and service revenue may fluctuate in future periods, depending upon our mix of instrument sales from which we typically record lower gross margins, as compared to our sales of consumable products or services, and potential expenses we may incur for regulatory compliance, quality assurance or related

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to the expansion of our manufacturing capacity. Costs related to collaboration revenue are included in research and development expense.

Research and Development Expense

Research and development expenses consist primarily of salaries and benefits, occupancy, laboratory supplies, engineering services, consulting fees, costs associated with licensing molecular diagnostics rights and clinical study expenses to support the regulatory approval or clearance of diagnostic products. We have made substantial investments in research and development since our inception. Our research and development efforts have focused primarily on the tasks required to enhance our technologies and to support development and commercialization of new and existing products and applications. We believe that our continued investment in research and development is essential to our long-term competitive position and expect these expenses to continue to increase in future periods. In particular, following our entry into the Lam collaboration in August 2017, which provides up to \$50.0 million of funding for our Hyb & Seq program, we have experienced a significant increase in related research and development expenses.

Given the size of our research and development staff and the number of active projects at any given time, we have found that it has been effective for us to manage our research and development activities on a departmental basis. Accordingly, other than for collaborations and certain major technology development programs, we have neither required employees to report their time by project nor allocated our research and development costs to individual projects. Research and development expense by functional area was as follows:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	% Change	2019	2018	% Change
	(In thousands)			(In thousands)		
Platform technology	\$ 8,553	\$ 7,670	12 %	\$ 24,035	\$ 19,878	21 %
Manufacturing process development	1,665	1,035	61 %	4,560	3,313	38 %
Life sciences products and applications	2,994	2,643	13 %	8,778	7,792	13 %
Diagnostic product development	1,230	2,516	(51)%	4,430	5,861	(24)%
Clinical, regulatory and medical affairs	816	1,322	(38)%	3,325	4,065	(18)%
Facility allocation	1,749	1,465	19 %	4,935	4,159	19 %
Total research and development expense	<u>\$ 17,007</u>	<u>\$ 16,651</u>	2 %	<u>\$ 50,063</u>	<u>\$ 45,068</u>	11 %

The increase in research and development expense for the three months ended September 30, 2019 as compared to the same period in 2018 is due primarily to higher stock-based compensation expense, which was driven by increases in our stock price and by our recent decision to implement the grant of restricted stock units, or RSUs, to our employees as a component of their stock-based compensation. In addition, we experienced increases in staffing and personnel-related costs and facility costs which were offset by decreases in professional fees, clinical trial costs, and lower lab supply costs. The trends in research and development expense during the three month period reflect the conclusion of activities related to our terminated Celgene collaboration agreement and a transition to a sustaining level of activity subsequent to the GeoMx DSP commercial launch.

For the nine months ended September 30, 2019, the increase in research and development expense reflects higher stock-based compensation expense, which was driven by increases in our stock price and by our recent decision to implement the grant of RSUs to our employees as a component of their stock-based compensation. In addition, we experienced increases to staffing and personnel-related costs to support activities related to the GeoMx DSP commercial launch, as well as increased facility costs. These increases were partially offset by decreases in professional fees and clinical trial costs primarily due to fewer diagnostic product related development activities associated with our terminated collaboration agreements as compared to the same period in 2018.

We expect our investments in research and development to remain in line with our current levels in future periods, as we transition to a sustaining level of activity. Lam has committed to provide up to \$50.0 million in funding to support the research and development activities relating to Hyb & Seq, of which \$46.8 million has been received as of September 30, 2019.

[Table of Contents](#)**Selling, General and Administrative Expense**

Selling, general and administrative expense consists primarily of costs for our sales and marketing, finance, human resources, information technology, business development, legal and general management functions, as well as professional fees for legal, consulting and accounting services. Our sales force includes roles which are focused mainly on sales of consumables to our existing instrument base, which enables our sales representatives to focus on instrument sales and support the growth of our installed instrument base. Legal, accounting and compliance costs have increased as a result of our being a public company, and we expect them to continue to increase as our business grows.

Selling, general and administrative expense was as follows:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	% Change	2019	2018	% Change
	(In thousands)			(In thousands)		
Selling, general and administrative expense	\$ 23,382	\$ 17,810	31%	\$ 69,317	\$ 57,897	20%

The increase in selling, general and administrative expense for the three and nine month periods ended September 30, 2019 as compared to the same periods in 2018 is primarily attributable to increased investment of \$5.1 million and \$9.5 million, respectively, in staffing and personnel-related costs to support activities related to the GeoMx DSP commercial launch, and to higher stock-based compensation expense, which was driven by increases in our stock price and by our recent decision to implement the grant of RSUs to our employees as a component of their stock-based compensation. In addition, professional fees have increased during the three and nine month periods ended September 30, 2019 related to accounting and tax support services, in particular activities relating to our compliance with the Sarbanes Oxley Act.

We expect selling, general and administrative expense to increase in future periods as the number of sales, technical support and marketing and administrative personnel grows to support the expected growth in our existing lines of business, as well as to support the introduction of new products and product platforms, including our GeoMx DSP.

Other Income (Expense)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	% Change	2019	2018	% Change
	(In thousands)			(In thousands)		
Interest income	\$ 763	\$ 384	99%	\$ 2,114	\$ 826	156%
Interest expense	(2,415)	(1,631)	48%	(6,052)	(4,798)	26%
Other expense, net	(322)	(46)	600%	(552)	(330)	67%
Total other expense, net	\$ (1,974)	\$ (1,293)	53%	\$ (4,490)	\$ (4,302)	4%

Interest expense increased for the three and nine months ended September 30, 2019 due primarily to increased borrowings outstanding under our term loan agreement. The average balance of long-term debt outstanding for the nine months ended September 30, 2019 and 2018 was \$70.2 million and \$49.9 million, respectively. The increases in interest expense were partially offset by increased interest income during the three and nine months ended September 30, 2019 resulting from higher average cash and investment balances on hand during the periods as compared to the same periods in 2018.

Liquidity and Capital Resources

As of September 30, 2019, we had cash, cash equivalents and short-term investments of \$128.9 million. We believe our existing cash, cash equivalents and short-term investments will be sufficient to meet our working capital and capital expenditure needs for at least the next 12 months. However, we may need to raise additional capital to expand the commercialization of our products, fund our operations and further our research and development activities. Our future funding requirements will depend on many factors, including: market acceptance and the level of sales of our existing products and new product candidates; the nature and timing of any additional research, product development or other partnerships or collaborations we may establish; the cost and timing of establishing additional sales, marketing and distribution capabilities; the cost of our research and development activities; the cost and timing of regulatory clearances or approvals; 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.

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We may require additional funds in the future and we may not be able to obtain such funds on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or additional equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through partnership, collaboration or 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 are unable to raise adequate funds, we may have to liquidate some or all of our assets, delay or reduce the scope of or eliminate some or all of our research and development programs, delay development, launch activities or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize, or reduce marketing, customer support or other resources devoted to our products or cease operations.

Sources of Funds

Since inception, we have financed our operations primarily through the sale of equity securities and, to a lesser extent, from borrowings under term loan agreements. Our cash used in operations for the nine months ended September 30, 2019 was \$69.9 million, including \$12.9 million in cash receipts from our collaboration agreements. The timing and amount of such receipts in the future are uncertain, and therefore we may be required to secure larger amounts of cash to fund our planned operations.

Equity Financings

In March 2019, we completed an underwritten public offering of 3,175,000 shares of our common stock, including the exercise in full by the underwriters of their option to purchase 675,000 additional shares of common stock. An additional 2,000,000 shares were sold by a related party stockholder. Our total gross proceeds were \$73.0 million. We did not receive any proceeds from the sale of shares of common stock by the related party stockholder. After underwriter's commissions and other expenses of the offering, and net of proceeds received by the related party stockholder, our aggregate net proceeds were approximately \$68.3 million.

In July 2018, we completed an underwritten public offering of 4,600,000 shares of common stock, including the exercise in full by the underwriters of their option to purchase 600,000 additional shares of common stock in August 2018, for total gross proceeds of \$57.5 million. After underwriter's commissions and other expenses of the offering, our aggregate net proceeds were approximately \$53.8 million.

In January 2018, we entered into a sales agreement with a sales agent to sell shares of our common stock through an "at the market" equity offering program for up to \$40.0 million in gross cash proceeds. In March 2019, subsequent to our most recent underwritten public offering, we terminated this agreement. No shares of our common stock were sold under this agreement.

Debt Instruments

Term Loan Agreements

In April 2014, we entered into a term loan agreement, or the 2014 Term Loan, under which we borrowed \$45.0 million. The 2014 Term Loan accrues interest at an annual rate of 12.0%, payable quarterly, of which 3.0% can be deferred during the first six years of the term at our option and paid together with the principal at maturity. The 2014 Term Loan had an interest-only period through March 2021 and a final maturity date of March 2022.

In October 2018, we entered into an amended and restated term loan agreement, or the 2018 Term Loan, under which we may borrow up to \$100.0 million, with any amounts borrowed due and payable in September 2024. At closing, we received net proceeds of approximately \$7.8 million, pursuant to borrowings of \$60.0 million under the new facility, net of repayment of principal and interest outstanding under our prior term loan agreement of \$50.4 million, including deferred interest and transaction-related fees and expenses. In June 2019, we borrowed an additional \$20.0 million under the 2018 Term Loan, and have the option to borrow an additional \$20.0 million until March 2020, with the remaining potential borrowings subject to the achievement of annual revenue thresholds on or prior to December 31, 2019.

The 2018 Term Loan accrues interest at a rate of 10.5%, payable quarterly, of which 3.0% may be deferred during the six-year term at our option and repaid at maturity together with the principal. We paid an upfront fee of 0.5% of the aggregate principal amount of the initial borrowing under the 2018 Term Loan, and will pay a facility fee equal to 2.0% of the total amount borrowed including any deferred interest at the time the principal is repaid. A long-term liability of \$1.9 million is being accreted using the effective interest method for the facility fee over the term of the 2018 Term Loan. Additional borrowings under the 2018 Term Loan will bear the same upfront and facility fees as the initial borrowing.

In connection with entry into the 2018 Term Loan, warrants to purchase an aggregate of 341,578 shares of common stock with an exercise price per share of \$21.12 were issued to the lenders. In June 2019, in connection with the borrowing of

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an additional \$20.0 million principal amount, warrants to purchase an aggregate of 128,932 shares of common stock with an exercise price per share of \$34.20 were issued to the lenders. If additional amounts are borrowed under the 2018 Term Loan, additional warrants will be issued on each subsequent draw date for 0.3% of the fully-diluted shares then outstanding. The exercise price for additional warrants will be set at a 25.0% premium to the average closing trading price for the 30-day trading period as of the date immediately before the applicable draw date. The warrants issued in conjunction under the 2018 Term Loan were determined to be closely linked to our common stock and, as such, were recorded as an equity security in additional paid-in capital at their relative fair value of \$1.6 million and \$1.0 million, in October 2018 and June 2019, respectively, with a corresponding debt discount recorded against the 2018 Term Loan balance outstanding.

Total borrowings and deferred interest under the 2018 Term Loan were \$82.0 million and \$60.4 million as of September 30, 2019 and December 31, 2018, respectively. The balance of the 2018 Term Loan as of September 30, 2019 and December 31, 2018 is net of discounts related to the warrants, debt issuance costs and other upfront fees of \$2.8 million and \$2.0 million, respectively.

We have the option to prepay the 2018 Term Loan, in whole or part, at any time subject to payment of a redemption fee of up to 4.0% during the first year of the term, 3.0% during the second year of the term and with no redemption fee payable if prepayment occurs after the second year of the loan.

Obligations under the 2018 Term Loan are collateralized by substantially all of our assets. The 2018 Term Loan contains customary conditions to borrowings, events of default and covenants, including negative covenants that could limit our ability to, among other things, incur additional indebtedness, liens or other encumbrances; make dividends or other distributions; buy, sell or transfer assets; engage in any new line of business; and enter into certain transactions with affiliates. The 2018 Term Loan also includes a \$2.0 million minimum liquidity covenant and minimum annual revenue-based financial covenants. If our actual revenue is below the minimum annual revenue requirement for any given year, we may avoid a related default by generating proceeds from an equity or subordinated debt issuance equal to the shortfall between our actual revenues and the minimum revenue requirement. We were in compliance with our financial covenants under the 2018 Term Loan agreement as of September 30, 2019.

