NanoString Technologies Inc
Form 10-Q
November 04, 2016

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

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2016
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	20-0094687
(State or other jurisdiction of incorporation or organization)	(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)

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 ý No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ý No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ý
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

As of November 1, 2016 there were 21,004,015 shares of registrant’s common stock outstanding.

NANOSTRING TECHNOLOGIES, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2016
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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, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$10,468	$21,856
Short-term investments	43,116	27,188
Accounts receivable, net	21,041	19,725
Inventory	11,730	10,138
Prepaid expenses and other	4,385	3,886
Total current assets	90,740	82,793
Restricted cash	143	143
Deferred offering costs	229	181
Property and equipment, net	10,705	9,414
Other assets	440	338
Total assets	$102,257	$92,869
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$2,127	$3,243
Accrued liabilities	9,917	12,181
Deferred revenue, current portion	16,748	5,261
Deferred rent, current portion	5	—
Lease financing obligations, current portion	92	226
Total current liabilities	28,889	20,911
Deferred revenue, net of current portion	26,752	6,486
Deferred rent and other long-term liabilities	6,192	4,257
Long-term debt and lease financing obligations, net of current portion and debt issuance costs	46,980	41,000
Total liabilities	108,813	72,654
Commitment and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value, 15,000 shares authorized; none issued	—	—
Common stock, $0.0001 par value, 150,000 shares authorized; 19,928 and 19,570 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	2	2
Additional paid-in capital	251,399	242,693
Accumulated other comprehensive income (loss)	(10)	(29)
Accumulated deficit	(257,947)	(222,451)
Total stockholders' equity (deficit)	(6,556)	20,215
Total liabilities and stockholders' equity (deficit)	$102,257	$92,869

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

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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,	
	2016	2015	2016	2015
Revenue:				
Product and service	$19,167	$13,910	$48,791	$37,240
Collaboration	4,766	1,783	12,466	3,112
Total revenue	23,933	15,693	61,257	40,352
Costs and expenses:				
Cost of product and service revenue	8,075	6,289	21,816	17,500
Research and development	8,717	5,812	24,724	17,526
Selling, general and administrative	15,607	12,036	46,018	38,984
Total costs and expenses	32,399	24,137	92,558	74,010
Loss from operations	(8,466)	(8,444)	(31,301)	(33,658)
Other income (expense):				
Interest income	104	58	266	181
Interest expense	(1,509)	(1,022)	(4,150)	(3,007)
Other income (expense), net	(179)	(59)	(238)	(281)
Total other income (expense), net	(1,584)	(1,023)	(4,122)	(3,107)
Net loss before provision for income tax	(10,050)	(9,467)	(35,423)	(36,765)
Provision for income tax	(38)	—	(73)	—
Net loss	$(10,088)	$(9,467)	(35,496)	(36,765)
Net loss per share - basic and diluted	$(0.51)	$(0.49)	$(1.79)	$(1.95)
Weighted average shares used in computing basic and diluted net loss per share	19,864	19,431	19,779	18,862

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	$(10,088)	$(9,467)	$(35,496)	$(36,765)
Change in unrealized gain or loss on short-term investments	(37)	25	19	39
Comprehensive loss	$(10,125)	$(9,442)	$(35,477)	$(36,726)

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

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

	Nine Months Ended September 30,	
	2016	2015
Operating activities		
Net loss	$(35,496)	$(36,765)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	2,215	1,420
Stock-based compensation expense	6,504	4,749
Amortization of premium on short-term investments	90	287
Interest accrued on long-term debt	115	—
Conversion of accrued interest to long-term debt	993	815
(Gain) loss on sale of property and equipment	(2)	2
Changes in operating assets and liabilities:		
Accounts receivable, net	(1,320)	(467)
Inventory	(2,713)	(6,769)
Prepaid expenses and other	(532)	634
Other assets	(111)	104
Accounts payable	(1,178)	(857)
Accrued liabilities	(1,775)	(3,013)
Deferred revenue	31,755	87
Deferred rent	1,806	1,011
Net cash provided by (used in) operating activities	351	(38,762)
Investing activities		
Purchases of property and equipment	(2,709)	(1,847)
Proceeds from sale of property and equipment	4	20
Proceeds from sale of short-term investments	3,400	3,000
Proceeds from maturity of short-term investments	29,200	46,178
Purchases of short-term investments	(48,600)	(23,150)
Net cash (used in) provided by investing activities	(18,705)	24,201
Financing activities		
Borrowings under long-term debt agreement	5,000	—
Repayment of lease financing obligations	(192)	(203)
Proceeds from sale of common stock, net	—	12,508
Deferred offering costs	(44)	(137)
Proceeds from issuance of common stock for employee stock purchase plan	1,489	1,296
Proceeds from exercise of stock options	714	546
Net cash provided by financing activities	6,967	14,010
Net decrease in cash and cash equivalents	(11,387)	(551)
Effect of exchange rate changes on cash and cash equivalents	(1)	(37)
Cash and cash equivalents		
Beginning of period	21,856	17,223
End of period	$10,468	$16,635