2018 Revolving Loan Facility

In January 2018, we entered into a \$15.0 million secured revolving loan facility, with availability subject to a borrowing base consisting of eligible accounts receivable. In November 2018, we entered into an amended and restated loan and security agreement to increase the borrowing capacity under the facility to \$20.0 million, amend the borrowing base to include finished goods inventory, and extend the final maturity under the facility to November 2021. As of September 30, 2019 and December 31, 2018, no amounts had been drawn on the facility.

Interest on borrowings is payable monthly and accrues at a yearly rate equal to the greater of (i) the prime rate as reported in the Wall Street Journal plus 0.50%, and (ii) 4.75%. During an event of default, amounts drawn accrue interest at a yearly rate equal to 8.75%. Obligations under the agreement are secured by our cash and cash equivalents, accounts receivable and proceeds thereof, and inventory and proceeds from the sale thereof. The lender's interest in the collateral under the loan facility is senior to the lender's interest in such collateral under the term loan agreement. The loan facility contains various customary representations and warranties, conditions to borrowing, events of default, including cross default provisions with respect to the loan facility, and covenants, including financial covenants requiring the maintenance of minimum annual revenue and liquidity. We were in compliance with our financial covenants under the secured revolving loan facility as of September 30, 2019.

Use of Funds

Our principal uses of cash are funding our operations, capital expenditures, working capital requirements and satisfaction of any outstanding obligations under our revolving or term loan facilities, respectively. Over the past several years, our revenue has increased significantly from year to year and, as a result, our cash flows from customer collections have increased. However, our operating expenses have also increased as we have invested in our sales and marketing activities and in research and development of new product platforms and technologies that we believe have the potential to drive the long-term growth of our business.

Our operating cash requirements may increase in the future as we invest in research and development related to existing or new product platforms, including our nCounter and GeoMx DSP product platforms, as well as in sales and marketing activities to expand the installed base of our nCounter Analysis and GeoMx DSP systems and related consumable usage. We cannot be certain our revenue will grow sufficiently to offset our operating expense increases, nor can we be certain that we will be successful in continuing to generate cash from new partnerships or collaborations to help fund our operations. As a result, we may need to raise additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, our operations and ability to execute our business strategy could be adversely affected.

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Historical Cash Flow Trends

The following table shows a summary of our cash flows for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2019	2018
Cash used in operating activities	\$ (69,885)	\$ (39,650)
Cash used in investing activities	(37,346)	(25,495)
Cash provided by financing activities	106,371	60,094

Operating Cash Flows

We derive operating cash flows from cash collected from the sale of our products and services and from collaborations. These cash flows received are currently offset by our use of cash for operating expenses to support the growth of our business. As a result, we have historically experienced negative cash flows from operating activities, with such negative cash flows likely to continue for the foreseeable future.

For the nine months ended September 30, 2019, net cash used in operating activities consisted of our net loss of \$64.7 million, and net increases in our operating assets and liabilities of \$26.5 million, partially offset by \$21.3 million of net non-cash income and expense items, such as stock-based compensation, depreciation and amortization, amortization of our right-of-use assets, deferred interest converted to principal pursuant to our term loan agreement, and provisions for inventory obsolescence.

For the nine months ended September 30, 2018, net cash used in operating activities consisted of our net loss of \$56.3 million which was offset by \$14.5 million of net non-cash items, such as stock-based compensation, depreciation and amortization, deferred interest converted to principal for the term loan, and provisions for bad debts and inventory, as well as \$2.1 million of net decreases in our operating assets and liabilities.

Investing Cash Flows

Our most significant investing activities for the nine months ended September 30, 2019 and 2018 were related to the purchase, maturity and sale of short-term investments. Because we manage our cash usage with respect to our total cash, cash equivalents and short-term investments, we do not consider these cash flows to be important to an understanding of our liquidity and capital resources.

During the nine month periods ended September 30, 2019 and 2018, we purchased property and equipment totaling \$1.8 million and \$2.9 million, respectively, which we believe will be required to support the growth and expansion of our operations.

Financing Cash Flows

Historically, we have funded our operations through the issuance of equity securities and debt borrowings.

Net cash provided by financing activities for the nine months ended September 30, 2019 consisted primarily of net proceeds of \$68.3 million from an underwritten public offering of our common stock, borrowings of \$20.0 million under our term loan agreement, and \$16.4 million of net proceeds from the exercise of stock options and other equity awards and our Employee Stock Purchase Plan.

Net cash provided by financing activities for the nine months ended September 30, 2018 consisted primarily of net proceeds of \$53.8 million from an underwritten public offering and \$4.0 million of net proceeds from the exercise of stock options and other equity awards and our Employee Stock Purchase Plan.

Contractual Obligations and Commitments

Our future significant contractual obligations as of December 31, 2018 were reported in our Annual Report on Form 10-K, filed with the SEC on March 11, 2019.

As of September 30, 2019, there have been no material changes from the contractual commitments previously disclosed in the Annual Report on Form 10-K, other than an increase in long-term debt obligations of \$20.0 million resulting from additional borrowings in June 2019 pursuant to the terms of our existing term loan agreement, increases of approximately \$6.7 million related to new office lease obligations entered into during the nine months ended September 30, 2019, as well as fluctuations resulting from general working capital requirements.

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Critical Accounting Policies and Significant Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and related disclosure of contingent assets and liabilities, revenue and expenses at the date of the financial statements. Generally, we base our estimates on historical experience and on various other assumptions in accordance with GAAP that we believe to be reasonable under the circumstances. Actual results may differ from these estimates.

Critical accounting policies and significant estimates are those that we consider the most important to the portrayal of our financial condition and results of operations because they require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting policies and estimates include those related to:

- revenue recognition;
- stock-based compensation;
- inventory valuation;
- fair value measurements; and
- income taxes.

There have been no material changes in our critical accounting policies and significant estimates in the preparation of our condensed consolidated financial statements for the nine months ended September 30, 2019 compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on March 11, 2019.

Recent Accounting Pronouncements

For information regarding recent accounting pronouncements, see Note 2 of the Notes to the Condensed Consolidated Financial Statements under Item 1 of this report.

Off-Balance Sheet Arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or for any other contractually narrow or limited purpose.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

We are exposed to various market risks, including changes in commodity prices and interest rates. Market risk is the potential loss arising from adverse changes in market rates and prices. Prices for our products are largely denominated in U.S. dollars and, as a result, we do not face significant risk with respect to foreign currency exchange rates.

Interest Rate Risk

Generally, our exposure to market risk has been primarily limited to interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term debt securities. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. To minimize risk, we maintain our portfolio of cash, cash equivalents and short-term investments in a variety of interest-bearing instruments, which have included U.S. government and agency securities, high-grade U.S. corporate bonds, asset-backed securities, and money market funds. Declines in interest rates, however, would reduce future investment income. A 10% decline in interest rates, occurring on October 1, 2019 and sustained throughout the period ended September 30, 2020, would not be material.

As of September 30, 2019, the principal and deferred interest outstanding under our term borrowings was \$82.0 million. The interest rates on our term borrowings under our credit facility are fixed. If overall interest rates had increased by 10% during the periods presented, our interest expense would not have been affected.

Foreign Currency Exchange Risk

As we continue to expand internationally our results of operations and cash flows will become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Historically, a majority of our revenue has been denominated in U.S. dollars, although we sell our products and services directly in certain markets outside of the United States denominated in

local currency, principally the Euro. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States. The effect of a 10% adverse change in exchange rates on foreign denominated cash, receivables and payables would not have been material for the periods presented. As our operations in countries outside of the United States grow, our results of operations and cash flows will be subject to potentially greater fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. To date, we have not entered into any material foreign currency hedging contracts although we may do so in the future.

Inflation Risk

We do not believe that inflation has had a material effect on our business, financial condition or results of operations. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases. Our inability or failure to do so could adversely affect our business, financial condition and results of operations.

Item 4. Controls and Procedures.

(a) *Evaluation of disclosure controls and procedures.* Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this quarterly report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this quarterly report, certain of our disclosure controls and procedures were not effective due to material weaknesses in internal control over financial reporting, specifically with respect to certain information technology general controls, that were disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

(b) *Changes in internal control over financial reporting.* There were no changes in our internal control over financial reporting during the quarter ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, other than those disclosed in (c) below.

(c) *Remediation Efforts.* As previously described in Part II, Item 9A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, we have implemented a remediation plan to address the material weaknesses mentioned above. During the quarter ended September 30, 2019, the remediation actions taken included: (i) implementing improved information technology related processes and controls, including the establishment of a change control board, for approving, monitoring and implementing changes to key information systems which impact our financial reporting; (ii) implementing standardized processes, and related controls, for requesting, authorizing, and reviewing user access to key systems, including systems relating to the posting of journal entries, which may impact our financial reporting, including identifying access to roles where manual business process controls may be required, as well as expanding the scope of systems and points of access required to be reviewed; (iii) enhancing our training programs and documentation practices which address information technology related processes and controls, and related policies; and (iv) reporting on the status of our remediation measures to the Audit Committee of the Board of Directors more frequently. The material weaknesses will not be considered remediated until internal controls have been designed and implemented or redesigned which specifically address the material weaknesses, and these internal controls must operate for a sufficient period of time and management must then conclude, through testing, that these controls are operating effectively.

Inherent limitation on the effectiveness of internal control over financial reporting.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

We are not engaged in any material legal proceedings. From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. We believe that there are no claims or actions pending against us currently, the ultimate disposition of which would have a material adverse effect on our consolidated results of operation, financial condition or cash flows.

Item 1A. Risk Factors.

You should carefully consider the following risk factors, in addition to the other information contained in this report, including the section of this report captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, our business, operating results and financial condition could be seriously harmed. This report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report.

Risks Related to Our Business and Strategy

We have incurred losses since we were formed and expect to incur losses in the future. We cannot be certain that we will achieve or sustain profitability.

We have incurred losses since we were formed and expect to incur losses in the future. We incurred net losses of \$64.7 million and \$56.3 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of \$455.9 million. We expect that our losses will continue for at least the next several years as we will be required to invest significant additional funds toward ongoing development and commercialization of our technology. We also expect that our operating expenses will continue to increase as we grow our business, but there can be no assurance that our revenue and gross profit will increase sufficiently such that our net losses decline, or we attain profitability, in the future. Our ability to achieve or sustain profitability is based on numerous factors, many of which are beyond our control, including the market acceptance of our products, future product development and our market penetration and margins. We may never be able to generate sufficient revenue to achieve or sustain profitability.

Our financial results may vary significantly from quarter to quarter which may adversely affect our stock price.

Investors should consider our business and prospects in light of the risks and difficulties we expect to encounter in the new, uncertain and rapidly evolving markets in which we compete. Because these markets are new and evolving, predicting their future growth and size is difficult. We expect that our visibility into future sales of our products, including volumes, prices and product mix between instruments and consumables, and the amount and timing of payments pursuant to collaboration agreements will continue to be limited and could result in unexpected fluctuations in our quarterly and annual operating results.

Numerous other factors, many of which are outside our control, may cause or contribute to significant fluctuations in our quarterly and annual operating results. These fluctuations may make financial planning and forecasting difficult. In addition, these fluctuations may result in unanticipated changes in our available cash, which could negatively affect our business and prospects. Factors that may contribute to fluctuations in our operating results include many of the risks described in this section. Also, one or more of such factors may cause our revenue or operating expenses in one period to be disproportionately higher or lower relative to the others. Furthermore, our instruments involve a significant capital commitment by our customers and accordingly involve a lengthy sales cycle. We may expend significant effort in attempting to make a particular sale, which may be deferred by the customer or never occur. Accordingly, comparing our operating results on a period-to-period basis may not be meaningful, and investors should not rely on our past results as an indication of our future performance. If such fluctuations occur or if our operating results deviate from our expectations or the expectations of securities analysts, our stock price may be adversely affected. In addition, we have certain collaborations where our financial results may vary significantly if circumstances change. For example, in May 2019, we were notified that our collaboration agreement with Celgene was terminated effective July 2019 and resulted in the recognition of \$3.1 million of collaboration revenue during the three months ended June 30, 2019.

If we do not achieve, sustain or successfully manage our anticipated growth, our business and growth prospects will be harmed.

We have experienced significant revenue growth in recent periods and we may not achieve similar growth rates in the future. Investors should not rely on our operating results for any prior periods as an indication of our future operating performance. If we are unable to maintain adequate revenue growth, our financial results could suffer and our stock price could decline. Furthermore, growth will place significant strains on our management and our operational and financial systems and processes. For example, the recent commercial launch of our GeoMx DSP system is a key element of our growth strategy and will require us to hire and retain additional sales and marketing personnel and resources. If we do not successfully generate demand for GeoMx DSP or other new product offerings, or manage our anticipated expenses accordingly, our operating results will be harmed.

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

Our current customer base is primarily composed of academic and government research laboratories, biopharmaceutical companies and clinical laboratories (including physician-owned laboratories) that perform analyses using our nCounter Analysis Systems. Our success will depend, in part, upon our ability to increase our market penetration among all of these customers and to expand our market by developing and marketing new research applications, new instruments, and new diagnostic products. We expect that increasing the installed base of our nCounter Analysis Systems will drive demand for our relatively high margin consumable products. If we are not able to successfully increase our installed base of nCounter Analysis Systems, sales of our consumable products and our margins may not meet expectations. Moreover, we must convince physicians and third-party payors that our diagnostic products, such as Prosigna, are cost effective in obtaining information that can help inform treatment decisions and that our nCounter Analysis Systems could enable an equivalent or superior approach that lessens reliance on centralized laboratories. In the United States, Medicare and most private insurers provide coverage and payment for patients to be tested with Prosigna; however, other countries, such as Germany, provide more limited coverage and payment for Prosigna.

We also plan to develop and introduce new products which would be sold primarily to new customer types, such as our GeoMx DSP instrument for use in pathology labs and a sequencer based on our Hyb & Seq chemistry targeted for use by hospitals and oncology clinics. Our GeoMx DSP instrument became commercially available in 2019 and we anticipate that scaling and training our sales force to attract new customers will require substantial time and expense. Any failure to expand our existing customer base through the launch of our GeoMx DSP instrument, or other new applications and products would adversely affect our operating results.

Our research business depends on levels of research and development spending by academic and governmental research institutions and biopharmaceutical companies, a reduction in which could limit demand for our products and adversely affect our business and operating results.

In the near term, we expect that a large portion of our revenue will be derived from sales of our nCounter Analysis Systems to academic and government research laboratories and biopharmaceutical companies worldwide for research and development applications. The demand for our products will depend in part upon the research and development budgets of these customers, which are impacted by factors beyond our control, such as:

- changes in government programs (such as the National Institutes of Health) that provide funding to research institutions and companies;
- macroeconomic conditions and the political climate;
- changes in the regulatory environment;
- differences in budgetary cycles;
- competitor product offerings or pricing;
- market-driven pressures to consolidate operations and reduce costs; and
- market acceptance of relatively new technologies, such as our GeoMx DSP instrument.

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 these customers. 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 business, operating results and financial condition.

Our sales cycle is lengthy and variable, which makes it difficult for us to forecast revenue and other operating results.

Our sales process involves numerous interactions with multiple individuals within an organization, and often includes in-depth analysis by potential customers of our products, performance of proof-of-principle studies, preparation of extensive documentation and a lengthy review process. As a result of these factors, the large capital investment required in purchasing our instruments and the budget cycles of our customers, the time from initial contact with a customer to our receipt of a purchase order can vary significantly and be up to 12 months or longer. In addition, the recent introduction of GeoMx DSP in 2019 may decrease our near-term visibility as to the timing of our total sales or the length of our overall sales cycle. Given the length and uncertainty of our sales cycle, we have in the past experienced, and likely will in the future experience, fluctuations in our instrument sales on a period-to-period basis. These factors also make it difficult to forecast revenue on a quarterly basis. In addition, any failure to meet customer expectations could result in customers choosing to continue to use their existing systems or to purchase systems other than ours.

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Our reliance on distributors for sales of our products outside of the United States, and on clinical laboratories for delivery of Prosigna testing services, could limit or prevent us from selling our products and impact our revenue.

We have established distribution agreements for our nCounter Analysis Systems and related consumable products in many countries where we do not sell directly. We intend to continue to grow our business internationally, and to do so we must attract additional distributors and retain existing distributors to maximize the commercial opportunity for our products. There is no guarantee that we will be successful in attracting or retaining desirable sales and distribution partners or that we will be able to enter into such arrangements on favorable terms. Distributors may not commit the necessary resources to market and sell our products to the level of our expectations or may choose to favor marketing the products of our competitors. If current or future distributors do not perform adequately, or we are unable to enter into effective arrangements with distributors in particular geographic areas, we may not realize long-term international revenue growth.

Similarly, we or our distributors have entered into agreements with clinical laboratories globally to provide Prosigna testing services. We do not provide testing services directly and, thus, we are reliant on these clinical laboratories to actively promote and sell Prosigna testing services. These clinical laboratories may take longer than anticipated to begin offering Prosigna testing services and may not commit the necessary resources to market and sell Prosigna testing services to the level of our expectations. Furthermore, we intend to contract with additional clinical laboratories to offer Prosigna testing services, including physician-owned laboratories, and we may be unsuccessful in attracting and contracting with new clinical laboratory providers. If current or future Prosigna testing service providers do not perform adequately, or we are unable to enter into contracts with additional clinical laboratories to provide Prosigna testing services, we may not be successful selling Prosigna and our future revenue prospects may be adversely affected.

Our future capital needs are uncertain and we may need to raise additional funds in the future.

We believe that our existing cash and cash equivalents, together with funds available under our term loan agreement and revolving credit facility, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. However, we may need to raise substantial additional capital to:

- expand the commercialization of our products;
- fund our operations; and
- further our research and development.

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

- market acceptance of our products;
- the cost and timing of establishing additional sales, marketing and distribution capabilities;
- revenue and cash flow derived from existing or future collaborations;
- the cost of our research and development activities;
- the cost and timing of regulatory clearances or approvals;
- the effect of competing technological and market developments; and
- the extent to which we engage in strategic transactions, such as the acquisition of, investment in or disposal of businesses, assets, products and technologies, including inbound or outbound licensing arrangements.

We cannot assure you that we will be able to obtain additional funds on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, or convertible debt, our stockholders may experience dilution. For example, in July 2018 and August 2018, we sold an aggregate of 4,600,000 shares of common stock in an underwritten public offering for net proceeds of \$53.8 million and in March 2019, we sold an aggregate of 3,175,000 shares of common stock in an underwritten public offering for net proceeds of \$68.3 million. In October 2018, we entered into a new \$100.0 million term loan facility with CR Group L.P. Additional debt financing, if available, may involve additional covenants restricting our operations or our ability to incur additional debt. Any debt or additional equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through strategic transactions with third parties, such as collaborations, asset sales and licensing arrangements, 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. We have in the past pursued these types of transactions, and may in the future pursue similar transactions or other strategic transactions, on our own or with other advisors, that may impact our business and prospects and the value of our common stock. 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 or other resources devoted to our products or cease operations. Any of these factors could harm our operating results.

Our research and development efforts will be hindered if we are not able to contract with third parties for access to archival tissue samples.

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Under standard clinical practice, tumor biopsies removed from patients are preserved and stored in formalin-fixed paraffin embedded, or FFPE, format. We rely on our ability to secure access to these archived FFPE tumor biopsy samples, as well as information pertaining to the clinical outcomes of the patients from which they were derived for our clinical development activities. Others compete with us for access to these samples. Additionally, the process of negotiating access to archived samples is lengthy because it typically involves numerous parties and approval levels to resolve complex issues such as usage rights, institutional review board approval, privacy rights, publication rights, intellectual property ownership and research parameters. In January 2017, the Department of Health and Human Services finalized new rules, which became effective as of January 19, 2018, expanding the language to be included in informed consent forms related to the collection of identifiable private information or identifiable biospecimens. If this new requirement, or other factors arising in the future, impact our ability to negotiate access to archived tumor tissue samples with hospitals, clinical partners, pharmaceutical companies, or companies developing therapeutics on a timely basis or on commercially reasonable terms, or at all, or if other laboratories or our competitors secure access to these samples before us, our ability to research, develop and commercialize future products will be limited or delayed.

We may not be able to develop new products, enhance the capabilities of our systems to keep pace with rapidly changing technology and customer requirements or successfully manage the transition to new product offerings, any of which could have a material adverse effect on our business 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 products and systems. Existing markets for our products, including gene expression analysis, gene fusions and copy number variation, as well as new markets, such as protein expression and gene mutations, and potential markets for our research and diagnostic product candidates, are characterized by rapid technological change and innovation. Competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. We anticipate that we will 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. It is critical to our success that we anticipate changes in technology and customer requirements and successfully introduce new, enhanced and competitive technologies to meet our customers' and prospective customers' needs on a timely and cost-effective basis. If we do not successfully innovate and introduce new technology into our product lines, our business and operating results will be adversely impacted.

The development and manufacture of new products typically requires new scientific discoveries or advancements and complex technology and engineering, including the design of sophisticated software. Such developments may involve external suppliers and service providers, making the management of development projects complex and subject to risks and uncertainties regarding timing, timely delivery of required components, software or services and satisfactory technical performance of such software, components or assembled products. For example, since 2017, we have worked with our supplier of cartridges used in our nCounter SPRINT systems to improve the design to address leakage and other issues in the microfluidic device produced for us. If we do not achieve the required technical specifications or successfully manage new product development processes, or if development work and manufacturing is not performed according to schedule, then such new technologies or products may be adversely impacted and our business and operating results may be harmed. Any delays in bringing new products to market may lead our customers to purchase our competitors' products or cancel outstanding purchase orders.

Additionally, we must carefully manage the introduction of new products. If customers believe that such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. If customers conclude that such new products offer better value as compared to our existing products, we may suffer from reduced sales of our existing products and our overall revenue may decline. We may also have excess or obsolete inventory of older products as we transition to new products and our experience in managing product transitions is limited. If we do not effectively manage the transitions to new product offerings, our revenue, results of operations and business will be adversely affected.

New market opportunities may not develop as quickly as we expect, limiting our ability to successfully market and sell our products.

The market for our products is new and evolving. Accordingly, we expect the application of our technologies to emerging opportunities will take several years to develop and mature and we cannot be certain that these market opportunities will develop as we expect. For example, in 2017 we launched our 360 panels for use in breast cancer, immuno-oncology and hematology. In 2018, we expanded beyond oncology and launched panels in neuroscience and CAR-T characterization. We also recently launched our GeoMx DSP product, which will target the pathology market, a market we have not previously targeted and in which we have limited marketing and selling experience.

The future growth of the market for these new products depends on many factors beyond our control, including recognition and acceptance of our applications by the scientific community and the growth, prevalence and costs of competing

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methods of genomic analysis. If the markets for our new products do not develop as we expect, our business may be adversely affected. 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.

We are dependent on single 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 Precision System Science, Co., Ltd of Chiba, Japan, to build our nCounter Prep Station, Korvis LLC of Corvallis, Oregon, to build our nCounter Digital Analyzer and GeoMx DSP, Paramit Corporation of Morgan Hill, California, to build our new nCounter SPRINT Profiler and IDEX Corporation of Lake Forest, Illinois to build the fluidics cartridge, a key component of our nCounter SPRINT Profiler. Each of these contract manufacturers are sole suppliers. Since our contracts with these instrument suppliers do not commit them to carry inventory or make available any particular quantities, they may give other customers' needs higher priority than ours, and we may not be able to obtain adequate supplies in a timely manner or on commercially reasonable terms. We also rely on sole suppliers for various components we use to manufacture our consumable products. We periodically forecast our needs for such components and enter into standard purchase orders with them. If we were to lose such suppliers, or if the products provided by such suppliers are unable to meet our performance specifications, there can be no assurance that we will be able to identify or enter into agreements with alternative suppliers on a timely basis on acceptable terms, if at all. If we should encounter delays or difficulties in securing the quality and quantity of materials we require for our products, our supply chain would be interrupted which would adversely affect sales. If any of these events occur, our business and operating results could be harmed.