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

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

1. Description of Business

NanoString Technologies, Inc. (the "Company") was incorporated in the state of Delaware on June 20, 2003. The Company's headquarters are located in Seattle, Washington. The Company's technology 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 markets its proprietary nCounter Analysis System, consisting of instruments and consumables, including its Prosigna Breast Cancer Assay, to academic, government, biopharmaceutical and clinical laboratory customers.

The Company has incurred losses to date and expects to incur additional losses in the foreseeable future. The Company continues to devote the majority of its resources to the growth of its business in accordance with its business plan. The Company's activities have been financed primarily through the sale of equity securities, incurrence of indebtedness and, to a lesser extent, capital leases and other borrowings.

2. Basis of Presentation and 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, 2015 has been derived from the audited consolidated financial statements at that date but does not include all of the 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, 2015. 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 of the 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, 2016 are not necessarily indicative of the results to be expected for the full year or for any other period.

Revenue Recognition

The Company recognizes revenue when (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price to the customer is fixed or determinable and (4) collectability is reasonably

assured. The Company generates the majority of its revenue from the sale of products and services. The Company's products consist of its proprietary nCounter Analysis Systems and related consumables. Services consist of extended warranties and service fees for assay processing. A delivered product or service is considered to be a separate unit of accounting when it has value to the customer on a stand-alone basis. Products or services have value on a stand-alone basis if they are sold separately by any vendor or the customer could resell the delivered product.

Instruments, consumables and in vitro diagnostic kits are considered to be separate units of accounting as they are sold separately and revenue is recognized upon transfer of ownership, which is generally upon shipment. Instrument revenue related to installation and calibration services is recognized when services are rendered by the Company. Such services can also be provided by the Company's distribution partners and other third parties. For instruments sold solely to run Prosigna assays,

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training must be provided prior to instrument revenue recognition. Instrument revenue from leased instruments is recognized ratably over the lease term.

Service revenue is recognized when earned, which is generally upon the rendering of the related services. Service agreements and service fees for assay processing are each considered separate units of accounting as they are sold separately. The Company offers service agreements on its nCounter Analysis Systems for periods ranging from 12 to 36 months after the end of the standard 12-month warranty period. Service agreements are generally separately priced. Revenue from service agreements is deferred and recognized in income on a straight-line basis over the service period.

For arrangements with multiple deliverables, the Company allocates the agreement consideration at the inception of the agreement to the deliverables based upon their relative selling prices. To date, selling prices have been established by reference to vendor specific objective evidence based on stand-alone sales transactions for each deliverable. Vendor specific objective evidence is considered to have been established when a substantial majority of individual sales transactions within the previous 12-month period fall within a reasonably narrow range, which the Company has defined to be plus or minus 15% of the mean sales price of actual stand-alone sales transactions. The Company uses its best estimate of selling price for individual deliverables when vendor specific objective evidence or third-party evidence is unavailable. Allocated revenue is only recognized for each deliverable when the revenue recognition criteria have been met.

The Company enters into collaborative agreements that may generate upfront fees with subsequent milestone payments that may be earned upon completion of development-related milestones. The Company is able to estimate the total cost of services under the arrangements and recognizes collaboration revenue using a 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 and non-contingent amounts contractually due. Changes in estimates of total expected costs are accounted for prospectively as a change in estimate. From period to period, collaboration revenue can fluctuate substantially based on the achievement of development-related milestones.

Recent Accounting Pronouncements

As an “emerging growth company,” the Jumpstart Our Business Startups (“JOBS”) Act allows the Company to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies.

In May 2014, the Financial Accounting Standards Board (“FASB”) issued an Accounting Standards Update (“ASU”) entitled “ASU 2014-09, Revenue from Contracts with Customers.” The standard requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to a customer. This guidance will replace most existing revenue recognition guidance and will become effective for the Company in fiscal year 2018, including interim periods within that reporting period, based on the FASB decision in July 2015 (ASU 2015-14, Revenue from Contracts with Customers - Deferral of the Effective Date) to delay the effective date of the new revenue recognition standard by one year, but providing entities a choice to adopt the standard as of the original effective date. In March 2016, the FASB issued “ASU 2016-08, Principal vs Agent Considerations (Reporting Revenue Gross versus Net)” which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued “ASU 2016-10, Identifying Performance Obligations and Licensing” which clarifies the implementation guidance on identifying performance obligations and the licensing implementation guidance. In May 2016, the FASB issued “ASU 2016-12, Narrow-Scope Improvements and Practical Expedients” which provides practical expedient for contract modifications and clarification on assessing the collectability criterion, presentation of sales taxes, measurement date for noncash consideration and completed contracts at transition. These standards permit the use of either the retrospective or cumulative effect transition method. The Company has not selected a transition

method and is currently evaluating the impact these standards will have on its consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

In August 2014, FASB issued “ASU 2014-15, Presentation of Financial Statements – Going Concern.” The standard requires entities to evaluate for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). The standard will become effective for the Company beginning January 1, 2017.

In July 2015, FASB issued “ASU 2015-11, Inventory – Simplifying the Measurement of Inventory.” The standard requires entities to measure inventory at the lower of cost and net realizable value. The standard will become effective for the

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Company beginning January 1, 2017. The Company does not anticipate adoption of the standard will have a material impact on its consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

In November 2015, FASB issued “ASU 2015-17, Balance Sheet Classification of Deferred Taxes.” The standard requires deferred income tax liabilities and assets be classified as noncurrent in the consolidated balance sheet. The standard will become effective for the Company beginning January 1, 2018. The Company does not anticipate adoption of the standard will have a material impact on its consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

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. The standard requires lessors to classify leases as either sales-type, finance or operating. A sales-type lease occurs if the lessor transfers all of the risks and rewards, as well as control of the underlying asset, to the lessee. If risks and rewards are conveyed without the transfer of control, the lease is treated as a financing lease. If the lessor does not convey risks and rewards or control, an operating lease results. The standard will become effective for the Company beginning January 1, 2019. 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 March 2016, FASB issued “ASU 2016-09, Improvements to Employee Share-Based Payment Accounting” which amends Accounting Standard Codification Topic 718, “Compensation – Stock Compensation”. The standard includes provisions intended to simplify various aspects related to the accounting and presentation for stock-based payments in the financial statements, including the income tax effects of stock-based payments, minimum withholding requirements upon award settlement, and the method of calculating forfeitures in the recognition of stock compensation expense. The standard will become effective for the Company beginning January 1, 2018. 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.

3. 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. Any outstanding stock options and warrants have not been included in the calculation of the 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 and warrants were excluded from the computation of basic and diluted net loss per share for the periods presented because their effect would have been anti-dilutive (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Options to purchase common stock	4,752	4,208	4,665	4,025
Restricted stock units	117	15	106	15
Common stock warrants	483	572	524	572

4. 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 any significant credit losses to date.

The Company had one customer/collaborator that individually represented 11% and 13% of total revenue during the three and nine months ended September 30, 2016, respectively, one customer/collaborator that represented 11% of total revenue during the three months ended September 30, 2015, and no customers that represented more than 10% of total revenue for the nine months ended September 30, 2015. The Company had one customer/collaborator that represented 11% of total accounts

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receivable as of September 30, 2016 and no customers or collaborators that represented more than 10% of total accounts receivable as of December 31, 2015.

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.

5. Short-term Investments

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

Type of securities as of September 30, 2016	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Corporate debt securities	$ 29,811	$ 1	$ (17)	$ 29,795
U.S. government-related debt securities	13,315	7	(1)	13,321
Total available-for-sale securities	$ 43,126	$ 8	$ (18)	$ 43,116

Type of securities as of December 31, 2015	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Corporate debt securities	$ 26,116	$ —	$ (28)	$ 26,088
U.S. government-related debt securities	1,101	—	(1)	1,100
Total available-for-sale securities	$ 27,217	$ —	$ (29)	$ 27,188

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

	September 30, 2016	December 31, 2015
Maturing in one year or less	$ 33,799	$ 27,188
Maturing in one to three years	9,317	—
Total available-for-sale securities	$ 43,116	$ 27,188

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 sheet. The Company has no investments that have been in a continuous unrealized loss position as of September 30, 2016.