We may experience manufacturing problems or delays that could limit our growth or adversely affect our operating results.

Our consumable products are manufactured at our Seattle, Washington facility using complex processes, sophisticated equipment and strict adherence to specifications and quality systems procedures. We also anticipate bringing a second reagent manufacturing facility in Bothell, Washington online in the near-term. Any unforeseen manufacturing problems, such as contamination of our facility, equipment malfunction, quality issues with components and materials sourced from third-party suppliers or failure to strictly follow procedures or meet specifications, could result in delays or shortfalls in production or require us to voluntarily recall our consumable products. Identifying and resolving the cause of any such manufacturing or supplier issues could require substantial time and resources. If we are unable to keep up with demand for our products by successfully manufacturing 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 or cancel outstanding purchase orders.

In addition, the introduction of new products may require the development of new manufacturing processes and procedures as well as new suppliers. For example, our GeoMx DSP systems require that we establish supply relationships with antibody providers. While all of our CodeSets are produced using the same basic processes, significant variations may be required to meet new product specifications. Developing new processes and negotiating supply agreements can be very time consuming, and any unexpected difficulty in doing so could delay the introduction of a product.

If our Seattle area facilities become unavailable or inoperable, we will be unable to continue our research and development, manufacturing our consumables or processing sales orders, and our business will be harmed.

We manufacture our consumable products in our headquarters facilities in Seattle, Washington and also expect to bring a second reagent manufacturing facility in Bothell, Washington online in the near-term. In addition, Seattle is the center for research and development, order processing, receipt of our instruments manufactured by third-party contract manufacturers and shipping products to customers. Our facilities and the equipment we use to manufacture our consumable products would be costly, and would require substantial lead time, to repair or replace. The Seattle area is situated near active earthquake fault lines. These facilities may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes and power outages, which may render it difficult or impossible for us to produce our products for some period of time. The inability to manufacture consumables or to ship products to customers for even a short period of time may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance, and in particular earthquake insurance, which is limited, may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

We expect to generate a substantial portion of our product and service revenue internationally and are subject to various risks relating to our international activities, which could adversely affect our operating results.

Our product and service revenue generated from sales to customers located outside of North America was approximately 36% and 39% for the nine months ended September 30, 2019 and 2018, respectively. We believe that a

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significant percentage of our future revenue will come from international sources as we expand our overseas operations and develop opportunities in additional areas. Engaging in international business involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign regulatory requirements and laws;
- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act and U.K. Bribery Act, data privacy requirements, labor laws and anti-competition regulations;
- export or import restrictions;
- various reimbursement and insurance regimes;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability, such as the anticipated exit of the United Kingdom from the European Economic Community;
- 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.

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. Historically, most of our revenue has been denominated in U.S. dollars, although we have sold our products and services in local currency outside of the United States, principally the Euro. Our expenses are generally denominated in the currencies of the countries in which our operations are located, which is primarily in the United States. As our operations in countries outside of the United States grow, our results of operations and cash flows will increasingly be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. For example, if the value of the U.S. dollar increases relative to foreign currencies, our product and service revenue could be adversely affected as we convert revenue from local currencies to U.S. dollars. Similarly, a strong U.S. dollar relative to the local currencies of our international customers can potentially reduce demand for our products, which may compound the adverse effect of foreign exchange translation on our revenue. If we dedicate significant resources to our international operations and are unable to manage these risks effectively, our business, operating results and prospects will suffer.

Significant United Kingdom or European developments stemming from the United Kingdom's decision to withdraw from the European Union could have a material adverse effect on us.

In June 2016, the United Kingdom held a referendum and voted in favor of leaving the European Union, and in March 2017, the government of the United Kingdom formally initiated the withdrawal process. The timing of the United Kingdom's exit from the European Union, or Brexit, remains uncertain; the European Union has extended the deadline for the United Kingdom to exit the European Union until January 31, 2020. Negotiations related to Brexit have created political and economic uncertainty, particularly in the United Kingdom and the European Union, and this uncertainty may last for years. Our business in the United Kingdom, the European Union, and worldwide could be affected during this period of uncertainty, and perhaps longer, by the impact of the United Kingdom's referendum. There are many ways in which our business could be affected, only some of which we can identify as of the date of this report.

The decision of the United Kingdom to withdraw from the European Union has caused and, along with events that could occur in the future as a consequence of the United Kingdom's withdrawal may continue to cause significant volatility in global financial markets, including in global currency and debt markets. This volatility could cause a slowdown in economic activity in the United Kingdom, Europe or globally, which could adversely affect our operating results and growth prospects. In addition, our business could be negatively affected by new trade agreements or data transfer agreements between the United Kingdom and other countries, including the United States, and by the possible imposition of trade or other regulatory and immigration barriers in the United Kingdom. In addition, the Europe-wide market authorization framework for our products (and for the drugs sold by our collaboration partners in the pharmaceutical industry) and access to European Union research funding by research scientists based in the United Kingdom may also change. Furthermore, we currently operate in Europe through a subsidiary based in the United Kingdom, which provides us with certain operational, tax and other benefits, as well as through other subsidiaries in Europe. The United Kingdom's withdrawal from the European Union could adversely affect our ability to realize those benefits and we may incur costs and suffer disruptions in our European operations as a result. These possible negative impacts, and others resulting from the United Kingdom's actual or threatened withdrawal from the European Union, may adversely affect our operating results and growth prospects.

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Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the legislation commonly known as the Tax Cut & Jobs Act, which was signed into law on December 22, 2017, significantly revised the Internal Revenue Code of 1986, as amended, or the Code. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including a reduction of the federal statutory rates from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income, elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. It is also unknown if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is likewise uncertain and could be adverse.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2018, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of approximately \$288.7 million. The federal NOL carryforwards generated during and after fiscal 2018 totaling \$55.0 million are carried forward indefinitely, while all others, if not utilized, will expire in various years beginning in 2025. A lack of future taxable income would adversely affect our ability to utilize these NOLs. In addition, under Section 382 of the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We may have already experienced one or more ownership changes. Depending on the timing of any future utilization of our carryforwards, we may be limited as to the amount that can be utilized each year as a result of such previous ownership changes. However, we do not believe such limitations will cause our NOL and credit carryforwards to expire unutilized. In addition, future changes in our stock ownership as well as other changes that may be outside of our control, could result in additional ownership changes under Section 382 of the Code. Our NOLs may also be impaired under similar provisions of state law or limited pursuant to provisions of the recent Tax Cut and Jobs Act amendments to the Code. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Provisions of our debt instruments may restrict our ability to pursue our business strategies.

Our term loan agreement with CR Group L.P. and revolving credit facility with Silicon Valley Bank require us, and any debt instruments we may enter into in the future may require us, to comply with various covenants that limit our ability to, among other things:

- dispose of assets;
- complete mergers or acquisitions;
- incur indebtedness;
- encumber assets;
- pay dividends or make other distributions to holders of our capital stock;
- make specified investments;
- engage in any new line of business;
and
- engage in certain transactions with our affiliates.

These restrictions could inhibit our ability to pursue our business strategies. In addition, we are subject to financial covenants based on total revenue and minimum cash balances. If we default under our term loan agreement or revolving credit facility, and such event of default is not cured or waived, the lenders could terminate commitments to lend and cause all amounts outstanding with respect to the debt to be due and payable immediately, which in turn could result in cross defaults under other debt instruments. Our assets and cash flow may not be sufficient to fully repay borrowings under all of our outstanding debt instruments if some or all of these instruments are accelerated upon a default. We may incur additional indebtedness in the future. The debt instruments governing such indebtedness could contain provisions that are as, or more, restrictive than our existing debt instruments. If we are unable to repay, refinance or restructure our indebtedness when payment is due, the lenders could proceed against the collateral granted to them to secure such indebtedness or force us into bankruptcy.

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or liquidation.

Acquisitions or joint ventures could disrupt our business, cause dilution to our stockholders and otherwise harm our business.

We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses. We have not made any acquisitions to date, and our ability to do so successfully is unproven. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with customers, distributors or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- diversion of management time and focus from operating our business;
- increases in our expenses and reductions in our cash available for operations and other uses; and
- possible write-offs or impairment charges relating to acquired businesses.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the anticipated benefit of any strategic transaction may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

If we are unable to recruit, train and retain key personnel, we may not achieve our goals.

Our future success depends on our ability to recruit, train, retain and motivate key personnel, including our senior management, research and development, manufacturing and sales and marketing personnel. Competition for qualified personnel is intense, particularly in the Seattle, Washington area. Our growth depends, in particular, on attracting, retaining and motivating highly-trained sales personnel with the necessary scientific background and ability to understand our systems at a technical level to effectively identify and sell to potential new customers. We do not maintain fixed term employment contracts or key man life insurance with any of our employees. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to attract, train, retain and motivate qualified personnel could materially harm our operating results and growth prospects.

Undetected errors or defects in our products could harm our reputation, decrease market acceptance of our products or expose us to product liability claims.

Our products may contain undetected errors or defects when first introduced or as new versions are released. Disruptions or other performance problems with our products may damage our customers' businesses, harm our reputation and result in reduced revenues. If that occurs, we may also incur significant costs, the attention of our key personnel could be diverted, or other significant customer relations problems may arise. We may also be subject to warranty and liability claims for damages related to errors or defects in our products. A material liability claim or other occurrence that harms our reputation or decreases market acceptance of our products could adversely impact our business and operating results.

The sale and use of products or services based on our technologies, or activities related to our research and clinical studies, could lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect which resulted in the failure to adequately perform the analysis for which it was designed. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We cannot assure investors that our product liability insurance would adequately protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

We face risks related to handling of hazardous materials and other regulations governing environmental safety.

Our operations are subject to complex and stringent environmental, health, safety and other governmental laws and regulations that both public officials and private individuals may seek to enforce. Our activities that are subject to these regulations include, among other things, our use of hazardous materials in manufacturing and in our products, and the generation, transportation and storage of waste. We could discover that we, an acquired business or our suppliers are not in

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material compliance with these regulations. For example, our products must be compliant with an EU regulation, Delegated Directive (EU) 2015/863, or RoHS3, which expands the list of prohibited substances from six to ten by adding four new types of phthalates. If our only products are not compliant by the deadlines as determined by RoHS3, we may be unable to ship our products into the EU market and our results of operations may suffer. Existing laws and regulations may also be revised or reinterpreted, or new laws and regulations may become applicable to us, whether retroactively or prospectively, that may have a negative effect on our business and results of operations. It is also impossible to eliminate completely the risk of accidental environmental contamination or injury to individuals. In such an event, we could be liable for any damages that result, which could adversely affect our business.

If we experience a significant disruption in our information technology systems or breaches of data security, our business could be adversely affected.

We rely on information technology systems to keep financial records, manage our manufacturing operations, fulfill customer orders, capture laboratory data, maintain corporate records, communicate with staff and external parties and operate other critical functions. Our information technology systems are potentially vulnerable to disruption due to breakdown, malicious intrusion and computer viruses or other disruptive events including but not limited to natural disaster. If we were to experience a prolonged system disruption in our information technology systems or those of certain of our vendors, it could negatively impact our ability to serve our customers, which could adversely impact our business. Although we maintain offsite back-ups of our data, if operations at our facilities were disrupted, it may cause a material disruption in our business if we are not capable of restoring function on an acceptable timeframe. In addition, our information technology systems are potentially vulnerable to data security breaches — whether by employees or others — which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, customers and others, any of which could have a material adverse effect on our business, reputation, financial condition and results of operations. In addition, any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, including state data protection regulations and the E.U. General Data Protection Regulation, or GDPR, and other regulations, the breach of which could result in significant penalties. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

We intend to seek strategic collaborations and partnerships and other transactions, which may result in the use of a significant amount of our management resources or significant costs, and we may not be able to fully realize the potential benefit of such transactions.