The Company invests in securities that are rated investment grade or better. The unrealized losses on investments as of September 30, 2016 and December 31, 2015 were primarily caused by interest rate increases.

The Company reviews the individual securities in its portfolio to determine whether a decline in a security’s fair value below the amortized cost basis is other-than-temporary. The Company determined that as of September 30, 2016, there were no investments in its portfolio that were other-than-temporarily impaired.

6. 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:

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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 and 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.

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

As of September 30, 2016	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market fund	$9,009	$—	$ —	$9,009
Short-term investments:				
Corporate debt securities	—	29,795	—	29,795
U.S. government-related debt securities	—	13,321	—	13,321
Total	$9,009	$43,116	$ —	$52,125

As of December 31, 2015	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market fund	$5,371	$—	$ —	$5,371
Short-term investments:				
Corporate debt securities	—	26,088	—	26,088
U.S. government-related debt securities	—	1,100	—	1,100
Total	$5,371	$27,188	$ —	$32,559

7. Inventory

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

	September 30, 2016	December 31, 2015
Raw materials	$ 4,999	$ 3,575
Work in process	3,443	2,895
Finished goods	3,288	3,668
	$ 11,730	$ 10,138

8. Long-term Debt and Lease Financing Obligations

In April 2014, the Company entered into a term loan agreement under which it could borrow up to $45.0 million, including an option to defer payment of a portion of the interest that would accrue on the borrowing under the term loan agreement. Upon initial closing, the Company borrowed $20.0 million, and in October 2014, the Company borrowed an additional $10.0 million under the term loan agreement.

In October 2015, the Company amended the term loan agreement to, among other provisions, increase the maximum borrowing capacity to $60.0 million (excluding deferred interest), reduce the applicable interest rate from 12.5% to 12.0%, extend the interest-only period through March 2021, and extend the final maturity to March 2022. Under the

amended agreement, borrowings accrue interest at 12.0% annually, 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 Company has elected to exercise the option to defer payment of interest and has recorded $2.5 million of deferred interest through September 30, 2016. In December 2015, the Company borrowed an additional $10.0 million under the terms of the amended agreement. In June 2016, the Company borrowed an additional $5.0 million. At its option, the Company may borrow up to an additional $15.0

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million through December 31, 2016. Total borrowings and deferred interest under the amended term loan agreement were $47.5 million and $41.5 million as of September 30, 2016 and December 31, 2015, respectively.
Under the amended term loan agreement, the Company may pay interest-only for the first seven years of the term and principal payments are due in four equal installments during the eighth year of the term. The Company has the option to prepay the term loan, in whole or part, at any time subject to payment of a redemption fee of up to 4%, which declines 1% annually, with no redemption fee payable if prepayment occurs after the fourth year of the loan. In addition, a facility fee equal to 2.0% of the amount borrowed plus any accrued interest is payable at the end of the term or when the loan is repaid in full. A long-term liability of $1.1 million is being accreted using the effective interest method for the facility fee over the term of loan agreement. Obligations under the term loan agreement are collateralized by substantially all of the Company's assets.

The term loan agreement contains customary conditions to borrowings, events of default and negative covenants, including 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 term loan agreement also includes a $2.0 million minimum liquidity covenant and minimum revenue-based financial requirements, specifically $70.0 million for 2016 with annual increases of $15.0 million for each subsequent fiscal year thereafter. 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 revenue and the minimum revenue requirement. The Company was in compliance with its financial covenants as of September 30, 2016.

Long-term debt and lease financing obligations, consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Term loans payable	$47,480	$41,487
Lease financing obligations	92	284
Total long-term debt and lease financing obligations	47,572	41,771
Unamortized debt issuance costs	(500)	(545)
Current portion of lease financing obligations	(92)	(226)
Long-term debt and lease financing obligations, net of debt issuance costs and current portion	$46,980	$41,000

Scheduled future principal payments for outstanding debt and lease financing obligations were as follows at September 30, 2016 (in thousands):

Years Ending December 31,	
Remainder of 2016	$34
2017	58
2018	—
2019	—
2020	—
Thereafter	47,480
	$47,572

9. Collaboration Agreements

The Company uses a proportional performance model to recognize collaboration revenue over the Company's performance period for each collaboration agreement. 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 limited to cash received and amounts contractually due.

Changes in estimates of total expected costs are accounted for prospectively as a change in estimate. All amounts received or due are classified as collaboration revenue as they are earned.

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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 assay for use in screening patients with Diffuse Large B-Cell Lymphoma. The Company is eligible to receive payments totaling up to $45.0 million, of which $5.8 million was received as an upfront payment upon delivery of certain information to Celgene, $17.0 million is for potential success-based development and regulatory milestones, and the remainder is for potential commercial payments in the event sales of the test do not exceed certain pre-specified minimum annual revenue during the first three years following regulatory approval. In October 2015, the parties amended the collaboration agreement to include additional countries to conduct clinical trials and in return the Company received an upfront payment of $1.6 million in December 2015.

The Company will retain all commercial rights to the diagnostic test developed under this collaboration, subject to certain backup rights granted to Celgene to commercialize the diagnostic test in a particular country if the Company elects to cease distribution or elects not to distribute the diagnostic in such country. Assuming success in the clinical trial process, and subject to regulatory approval, the Company will market and sell the diagnostic assay.

The Company achieved and was paid for milestones totaling $6.0 million during 2014. 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. Accordingly, the Company is not able to reasonably estimate when, if at all, any additional milestone payments may be payable to the Company by Celgene.

The Company recognized collaboration revenue related to the Celgene agreement of $0.6 million and $0.2 million for the three months ended September 30, 2016 and 2015, respectively, and $2.3 million and $1.2 million for the nine months ended September 30, 2016 and 2015, respectively. At September 30, 2016, the Company had recorded $6.1 million of deferred revenue related to the Celgene collaboration, of which $1.8 million is estimated to be recognizable as revenue within one year.

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-1therapy, KEYTRUDA. Under the terms of the collaboration agreement, the Company was eligible to receive up to $4.0 million, of which $2.0 million was received as an upfront payment in July 2015 and $1.9 million was received as development payments during 2015. In February 2016, the Company expanded its collaboration with Merck by entering into a new development collaboration agreement to clinically develop and commercialize a novel diagnostic test, based on an optimized gene expression signature, to predict response to KEYTRUDA in multiple tumor types. Under the terms of the new collaboration agreement, the Company received $12.0 million upfront as a technology access fee, will receive additional development funding, and is eligible to receive up to $12.0 million of near-term preclinical milestone payments, of which $8.5 million was achieved and received during the nine months ended September 30, 2016, and other potential downstream regulatory milestone payments.

The Company recognized collaboration revenue of $2.2 million and $6.1 million related to the Merck agreement for the three and nine months ended September 30, 2016, respectively, and $1.6 million and $1.8 million for the three and nine months ended September 30, 2015, respectively. As of September 30, 2016, the Company had recorded $22.4 million of deferred revenue related to the Merck collaboration, $7.7 million of which is estimated to be recognized as

revenue within one year.

Medivation, Inc. and Astellas Pharma, Inc.
In January 2016, the Company entered into a collaboration agreement with Medivation, Inc. ("Medivation") and Astellas Pharma Inc. (“Astellas”) to pursue the translation of a novel gene expression signature algorithm discovered by Medivation into a companion diagnostic assay using the nCounter Analysis System. Under the terms of the collaboration agreement, the Company will modify its PAM50-based Prosigna Breast Cancer Assay for potential use as a companion diagnostic test for XTANDI (enzalutamide) for triple negative breast cancer. XTANDI is currently approved by the U.S. Food and Drug Administration for the treatment of metastatic castration-resistant prostate cancer.

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The modified Prosigna test will be based upon data from a Phase 2 trial conducted by Medivation and Astellas that evaluated enzalutamide in patients with triple negative breast cancer. Under the terms of the collaboration agreement, the Company will be responsible for developing and validating the diagnostic test and, if the parties thereafter determine to proceed, will also be responsible for seeking regulatory approval for and commercializing the test. During 2016, the Company received $6.0 million upfront for technology access, $6.0 million in pre-clinical milestones, and is eligible to receive up to $10.0 million in development funding over the term of the agreement, in addition to other potential downstream milestone payments.