We intend to seek strategic collaborations, partnerships and other transactions to support the continued growth of our company. However, there is no assurance that we will be successful in doing so. Accordingly, we may be engaged in evaluating potential transactions including, without limitation, strategic partnerships, divestitures of existing businesses or assets, a merger or consolidation with a third party that results in a change in control, a sale or transfer of all or a significant portion of our assets or a purchase by a third party of our securities that may result in a minority or control investment by such third party. From time to time, we may engage in discussions that may result in one or more transactions. Although there would be uncertainty that any of these discussions would result in definitive agreements or the completion of any transaction, we may devote a significant amount of our management resources to such a transaction, which could negatively impact our operations. In addition, we may incur significant costs in connection with seeking strategic transactions regardless of whether the transaction is completed. In the event that we consummate a strategic collaboration, partnership or other transaction in the future, we cannot assure you that we would fully realize the potential benefit of such a transaction or that the market would not have an adverse reaction to any such transaction. The failure to fully realize the potential benefit of such a transaction, adverse market reaction to any such transaction and any other issues we may encounter in connection with the consummation of any such transaction could adversely affect our future financial results or negatively impact the value of stockholders' investment in us.

Our strategy to seek to enter into strategic collaborations, licensing arrangements and other transactions with third parties to develop diagnostic tests and other products may not be successful.

We have relied, and expect to continue to rely, on strategic collaborations and licensing agreements with third parties for discoveries based on which we develop diagnostic tests and research products. For example, we licensed the rights to intellectual property that forms the basis of Prosigna from Bioclassifier, LLC, which was founded by several of our research customers engaged in translational research. Similarly, in connection with our collaboration with Celgene Corporation, we licensed the rights to intellectual property relating to a gene signature for lymphoma subtyping, which was discovered by a consortium of researchers including several of our research customers, from the National Institutes of Health. In connection with our collaboration with Merck to develop a companion diagnostic test and the subsequent termination of the collaboration agreement, Merck granted to us a non-exclusive license to certain intellectual property that relates to Merck's tumor

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inflammation signature. We intend to enter into more such arrangements with our research customers and other researchers, including biopharmaceutical companies and research institutions, for development of future diagnostic products. However, there is no assurance that we will be successful in doing so. Establishing collaborations and licensing arrangements is difficult and time-consuming. Discussions may not lead to collaborations or licenses on favorable terms, if at all. To the extent we agree to work exclusively with a party in a given area, our opportunities to collaborate with others could be limited. Certain parties may seek to partner with companies in addition to us in connection with a project. This, in turn, may limit the commercial potential of any products that are the subject of such collaborations. Potential collaborators or licensors may elect not to work with us based upon their assessment of our financial, regulatory, commercial or intellectual property position. In particular, our customers are not obligated to collaborate with us or license technology to us, and they may choose to develop diagnostic products themselves or collaborate with our competitors.

New diagnostic product development involves a lengthy and complex process, and we may be unable to commercialize on a timely basis, or at all, any of the tests or products we develop individually or with our collaborators.

Few research and development projects result in successful commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of a product candidate or we may be required to expend considerable resources repeating clinical studies, which would adversely impact potential revenue and our expenses. In addition, any delay in product development would provide others with additional time to commercialize competing products before we do, which in turn may adversely affect our growth prospects and operating results.

In addition, the success of the development programs for any product candidates or assays developed in collaboration with others will be dependent on the continued pursuit and success of the related drug trials by our collaborators.

In August 2017, we entered into a collaboration agreement with Lam Research Corporation, or Lam, with respect to the development and commercialization of our Hyb & Seq sequencing platform and related assays. Pursuant to the terms of the collaboration agreement, Lam will contribute up to \$50.0 million, payable quarterly, for allowable development costs. In exchange, Lam is eligible to receive certain single-digit percentage royalty payments on net sales by us of certain products and technologies developed under the collaboration agreement, if any. In addition, we issued Lam a warrant to purchase up to 1.0 million shares of our common stock. Any product development activities pursuant to this collaboration are uncertain and development costs may exceed \$50.0 million, in which case we would need to obtain additional funding to complete development of our Hyb & Seq sequencing platform and related assays. Ultimately the development may not be successful, which could negatively impact our prospects for future revenue growth.

Although we expect such collaborations to provide funding to cover our costs of development, the failure, discontinuation or modification of these clinical trials could negatively impact our ability to attract new collaboration partners, and would reduce our prospects for introducing new diagnostic products, revenue growth, and future operating results.

The life sciences research and diagnostic markets are highly competitive. If we fail to compete effectively, our business and operating results will suffer.

We face significant competition in the life sciences research and diagnostic markets. We currently compete with both established and early stage life sciences research companies that design, manufacture and market instruments and consumables for gene expression analysis, single-cell analysis, polymerase chain reaction, or PCR, digital PCR, other nucleic acid detection and additional applications. These companies use well-established laboratory techniques such as microarrays or quantitative PCR as well as newer technologies such as next generation sequencing such as RNA-sequencing. We believe our principal competitors in the life sciences research and diagnostic markets are Agilent Technologies, Becton-Dickinson, Bio-Rad, Bio-Techne, Fluidigm, HTG Molecular Diagnostics, Illumina, Luminex, Merck Millipore, O-Link, Perkin Elmer, Qiagen, Roche Applied Science, Thermo Fisher Scientific, and 10x Genomics. In addition, there are a number of new market entrants in the process of developing novel technologies for the life sciences market, including those that may compete with GeoMx DSP.

We also compete with commercial diagnostic laboratory companies. We believe our principal competitor in the breast cancer diagnostics market is Genomic Health, which provides gene expression analysis at its central laboratory in Redwood City, California and currently commands a substantial majority of the market. We also face competition from companies such as Agendia, Biotheranostics, and Myriad Genetics.

Many of our current competitors are large publicly-traded companies, or are divisions of large publicly-traded companies, and may enjoy a number of competitive advantages over us, including:

- greater name and brand recognition, financial and human resources;
- broader product lines;
- larger sales forces and more established distributor networks;
- substantial intellectual property portfolios;
- larger and more established customer bases and relationships; and

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- better established, larger scale, and lower cost manufacturing capabilities.

We believe that the principal competitive factors in all of our target markets include:

- cost of capital equipment;
- cost of consumables and supplies;
- reputation among customers;
- innovation in product offerings;
- flexibility and ease-of-use;
- accuracy and reproducibility of results; and
- compatibility with existing laboratory processes, tools and methods.

We believe that additional competitive factors specific to the diagnostics market include:

- availability of reimbursement for testing services;
- breadth of clinical decisions that can be influenced by information generated by tests;
- volume, quality, and strength of clinical and analytical validation data;
- inclusion in treatment guidelines; and
- economic benefit accrued to customers based on testing services enabled by products.

We cannot assure investors that our products will compete favorably or that we will be successful in the face of increasing competition from new products and technologies introduced by our existing competitors or new companies entering our markets. In addition, we cannot assure investors that our competitors do not have or will not develop products or technologies that currently or in the future will enable them to produce competitive products with greater capabilities or at lower costs than ours. For example, we recently concluded that certain of our customers have shifted certain types of experiments that previously had been performed on our nCounter system to RNA-sequencing technology. Although we are pursuing several strategies to mitigate this trend, there can be no assurance we will be successful in doing so. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

If Prosigna fails to achieve and sustain sufficient market acceptance, we will not generate expected revenue, and our prospects may be harmed.

Commercialization of Prosigna in Europe, the United States and the other jurisdictions in which we intend to pursue regulatory approval or clearance is a key element of our strategy. Currently, most oncologists seeking sophisticated gene expression analysis for diagnosing and profiling breast cancer in their patients ship tissue samples to a limited number of centralized laboratories typically located in the United States. We may experience reluctance, or refusal, on the part of physicians to order, and third-party payors to pay for, Prosigna if the results of our research and clinical studies, and our sales and marketing activities relating to communication of these results, do not convey to physicians and patients that Prosigna provides equivalent or better prognostic information than those centralized laboratories. In addition, our diagnostic tests are performed by pathologists in local laboratories, rather than by a vendor in a remote centralized laboratory, which requires us to educate pathologists regarding the benefits of this business model and oncologists regarding the reliability and consistency of results generated locally. Also, we offer Prosigna in other countries outside of the United States, where genomic testing for breast cancer is not widely available and the market for such tests is new. The future growth of the market for genomic breast cancer testing will depend on physicians' acceptance of such testing and the availability of reimbursement for such tests.

These hurdles may make it difficult to convince healthcare providers that tests using our technologies are appropriate options for cancer diagnostics, may be equivalent or superior to available tests, and may be at least as cost effective as alternative technologies. If we fail to successfully commercialize Prosigna on a widespread basis, we may never receive a return on the significant investments in sales and marketing, medical, regulatory, manufacturing and quality assurance personnel we have made, and further investments we intend to make, which would adversely affect our growth prospects, operating results and financial condition.

Risks Related to Government Regulation and Diagnostic Product Reimbursement

Our "Research Use Only" products for the research, life sciences market could become subject to more stringent regulatory surveillance as medical devices by the FDA or other regulatory agencies in the future which could increase our costs and delay our commercialization efforts, thereby materially and adversely affecting our business and results of operations.

In the United States, most of our products are currently labeled and sold for Research Use Only, or RUO, and not for the diagnosis or treatment of disease, and are sold to pharmaceutical and biotechnology companies, academic and government institutions and research laboratories. Because such products are not intended for diagnostic use, and the products do not

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include clinical or diagnostic claims or provide directions for use as diagnostic products, they are not subject to the same level of control by the Food and Drug Administration, or FDA, as medical devices. In particular, while the FDA regulations require that RUO products be appropriately labeled, “For Research Use Only,” the regulations do not subject such products to the FDA’s pre- and post-market controls for medical devices. Pursuant to FDA guidance on RUO products, a company may not make clinical or diagnostic claims about an RUO product or provide clinical directions or clinical support services to customers for RUO products. If the FDA were to modify its approach to regulating products labeled for Research Use Only, it could reduce our revenue or increase our costs and adversely affect our business, prospects, results of operations or financial condition. In the event that the FDA requires marketing authorization of our RUO products in the future, there can be no assurance that the FDA will ultimately grant any clearance or approval requested by us in a timely manner, or at all.

In addition, we sell dual-use instruments with software that has both FDA-cleared functions, and research functions for which FDA approval or clearance is not required. Dual-use instruments are subject to FDA regulation since they are intended, at least in part, for use by customers performing clinical diagnostic testing. In November 2014, the FDA issued a guidance document that described FDA’s approach to regulating molecular diagnostic instruments that combine both approved/cleared device functions and device functions for which approval/clearance is not required. There is a risk that the requirements for dual use instruments could change causing additional costs and delays for development of these products. For example, there could be enforcement action if the FDA determines that approval or clearance was required for those functions for which FDA approval or clearance has not been obtained, or the instruments are being promoted for off-label use. There is also a risk that the FDA could broaden its current regulatory enforcement of dual-use instruments through additional FDA oversight of such products or impose additional requirements upon such products. In July 2017, FDA adopted a new regulation exempting certain clinical multiplex test systems, like the ones used with our Prosigna assay, from premarket notification requirements. However, these new regulations will not impact the FDA clearance requirements for our nCounter Dx Analysis System which will still require 510(k) clearance for use with specific assays, such as Prosigna.

If Medicare and other third-party payors in the United States and foreign countries do not approve reimbursement for diagnostic tests enabled by our technology, or revise or rescind reimbursement rates, the commercial success of our diagnostic products would be compromised.

Successful commercialization of our diagnostic products depends, in large part, on the availability of adequate reimbursement for testing services that our diagnostic products enable from government insurance plans, managed care organizations and private insurance plans. There is significant uncertainty surrounding third-party reimbursement for the use of tests that incorporate new technology. For example, after the FDA clearance of Prosigna in September 2013, it took over two years to achieve broad Medicare reimbursement of Prosigna testing.