The Company recognized collaboration revenue of $1.5 million and $3.6 million related to the Medivation/Astellas agreement for the three and nine months ended September 30, 2016, respectively, and none for the three and nine months ended September 30, 2015. As of September 30, 2016, the Company had recorded $10.8 million of deferred revenue related to the Medivation/Astellas collaboration, $4.1 million of which is estimated to be recognized as revenue within one year.

10. Commitments and Contingencies

From time to time, the Company may become involved in litigation relating to claims arising from the ordinary course of business. 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 operation, financial condition or cash flows.

11. 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 Systems. The Company has one sales force that sells these systems to both research and clinical testing labs, and its nCounter Elements reagents can be used for both research and diagnostic testing. In addition, the Company's Prosigna Breast Cancer Assay is marketed to clinical laboratories. The Company has also entered into collaboration agreements with Celgene, Merck and Medivation and Astellas.

The following table of total revenue is based on the geographic location of the Company's customers, distributors and collaborators. For sales to distributors, their geographic location may be different from the geographic locations of the ultimate end user. Americas consists of the United States, Canada, Mexico and South America; and Asia Pacific includes Japan, China, South Korea, Singapore, Malaysia and Australia. Total revenue by geography was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Americas	$16,784	$10,929	$43,188	$26,584
Europe & Middle East	4,934	3,400	12,667	9,355
Asia Pacific	2,215	1,364	5,402	4,413
Total revenue	$23,933	$15,693	$61,257	$40,352

Total revenue in the United States was $16.2 million and $9.6 million for the three months ended September 30, 2016 and 2015, respectively, and $41.5 million and $24.5 million for the nine months ended September 30, 2016 and 2015, 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.

12. Subsequent Event

In October 2016, the Company sold 1,062,330 shares of its common stock through the "at the market" equity offering program under its sales agreement with Cowen & Company ("Cowen") for total gross proceeds of $21.2 million. The net proceeds from the sale of the shares, after deducting Cowen's commission and other expenses of the offering, were approximately $20.4 million. After completion of this sale, approximately $5.8 million of the Company's common stock remained available for sale under the "at the market" equity offering program.

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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 are identified by words such as "believe," "anticipate," "expect," "intend," "plan," "will," "may," and other similar expressions. 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 and operating and net loss;
- the implementation of our business model, strategic plans for our business and future product development plans;
- the regulatory regime and our ability to secure regulatory clearance or approval or reimbursement for the clinical use of our products, domestically and internationally;
- our ability to successfully commercialize Prosigna, our first in vitro diagnostic product;
- 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 expectations regarding the 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.

Overview

We develop, manufacture and sell robust, intuitive products that unlock scientifically valuable and clinically actionable biologic information from minute amounts of tissue. Our nCounter Analysis Systems directly profile hundreds of molecules simultaneously using a novel barcoding technology that is powerful enough for use in research, yet simple enough for use in clinical laboratories worldwide. We market instruments and related consumables to researchers in academic, government, and biopharmaceutical laboratories for use in understanding fundamental biology and the molecular basis of disease and to clinical laboratories and medical centers for diagnostic use. As of September 30, 2016, we have an installed base of approximately 450 systems, which our customers have used to

publish over 1,300 peer-reviewed papers. As researchers using our systems discover new biologic insights to improve clinical decision-making, these discoveries can be translated and validated as diagnostic tests, either using our nCounter Elements reagents or, in certain situations, by developing in vitro diagnostic assays. For example, our first molecular diagnostic product is the Prosigna Breast Cancer Assay, or Prosigna, which provides an assessment of a patient's risk of recurrence for breast cancer. In addition, we are collaborating with several biopharmaceutical companies to develop companion diagnostics, in vitro diagnostic tests to be used to identify which patients are most likely to respond to a particular drug therapy.

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We derive a substantial majority of our revenue from the sale of our products to life science researchers, which consist of our nCounter instruments and related proprietary consumables, which we call CodeSets, nCounter Elements reagents and Master Kits. After buying an nCounter Analysis System, research customers purchase consumables from us for use in their experiments. Our instruments are designed to work only with our consumable products. Accordingly, as the installed base of our instruments grows, we expect recurring revenue from consumable sales to become an increasingly important driver of our operating results. We also derive revenue from processing fees related to proof-of-principle studies we conduct for potential customers and extended service contracts for our nCounter Analysis Systems. Additionally, we generate revenue through development collaborations.