If we are unable to obtain positive policy decisions from third-party payors approving reimbursement for our tests at adequate levels, the commercial success of our diagnostic products would be compromised and our revenue would be significantly limited. Even if we do obtain reimbursement for our tests, Medicare, Medicaid and other payors may withdraw their coverage policies, cancel their contracts at any time, review and adjust the rate of reimbursement, require co-payments from patients or stop paying for our tests, which would reduce revenue for testing services based on our technology, and indirectly, demand for our diagnostic products. In addition, insurers, including managed care organizations as well as government payors such as Medicare and Medicaid, have increased their efforts to control the cost, utilization and delivery of healthcare services, which may include decreased coverage or reduced reimbursement.

From time to time, Congress has considered and implemented changes to the Medicare fee schedules in conjunction with budgetary legislation, and pricing and payment terms, including the possible requirement of a patient co-payment for Medicare beneficiaries for tests covered by Medicare, and are subject to change at any time. The Protecting Access to Medicare Act, or PAMA, of 2014 revised the Medicare Clinical Laboratory Fee Schedule, or CLFS, to base prices on private payor rates that are reported to the Centers for Medicare and Medicaid Services, or CMS. In June 2016, CMS released the final Clinical Diagnostic Tests Laboratory Payment System regulations, in response to PAMA. Under the definitions in the regulations, Prosigna is defined as a Clinical Diagnostic Laboratory Test, or CDLT, and therefore will be repriced every three years based on a weighted median of private payor payments submitted by reporting labs. As a result, if private payor payment amounts decline, there is a risk that Medicare prices will fall as well, though PAMA limits these reductions to no more than 10% less than the prior year during calendar years 2018-2020 and no more than 15% less during years 2021-2023. In 2017, as part of the market-based pricing determinations for 2018 required by PAMA, only one private payor payment from a single commercial laboratory was reported, and it was an anomalous payment amount, well below the current Medicare reimbursement price. CMS used that single payment amount as the weighted median, which triggered an automatic 10% reduction in Prosigna’s Medicare reimbursement rate of \$3,443 to \$3,099, effective January 1, 2018, followed by a subsequent 10% reduction to \$2,789, effective January 1, 2019. There will be an additional 10% automatic reduction in the Medicare reimbursement rate for Prosigna for calendar year 2020. Reductions in the prices at which testing services based on our technology are reimbursed could reduce our customers’ interest in offering Prosigna and have a negative impact on our revenue.

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Under PAMA, CMS is required to reprice CLDTs, including Prosigna, every three years. The next repricing will be announced by CMS in late 2020, based on private payor reimbursement data collected by reporting laboratories during the period January 1, 2019 to June 30, 2019. These new prices will take effect on January 1, 2021. Depending on the pricing data reported by these laboratories to CMS, Prosigna's Medicare reimbursement price may change.

In many countries outside of the United States, various coverage, pricing and reimbursement approvals are required. For example, we have received positive reimbursement decisions for Prosigna in France, certain regions of Spain and Italy, Canada, Israel, Switzerland and Denmark, but despite these positive developments, we continue to expect that it will take several years to establish broad coverage and reimbursement for testing services based on our products with most payors in countries outside of the United States, and our efforts may not be successful.

We continue to pursue positive reimbursement and coverage decisions from government insurance plans, managed care organizations and private insurance plans. From time to time, if positive coverage decisions are obtained, we may publicly announce such decisions. In most cases where coverage is denied by a third-party payor, there will be subsequent opportunities to submit additional information or clinical evidence and have such decision reconsidered. We intend to evaluate the benefit of continued pursuit of a positive reimbursement determination on a case by case basis and in most cases expect to continue to pursue a positive coverage decision with those payors based on additional information or subsequent clinical developments; as a result, we do not intend to publicly announce any denials of coverage or the absence of a coverage determination on a regular basis.

Our nCounter reagents may be used by clinical laboratories to create Laboratory-Developed Tests (LDTs), which could, in the future, be the subject of additional FDA regulation as medical devices, which could materially and adversely affect our business and results of operations.

A clinical laboratory can use our custom-manufactured reagents to create what is called a Laboratory Developed Test, or LDT. LDTs, according to the FDA, are diagnostic tests that are developed, validated and performed by a single laboratory and include genetic tests. Historically, LDTs generally have not been subject to FDA regulations. In October 2014, the FDA issued draft guidance documents proposing the use of a risk-based approach to regulating LDTs. Any restrictions on LDTs by the FDA could decrease demand for our reagents. Additionally, compliance with additional regulatory burdens could be time consuming and costly for our customers. While FDA announced in November 2016 that it did not intend to finalize the draft LDT guidance documents, FDA could alter its position or question a particular LDT that a laboratory is providing, or Congress could enact legislation that could result in FDA regulation of LDTs. To date, draft legislative proposals have been discussed, but no legislation has been formally introduced. If FDA changed its policy or legislation were enacted, it could adversely affect demand for these specialized reagents or our instruments.

Our nCounter reagents allow users to design and validate their own customized assays using standard sets of barcodes provided by us with the laboratories' choice of oligonucleotide probes. These reagents, which are offered to customers in the United States through a custom manufacturing service, may be used by laboratories in conjunction with analyte-specific reagents and general purpose reagents to create diagnostic tests or test systems validated within the accredited testing laboratory.

Approval, de novo marketing authorization, and/or clearance by the FDA and foreign regulatory authorities for our diagnostic tests will take significant time and require significant research, development and clinical study expenditures and ultimately may not succeed.

Before we begin to label and market our products for use as clinical diagnostics in the United States, unless an exemption applies, we are required to obtain prior 510(k) clearance, *de novo* marketing authorization, or pre-market approval from the FDA. In September 2013, we received FDA 510(k) clearance for Prosigna as a prognostic indicator for distant recurrence-free survival at 10 years in post-menopausal women with Stage I/II lymph node-negative or Stage II lymph node-positive (1-3 positive nodes) hormone receptor-positive breast cancer who have undergone surgery in conjunction with locoregional treatment and consistent with the standard of care. In August 2014, the FDA issued a companion diagnostics final guidance stating that if the device is essential to the safety or efficacy of the drug, the FDA generally will require approval, *de novo* marketing authorization or clearance for the device at the time when the FDA approves the drug. The FDA stated in the companion diagnostics final guidance that while in some instances a companion diagnostic could come to market through a 510(k) or *de novo*, FDA expects that companion diagnostics usually will require a premarket approval or PMA. In July 2016, the FDA issued a draft co-development companion diagnostic and therapeutic guidance document which similarly reflected this information. The draft guidance appears to also relate, at least in part, to what may be considered complementary diagnostics, i.e., diagnostics that are beneficial for therapeutic product development or clinical decision making but that do not meet the definition of an IVD companion diagnostic. If we developed a diagnostic device to be used in conjunction with a pharmaceutical product that was then cleared, authorized or approved, but not as a companion diagnostic for the therapeutic product, this may result in potentially reduced revenue for the test as the labeling of the drug may not reference the need for the diagnostic test.

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Any 510(k) clearance, *de novo* authorization or PMA approval we obtain for any future product would place substantial restrictions on how our device is marketed or sold. The FDA will continue to place considerable restrictions on our products, including, but not limited to, the obligation to comply with the QSR, registering manufacturing facilities, listing the products with the FDA, and complying with labeling, marketing, complaint handling, medical device reporting requirements, and reporting certain corrections and removals. Obtaining FDA clearance, authorization or approval for diagnostics can be expensive and uncertain, generally takes from several months to several years from submission, and generally requires detailed and comprehensive scientific and clinical data, as well as compliance with FDA regulations. In addition, we have limited experience in obtaining PMA approval from the FDA and are therefore supplementing our operational capabilities to manage the more complex processes needed to obtain and maintain PMAs. Notwithstanding the expense, these efforts may never result in FDA approval, *de novo* marketing authorization, or 510(k) clearance. Even if we were to obtain regulatory approval, authorization or clearance, it may not be for the uses we believe are important or commercially attractive, in which case we would not market our product for those uses.

Sales of our diagnostic products outside the United States are subject to foreign regulatory requirements governing clinical studies, vigilance reporting, marketing approval, manufacturing, regulatory inspections, product licensing, pricing and reimbursement. These regulatory requirements vary greatly from country to country. As a result, the time required to obtain approvals outside the United States may differ from that required to obtain FDA approval, *de novo* marketing authorization or clearance, and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. Approval, *de novo* marketing authorization, or clearance by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval or clearance by regulatory authorities in other countries or by the FDA, and foreign regulatory authorities could require additional testing beyond what the FDA requires. In addition, FDA regulates exports of medical devices. Failure to comply with these regulatory requirements or to obtain required approvals or clearances could impair our ability to commercialize our diagnostic products outside of the United States.

If we are unable to obtain additional regulatory clearances, de novo marketing authorizations, registrations, or approvals to market Prosigna in additional countries or if regulatory limitations are placed on our diagnostic products, our business and growth will be harmed. In addition, if we do not obtain additional regulatory clearances, de novo marketing authorizations or approvals necessary to market products other than Prosigna for diagnostic purposes, we will be limited to marketing such products for research use only.

We have received regulatory clearance in the United States under a 510(k) for a version of our first diagnostic product, Prosigna, providing an assessment of a patient's risk of recurrence for breast cancer; we have obtained a CE mark for Prosigna which permits us to market that assay for diagnostic purposes in the European Union, and we have received regulatory clearances in selected other jurisdictions. Other than with respect to Prosigna in such jurisdictions in which we have received regulatory clearance, we are limited to marketing our products for research use only, which means that we cannot make diagnostic or clinical claims. We intend to seek regulatory authorizations to market Prosigna in other jurisdictions and, potentially, for other indications.

In addition, pursuant to our collaborations with pharmaceutical companies for the development of companion diagnostic tests for use with their drugs, we are responsible for obtaining any regulatory authorizations needed to use the companion diagnostic tests in clinical trials as well as the regulatory approvals to sell the companion diagnostic tests following completion of such trials. For example, we have been collaborating with Celgene on the development of LymphMark as a companion diagnostic test for REVLIMID and, in April 2019, Celgene announced that the trial evaluating REVLIMID for the treatment of diffuse large B-cell lymphoma, or DLBCL, did not meet its primary endpoint. As a result, we will not file a PMA for LymphMark as a companion diagnostic for REVLIMID. Some of the compensation we expect to receive pursuant to these collaborations is based on the receipt of regulatory approvals. Any failure to obtain regulatory approvals, clearances, or *de novo* authorizations for our diagnostic tests in a particular jurisdiction may also reduce sales of our nCounter systems for clinical use in that jurisdiction, as the lack of a robust menu of available diagnostic tests would make those systems less attractive to testing laboratories.

We cannot assure investors that we will be successful in obtaining these regulatory clearances, registrations *de novo* marketing authorizations or approvals. If we do not obtain additional regulatory clearances, *de novo* marketing authorization or approvals to market future products or expand future indications for diagnostic purposes, if additional regulatory limitations are placed on our products or if we fail to successfully commercialize such products, the market potential for our diagnostic products would be constrained, and our business and growth prospects would be adversely affected.

We expect to rely on third parties in conducting any future studies of our diagnostic products that may be required by the FDA or other regulatory authorities, and to fulfill product registration requirements in foreign countries, and those third parties may not perform satisfactorily.

We do not have the ability to independently conduct the clinical studies or other studies that may be required to obtain FDA and other regulatory clearance, *de novo* marketing authorization or approval for our diagnostic products, including

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additional indications. Accordingly, we expect to rely on third parties, such as medical institutions, clinical investigators, consultants, and our pharmaceutical collaborators to conduct such studies. For example, we contract with clinical laboratories to perform the companion diagnostic tests we have developed that are used in the clinical trials run by pharmaceutical companies pursuant to our companion diagnostic collaborations. Our reliance on these third parties for clinical development activities will reduce our control over these activities. These third-party contractors may not complete activities on schedule or conduct studies in accordance with regulatory requirements or the study design. Our reliance on third parties that we do not control will not relieve us of any applicable requirement to ensure compliance with various procedures required under good clinical practices and regulatory requirements. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, the studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory clearance, *de novo* marketing authorization or approval for our diagnostic products. In addition, under our contracts with our pharmaceutical collaborators, we potentially could be held liable for the failure of our third-party subcontractors to perform their contractual obligations.