We use third-party contract manufacturers to produce the instruments comprising our nCounter Analysis Systems. We manufacture consumables at our Seattle, Washington facility. This operating model is designed to be capital efficient and to scale efficiently as our product volumes grow. We focus a substantial portion of our resources on developing new technologies, products and solutions. We sell our products through our own sales force in the United States, Canada, Singapore, Israel and certain European countries. We sell through distributors in other parts of the world.

Our total revenue has increased to $61.3 million for the nine months ended September 30, 2016 from $40.4 million for the first nine months of 2015. Historically, we have generated a substantial majority of our revenue from sales to customers in North America; however, we expect sales in other regions to increase over time. We have never been profitable and had net losses of $35.5 million and $36.8 million for the nine months ended September 30, 2016 and 2015, respectively, and as of September 30, 2016 our accumulated deficit was $257.9 million.

In January 2016, we entered into a collaboration with Medivation, Inc. and Astellas Pharma Inc. to pursue the translation of a novel gene expression signature algorithm discovered by Medivation into a companion diagnostic assay using the nCounter Analysis System. Under the terms of the collaboration agreement, we will modify our PAM50-based Prosigna Breast Cancer Assay for potential use as a companion diagnostic test for XTANDI (enzalutamide) for triple negative breast cancer. We will be responsible for developing and validating the diagnostic test and, if the parties thereafter determine to proceed, we will also be responsible for seeking regulatory approval for and commercializing the test. We received a $6.0 million upfront payment for technology access, $6.0 million of near-term preclinical milestone payments, and are eligible to receive up to $10.0 million in development funding over the term of the agreement, in addition to other potential downstream milestone payments.

In February 2016, we expanded our collaboration with Merck by entering into a new development collaboration agreement to clinically develop and commercialize a novel diagnostic test, based on an optimized gene expression signature, to predict response to KEYTRUDA in multiple tumor types. Under the terms of the new collaboration agreement, we received a $12.0 million upfront technology access fee and will receive additional development funding, and are eligible to receive up to $12.0 million of near-term preclinical milestone payments, of which $8.5 million was achieved and received during the nine months ended September 30, 2016, and other potential downstream regulatory milestone payments.

Results of Operations

Revenue

Our product revenue consists of sales of our nCounter Analysis Systems and related consumables, including Prosigna in vitro diagnostic kits. Service revenue consists of fees associated with extended service agreements and conducting proof-of-principle studies. Our customer base is primarily composed of academic institutions, government laboratories, biopharmaceutical companies and clinical laboratories that perform analyses or testing using our nCounter Analysis Systems and purchase related consumables. Collaboration revenue is derived primarily from our collaborations with Celgene, Merck and Medivation and Astellas.

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 user. Americas consists of the United States, Canada, Mexico and South America; and Asia Pacific includes Japan, China, South Korea, Singapore, Malaysia and Australia.

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	Three Months Ended September 30,			Nine Months Ended September 30,		
	2016	2015	% Change	2016	2015	% Change
	(In thousands)			(In thousands)		
Americas	$16,784	$10,929	54 %	$43,188	$26,584	62 %
Europe & Middle East	4,934	3,400	45	12,667	9,355	35
Asia Pacific	2,215	1,364	62	5,402	4,413	22
Total	$23,933	$15,693	53	$61,257	$40,352	52

The following table reflects the breakdown of revenue.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2016	2015	% Change	2016	2015	% Change
	(In thousands)			(In thousands)		
Product revenue:						
Instruments	$6,898	$4,256	62 %	$16,744	$13,026	29 %
Consumables	10,303	8,352	23	26,579	20,699	28
In vitro diagnostic kits	1,147	662	73	3,142	1,635	92
Total product revenue	18,348	13,270	38	46,465	35,360	31
Service revenue	819	640	28	2,326	1,880	24
Total product and service revenue	19,167	13,910	38	48,791	37,240	31
Collaboration revenue	4,766	1,783	167	12,466	3,112	301
Total revenue	$23,933	$15,693	53	$61,257	$40,352	52