Our pharmaceutical collaborators may decide to end their clinical program, modify or terminate a clinical trial, or not pursue regulatory filings for a companion diagnostic test. For example, in April 2019, Celgene announced that the trial evaluating REVLIMID for the treatment of DLBCL did not meet its primary endpoint. In May 2019, the Company's collaboration agreement with Celgene was terminated effective July 2019, and the Company does not intend to file a pre-market approval for LymphMark as a companion diagnostic for REVLIMID.

In many countries, we are not able to directly apply for product registrations, and therefore must rely on third-party contractors or product distributors resident in those countries to fulfill the product registration requirements. Our reliance on these third parties reduces our control over the registration activities, and those parties may not appropriately register the products. Our reliance on third parties does not relieve us of the obligation to comply with applicable requirements, and therefore any failure on the part of the third parties could subject us to enforcement action in the country in which the registration was not properly fulfilled.

We are subject to ongoing and extensive regulatory requirements, and our failure to comply with these requirements could substantially harm our business.

Certain of our products are regulated as *in vitro* diagnostic medical devices, including Prosigna and the nCounterFLEX Analysis System. Accordingly, we and certain of our contract manufacturers are subject to ongoing International Organization for Standardization, or ISO, obligations as well as regulation by the FDA and other national health authorities. These may include routine inspections by Notified Bodies, FDA, and other health authorities, of our manufacturing facilities and our records for compliance with requirements such as ISO 13485 and the Quality System Regulation, or QSR, which establish extensive requirements for quality assurance and control as well as manufacturing and change control procedures, among other things. We are also subject to other regulatory obligations, such as requirements pertaining to the registration of our manufacturing facilities and the listing of our devices with the FDA; continued adverse event and malfunction reporting; reporting certain corrections and removals; and labeling and promotional requirements. Other agencies may also issue guidelines and regulations that could impact the development of our products, including companion diagnostic tests. For example, the European Medicines Agency, a European Union agency which is responsible for the scientific evaluation of medicines used in the European Union, recently launched an initiative to determine guidelines for the use of genomic biomarkers in the development and life-cycle of drugs. On May 25, 2017, the European Union adopted the IVD Directive Regulation, which increases the regulatory requirements applicable to *in vitro* diagnostics in the EU and would require that we re-classify and obtain approval, registration, or clearance for our existing CE-marked IVD products within a five-year grace period (by May 25, 2022).

We may also be subject to additional FDA or global regulatory authority post-marketing obligations or requirements by the FDA or global regulatory authority to change our current product classifications which would impose additional regulatory obligations on us. The promotional claims we can make for Prosigna are limited to the intended use as cleared or approved by the applicable regulatory authority. If we are not able to maintain regulatory compliance, we may not be permitted to market our medical device products and/or may be subject to enforcement by EU Competent Authorities and the FDA and other global regulatory authority such as the issuance of warning or untitled letters, fines, injunctions, and civil penalties; recall or seizure of products; operating restrictions; and criminal prosecution. In addition, we may be subject to similar regulatory regimes of foreign jurisdictions as we continue to commercialize our products in new markets outside of the United States and Europe. Adverse Notified Body, EU Competent Authority or FDA or global regulatory authority action in any of these areas could significantly increase our expenses and limit our revenue and profitability.

We may be subject, directly or indirectly, to healthcare fraud and abuse laws and other laws applicable to our marketing practices. If we are unable to comply, or have not complied, with such laws, we could face substantial penalties.

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Our operations are directly, or indirectly through our customers, subject to various fraud and abuse laws, including, without limitation, the federal and state anti-kickback statutes and state, federal and foreign marketing compliance laws and gift bans. These laws may impact, among other things, our proposed sales and marketing and education programs and require us to implement additional internal systems for tracking certain marketing expenditures and reporting them to government authorities. In addition, we may be subject to privacy regulations by both the federal government and the states in which we conduct our business as well as by foreign governments and entities. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-kickback Law and state equivalents;
- the federal physician self-referral prohibition, commonly known as the Stark Law, and state equivalents;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended;
- the Medicare civil money penalty and exclusion requirements;
- the federal False Claims Act and state equivalents;
- state physician gift bans and state, federal and foreign marketing expenditure disclosure laws;
- state privacy laws, such as the California Consumer Privacy Act;
- the Foreign Corrupt Practices Act, which applies to our international activities; and
- the European Union's General Data Protection Regulation.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Healthcare policy changes, including legislation reforming the United States healthcare system, may have a material adverse effect on our financial condition and results of operations.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, enacted in March 2010, made changes that significantly impact the pharmaceutical and medical device industries and clinical laboratories. For example, beginning in 2013, each medical device manufacturer must pay a sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. In December 2015, Congress passed a two-year suspension of the medical device tax from January 1, 2016 to December 31, 2017. In January 2018, Congress suspended the tax again for a two-year period ending on December 31, 2019. The tax applies to our listed medical device products, which include the nCounter Dx Analysis System and Prosigna. The Budget Control Act of 2011 contained automatic spending cuts to the federal budget known as sequestration. As a result of sequestration, Medicare payments are reduced by 2% per year. For Prosigna, pricing changes can occur through the annual adjustment to the CLFS; this resulted in a 10% reduction in the Medicare reimbursement price for Prosigna starting on January 1, 2018 and future 10% reductions in 2019 and 2020. These or any future proposed or mandated reductions in payments may apply to some or all of the clinical laboratory tests that our customers use our technology to deliver to Medicare beneficiaries, and may indirectly reduce demand for our products.

Other significant measures contained in the ACA include coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The ACA also included significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increased potential penalties for such violations.

In addition to the ACA, the effect of which cannot presently be quantified, various healthcare reform proposals have also emerged from federal and state governments. Changes in healthcare policy, such as the creation of broad test utilization limits for diagnostic products in general or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially impact the sales of our tests, increase costs and divert management's attention from our business. In addition, sales of our tests outside of the United States will subject us to foreign regulatory requirements, which may also change over time.

We cannot predict whether future healthcare initiatives, including potential repeal of the ACA in whole or in part, will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. Changes in the United States healthcare industry may result in decreased profits to us, lower reimbursements by payors for our products or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.

Risks Related to Intellectual Property

If we are unable to protect our intellectual property effectively, our business would be harmed.

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. As of September 30, 2019, we owned or licensed 31 issued U.S. patents and approximately 28 pending U.S. patent applications, including provisional and non-provisional filings. We also owned or licensed approximately 282 pending and granted counterpart applications worldwide, including 125 country-specific validations of 14 European patents. We continue to file new patent applications to protect the full range of our technologies. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

Our success depends in part on obtaining patent protection for our products and processes, preserving trade secrets, patents, copyrights and trademarks, operating without infringing the proprietary rights of third parties, and acquiring licenses for technology or products. We cannot assure investors that any of our currently pending or future patent applications will result in issued patents, and we cannot predict how long it will take for such patents to be issued. As the patent and prior art landscape for translational research and molecular diagnostic life science products grows more crowded and becomes more complex we may find it more difficult to obtain patent protection for our products including those related to digital spatial profiling and sequencing, for example. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products and may therefore fail to provide us with any competitive advantage. Additionally, we cannot assure investors that our currently pending or future patent applications have or will be filed in all of our potential markets. Further, we cannot assure investors that other parties will not challenge any patents issued to us or that courts or regulatory agencies will hold our patents to be valid or enforceable. We cannot guarantee investors that we will be successful in defending challenges made against our patents and patent applications. Any successful third-party challenge to our patents could result in the third party or the unenforceability or invalidity of such patents and could deprive us of the ability to prevent others from using the technologies claimed in such issued patents.

The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States. Furthermore, in the biotechnology field, courts frequently render opinions that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for analyzing or comparing DNA.

In particular, the patent positions of companies engaged in development and commercialization of genomic diagnostic tests, like Prosigna, are particularly uncertain. Various courts, including the U.S. Supreme Court, have rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to genomic diagnostics. Specifically, these decisions stand for the proposition that patent claims that recite laws of nature (for example, the relationships between gene expression levels and the likelihood of risk of recurrence of cancer) are not themselves patentable unless those patent claims have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws rather than patent drafting efforts designed to monopolize the law of nature itself. What constitutes a "sufficient" additional feature is uncertain. Furthermore, in view of these decisions, in December 2014 the U.S. Patent and Trademark Office, or USPTO, published revised guidelines for patent examiners to apply when examining process claims for patent eligibility. This guidance was updated by the USPTO in July 2015 and additional illustrative examples provided in May 2016. The USPTO provided additional guidance on examination procedures pertaining to subject matter eligibility in April 2018 and June 2018. The guidance indicates that claims directed to a law of nature, a natural phenomenon, or an abstract idea that do not meet the eligibility requirements should be rejected as non-statutory, patent ineligible subject matter; however, method of treatment claims that practically apply natural relationships should be considered patent eligible. We cannot assure you that our patent portfolio will not be negatively impacted by the current uncertain state of the law, new court rulings or changes in guidance or procedures issued by the USPTO. From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability and validity of patents within the genomic diagnostic space, and any such changes could have a negative impact on our business.

The laws of some non-U.S. countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents. 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:

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- 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.
- Others may independently develop similar or alternative products and technologies or duplicate any of our products and technologies.
- It is possible that our pending patent applications will not result in issued patents, and even if they issue as patents, they may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties.
- We may not develop additional proprietary products and technologies that are patentable.
- The patents of others may have an adverse effect on our business.
- 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.

In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, corporate partners and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. In addition, competitors may develop their own versions of our tests in countries where we did not apply for patents, where our patents have not issued or where our intellectual property rights are not recognized and compete with us in those countries and markets. If our intellectual property is not adequately protected so as to protect our market against competitors' products and methods, our competitive position could be adversely affected, as could our business.

We have not yet registered certain of our trademarks in all of our potential markets. If we apply to register these trademarks, our applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

To the extent our intellectual property, including licensed intellectual property, offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition. If our intellectual property does not provide adequate protection against our competitors' products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

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.

We rely on licenses in order to be able to use various proprietary technologies that are material to our business, including our core digital molecular barcoding technology licensed from the Institute for Systems Biology, technology relating to Prosigna licensed from Bioclassifier, LLC, intellectual property relating to a gene signature for lymphoma subtyping from the National Institutes of Health, and intellectual property relating to the tumor inflammation signature from Merck. We do not own the patents that underlie these licenses. Our rights to use these technologies and employ the inventions claimed in the licensed patents are subject to the continuation of and compliance with the terms of those licenses.

We may need to license other technologies to commercialize future products. We may also need to negotiate licenses to patents and patent applications after launching any of our commercial products. Our business may suffer if the patents or patent applications are unavailable for license or if we are unable to enter into necessary licenses on acceptable terms.

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. Some of our patents and patent applications were either acquired from another company who acquired those patents and patent applications from yet another company, or are licensed from a third party. Thus, these patents and patent applications are not written by us or our attorneys, and we did not have control over the drafting and prosecution. The former patent owners and our licensors might not have given the same attention to the drafting

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and prosecution of these patents and applications as we would have if we had been the owners of the patents and applications and had control over the drafting and prosecution. We cannot be certain that drafting or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

Enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents is often subject to the control or cooperation of our licensors. Certain of our licenses contain provisions that allow the licensor to terminate the license upon specific conditions. Therefore, our business may suffer if these licenses terminate, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties or if the licensed patents or other rights are found to be invalid. 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 or termination of 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, we might be barred from producing and selling some or all of our products.

In addition, certain of the patents we have licensed relate to technology that was developed with U.S. government grants. Federal regulations impose certain domestic manufacturing requirements with respect to some of our products embodying these patents.

Involvement 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, could be time-intensive and costly and may adversely impact our business or stock price.

We have received notices of claims of infringement and misappropriation or misuse of other parties' proprietary rights in the past and may from time to time receive additional notices. Some of these claims have led and may lead to litigation. We cannot assure investors that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets, infringement by us of third-party patents and trademarks or other rights, or the validity of our patents, trademarks or other rights, will not be asserted or prosecuted against us.

Litigation may also be necessary for us to protect or enforce our patent and proprietary rights, defend against third-party claims or to determine the scope, coverage and validity of the proprietary rights of others. Litigation could result in substantial legal fees and could adversely affect the scope of our patent protection and reduce our ability to compete in the marketplace. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us. If we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, scope and coverage of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. Any litigation that may be necessary in the future could result in substantial costs and diversion of resources and could have a material adverse effect on our business, operating results or financial condition.

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. Our success depends in part on our non-infringement of the patents or proprietary rights of third parties. We develop complex products that integrate a wide range of technologies which may impact our ability to do so clear of third party rights and therefore may need to license other technologies or challenge the scope, coverage and validity of the proprietary rights of others to commercialize future products. As we develop new technologies such as those related to genomic diagnostic tests, digital spatial profiling and sequencing, for example, and move into new markets and applications for our products, we expect incumbent participants in such markets may assert their patents and other proprietary rights against us as part of a business strategy to slow our entry into such markets, impede our successful competition and/or extract substantial license and royalty payments from us. In addition, we may be unaware of pending third-party patent applications that relate to our technology and our competitors and others may have patents or may in the future obtain patents and claim that use of our products infringes these patents. Our competitors and others may now, and in the future, have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product revenue and against whom our own patents may provide little or no deterrence or protection. Therefore, our commercial success may depend in part on our non-infringement of the patents or proprietary rights of third parties. We are aware of a third party, Genomic Health, Inc., that has issued patents and pending patent applications in the United States, Europe and other jurisdictions that claim methods of using certain genes that are included in Prosigna. We believe that Prosigna does not infringe any valid issued claim. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have an adverse impact on our stock price, which may be disproportionate to the actual impact of the ruling itself. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be

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required to pay damages and obtain one or more licenses from third parties, or be prohibited from selling certain products. We may not be able to obtain these licenses at a reasonable cost, if at all. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. In addition, we could encounter delays in product introductions while we attempt to develop alternative methods or products to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing products, and the prohibition of sale of any of our products could materially affect our ability to grow and gain market acceptance for our products.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In addition, our agreements with some of our suppliers, distributors, customers, collaborators and other entities with whom we do business 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.

Many of our employees were previously employed at universities or other life sciences companies, including our competitors or potential competitors. Although no claims against us are currently pending, we or our employees may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. A loss of key research personnel work product could hamper or prevent our ability to commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Our products contain third-party open source software components, and failure to comply with the terms of the underlying open source software licenses could restrict our ability to sell our products.

Our products contain software tools licensed by third-party authors under "open source" licenses. Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the code. Some open source licenses contain requirements that we make available source code for modifications or derivative works we create based upon the type of open source software we use. If we combine our proprietary software with open source software in a certain manner, we could, under certain open source licenses, be required to release the source code of our proprietary software to the public. This would allow our competitors to create similar products with less development effort and time and ultimately could result in a loss of product sales.

Although we monitor our use of open source software to avoid subjecting our products to conditions we do not intend, the terms of many open source licenses have not been interpreted by U.S. courts, and there is a risk that these licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to commercialize our products. Moreover, we cannot assure investors that our processes for controlling our use of open source software in our products will be effective. If we are held to have breached the terms of an open source software license, we could be required to seek licenses from third parties to continue offering our products on terms that are not economically feasible, to re-engineer our products, to discontinue the sale of our products if re-engineering could not be accomplished on a timely basis, or to make generally available, in source code form, our proprietary code, any of which could adversely affect our business, operating results, and financial condition.

We use third-party software that may be difficult to replace or cause errors or failures of our products that could lead to lost customers or harm to our reputation.

We use software licensed from third parties in our products. In the future, this software may not be available to us on commercially reasonable terms, or at all. Any loss of the right to use any of this software could result in delays in the production of our products until equivalent technology is either developed by us, or, if available, is identified, obtained and integrated, which could harm our business. In addition, any errors or defects in third-party software, or other third-party

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software failures could result in errors, defects or cause our products to fail, which could harm our business and be costly to correct. Many of these providers attempt to impose limitations on their liability for such errors, defects or failures, and if enforceable, we may have additional liability to our customers or third-party providers that could harm our reputation and increase our operating costs.

We will need to maintain our relationships with third-party software providers and to obtain software from such providers that does not contain any errors or defects. Any failure to do so could adversely impact our ability to deliver reliable products to our customers and could harm our results of operations.

Risks Related to Our Common Stock

The price of our common stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock has fluctuated and may continue to fluctuate substantially. The trading price of our common stock depends on a number of factors, including those described in this “Risk Factors” section, many of which are beyond our control and may not be related to our operating performance. These fluctuations could cause stockholders to lose all or part of their investment in our common stock. Factors that could cause fluctuations in the trading price of our common stock include the following:

- actual or anticipated quarterly variation in our results of operations or the results of our competitors;
- announcements by us or our competitors of new products, significant contracts or commercial relationships;
- failure to obtain or delays in obtaining product approvals or clearances from the FDA or foreign regulators;
- adverse regulatory or reimbursement announcements;
- 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 research and diagnostics markets;
- manufacturing disruptions;
- any future sales of our common stock or other securities;
- any change to the composition of the board of directors or key personnel;
- announcements by us or our competitors of significant acquisitions or divestitures, strategic partnerships, joint ventures or capital commitments;
- general economic conditions and slow or negative growth of our markets; and
- the other factors described in this “Risk Factors” section.

The stock market in general, and market prices for the securities of life sciences and diagnostic 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. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts who cover us issues an adverse opinion about our company, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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, including by our officers, directors and their respective affiliates. 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.

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We register the offer and sale of all shares of common stock that we may issue under our equity compensation plans. 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. For example, in July and August 2018, we sold an aggregate of 4,600,000 shares of common stock in an underwritten public offering for net proceeds of \$53.8 million and in March 2019, we sold an aggregate of 3,175,000 shares of common stock in an underwritten public offering for net proceeds of \$68.3 million. Any such future issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

We have broad discretion over the use of the proceeds to us from our 2018 and 2019 underwritten public offerings and our October 2018 term loan agreement and may apply the proceeds to uses that do not improve our operating results or the value of your securities.

We have broad discretion over the use of proceeds to us from our 2018 and 2019 underwritten public offerings and our October 2018 term loan agreement and investors will be relying solely on the judgment of our board of directors and management regarding the application of these proceeds. Our use of the proceeds may not improve our operating results or increase the value of the securities offered pursuant to the foregoing fundraising transactions.

Anti-takeover provisions in our charter documents and under Delaware or Washington law could make an acquisition of us difficult, limit attempts by our stockholders to replace or remove our current management and limit our stock price.

Provisions of our certificate of incorporation and bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our stock. Among other things, the certificate of incorporation and bylaws:

- permit the board of directors to issue up to 15,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that all vacancies, including newly-created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide the board of directors into three classes;
- provide that a director may only be removed from the board of directors by the stockholders for cause;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and meet specific requirements as to the form and content of a stockholder's notice;
- prevent cumulative voting rights (therefore allowing the holders of a plurality of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chairman of the board, our chief executive officer or by the board of directors; and
- provide that stockholders are permitted to amend the bylaws only upon receiving at least two-thirds of the total votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. Likewise, because our principal executive offices are located in Washington, the anti-takeover provisions of the Washington Business Corporation Act may apply to us under certain circumstances now or in the future. These provisions prohibit a "target corporation" from engaging in any of a broad range of business combinations with any stockholder constituting an "acquiring person" for a period of five years following the date on which the stockholder became an "acquiring person."

Complying with the laws and regulations affecting public companies increases our costs and the demands on management and could harm our operating results.

As a public company, we incur and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. We ceased to be an “emerging growth company” on December 31, 2018 and are no longer eligible for reduced disclosure requirements and exemptions applicable to “emerging growth companies.” We expect that our loss of “emerging growth company” status will require additional attention from management and will result in increased costs to us, which could include higher legal fees, accounting fees and fees associated with investor relations activities, among others. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and The Nasdaq Global Market impose numerous requirements on public companies, including requiring changes in corporate governance practices. Also, the Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel must devote a substantial amount of time to compliance with these laws and regulations. These burdens may increase as new legislation is passed and implemented, including any new requirements that the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 may impose on public companies. These requirements have increased and will likely continue to increase our legal, accounting, and financial compliance costs and have made and will continue to make some activities more time consuming and costly. For example, as a public company it is more difficult and more expensive for us to obtain director and officer liability insurance, and in the future we may be required to accept reduced policy limits and coverage or to incur substantial costs to maintain the same or similar coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or our board committees or as executive officers.

The Sarbanes-Oxley Act requires the SEC to implement new requirements on registrants, and these new requirements that were implemented require, among other things, that we assess the effectiveness of our internal control over financial reporting annually and SEC requirements also require us to assess the effectiveness of our disclosure controls and procedures quarterly. In particular, Section 404 of the Sarbanes-Oxley Act, or Section 404, requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm to attest to, the effectiveness of our internal control over financial reporting. As an “emerging growth company,” we availed ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption since we ceased to be an “emerging growth company” on December 31, 2018. As a result, our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting and the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements.

As disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 11, 2019, during the fourth quarter of 2018, management identified material weaknesses in internal control related to ineffective aspects of its overall control environment related to information technology general controls. This material weakness contributed to additional material weaknesses, specifically in the areas of: (i) user access and program change management over certain information technology systems and (ii) controls over monitoring of certain access rights related to processing journal entries, both of which support our financial reporting processes. As a result, management concluded that our internal control over financial reporting was not effective as of December 31, 2018. We have taken steps to implement remediation efforts; however, there can be no assurance that our efforts to remediate the material weaknesses will be successful or will be completed by the end of 2019. Pursuing these remediation efforts will result in additional technology and other expenses.

If we are unable to remediate these material weaknesses, or are otherwise unable to maintain effective internal control over financial reporting or disclosure controls and procedures, our ability to record, process and report financial information accurately, and to prepare financial statements within required time periods, could be adversely affected, which could subject us to litigation or investigations requiring management resources and payment of legal and other expenses and negatively impact the price of our common stock. In addition, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Furthermore, investor perceptions of our company may suffer as a result of the material weaknesses in our internal controls, and this could cause a decline in the market price of our stock. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our stated operating results and harm our reputation. If we are unable to remediate the material weaknesses effectively or efficiently or avoid future material weaknesses, it could harm our operations, financial reporting, or financial results and could result in an adverse opinion on our internal control over financial reporting from our independent registered public accounting firm.

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Item 6. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit Number	Description
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

* The Certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of NanoString Technologies, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

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.

NANOSTRING TECHNOLOGIES, INC.

Date: November 5, 2019

By: /s/ R. Bradley Gray
R. Bradley Gray
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2019

By: /s/ K. Thomas Bailey
K. Thomas Bailey
Chief Financial Officer
(Principal Financial and Accounting Officer)

CERTIFICATIONS

I, R. Bradley Gray, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of NanoString Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2019

/s/ R. Bradley Gray

R. Bradley Gray

President and Chief Executive Officer

(Principal Executive Officer)

CERTIFICATIONS

I, K. Thomas Bailey, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of NanoString Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2019

/s/ K. Thomas Bailey

K. Thomas Bailey

Chief Financial Officer

(Principal Financial and Accounting Officer)

**NANOSTRING TECHNOLOGIES, INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of NanoString Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, R. Bradley Gray, President and Chief Executive Officer (*Principal Executive Officer*) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934;
and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ R. Bradley Gray

R. Bradley Gray

President and Chief Executive Officer

(Principal Executive Officer)

Date: November 5, 2019

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of NanoString Technologies, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

NANOSTRING TECHNOLOGIES, INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of NanoString Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, K. Thomas Bailey, Chief Financial Officer (*Principal Financial and Accounting Officer*) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934;
and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ K. Thomas Bailey

K. Thomas Bailey

Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: November 5, 2019

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of NanoString Technologies, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.