The growth in instrument revenue was driven by an increase in the number of instruments sold for both the three and nine months ended September 30, 2016 as compared to the same period in 2015. For the three and nine months ended September 30, 2016, the increase in instrument revenue was partially offset by the lower selling price of the new nCounter SPRINT Profiler system, which was anticipated. Approximately half of the systems sold during the three and nine months ended September 30, 2016 were SPRINT Profilers, consistent with our expectations. The increase in consumables revenue for both the three and nine month periods was driven by growth in our installed base of instruments. Revenue from in vitro diagnostic kits increased for both the three and nine month periods as sales of Prosigna kits continued to grow as more laboratories have adopted the test and coverage by third-party payers has increased since we launched the product in late 2013. The increase in service revenue for both the three and nine month periods was primarily related to an increase in the number of instruments covered by service agreements. The increase in collaboration revenue for both the three and nine month periods was primarily due to the impact of our new collaborations with Merck and Medivation and Astellas, and the achievement of $14.5 million of milestones during the nine months ended September 30, 2016, a proportional amount of which was reflected as collaboration revenue over the same period.

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.

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	Three Months Ended September 30,			Nine Months Ended September 30,		
	2016	2015	% Change	2016	2015	% Change
	(Dollars in thousands)			(Dollars In thousands)		
Cost of product and service revenue	$8,075	$6,289	28 %	$21,816	$17,500	25 %
Product and service gross profit	$11,092	$7,621	46	$26,975	$19,740	37
Product and service gross margin	58 %	55 %		55 %	53 %	

The increase in cost of product and service revenue for the three and nine months ended September 30, 2016 was related to the overall increased volume of products and services sold. The increase in gross margin on product and service revenue for the three-month period was primarily due to improved gross margin on consumable revenue resulting from efficiencies of scale and a favorable mix of consumable products sold during the quarter, in addition to a reduced technology royalty rate across all products. For the nine-month period, the same factors contributed to the improvement in gross margin, but to a lesser extent. 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 (including the cost of tissue samples) 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.

Given the relatively small size of our research and development staff and the limited number of active projects at any given time, we have found that, to date, it has been effective for us to manage our research and development activities on a departmental basis. Accordingly, we do not require employees to report their time by project, nor do we allocate our research and development costs to individual projects, other than for collaborations. Research and development expense by functional area was as follows:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2016	2015	% Change	2016	2015	% Change
	(In thousands)			(In thousands)		
Core nCounter platform technology	$2,807	$1,496	88 %	$7,126	$4,894	46 %
Manufacturing process development	651	421	55	1,900	1,313	45
Life sciences products and applications	1,504	1,157	30	4,623	3,561	30
Diagnostic product development	1,750	946	85	4,765	2,604	83
Clinical, regulatory and medical affairs	1,043	1,109	(6)	3,510	3,409	3
Facility allocation	962	683	41	2,800	1,745	60
Total	$8,717	$5,812	50	$24,724	$17,526	41

The increase in research and development expense for the three and nine months ended September 30, 2016 was primarily attributable to increased personnel-related expenses and supply costs supporting the advancement of our biopharma diagnostic collaborations and technology and product development activities, including 3D Biology, digital immunohistochemistry (IHC) and Hyb & Seq sequencing chemistry. In addition, facility costs increased due to expansion of our leased space for research and development activities. These increases were partially offset by decreases in engineering and consulting costs largely for the development of our nCounter SPRINT Profiler in 2015, as well as clinical trial costs related to Prosigna development activities.

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Selling, General and Administrative Expense

Selling, general and administrative expense consists primarily of costs for our sales and marketing, finance, legal, human resources, information technology, business development and general management functions, as well as professional services, such as legal, consulting and accounting services. 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 as we continue to introduce new products, broaden our customer base and grow our business. Also, legal, accounting and compliance costs are expected 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,		
	2016	2015	% Change	2016	2015	% Change
	(In thousands)			(In thousands)		
Selling, general and administrative expense	$15,607	$12,036	30 %	$46,018	$38,984	18 %

The increase in selling, general and administration expense for the three and nine months ended September 30, 2016 was primarily attributable to personnel-related costs, an increase in legal and other professional fees, and increased state and local gross receipts-based taxes related to amounts received under our collaboration agreements.

Other Income (Expense)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2016	2015	% Change	2016	2015	% Change
	(In thousands)			(In thousands)		
Interest income	$104	$58	79 %	$266	$181	47 %
Interest expense	(1,509)	(1,022)	48	(4,150)	(3,007)	38
Other income (expense), net	(179)	(59)	203	(238)	(281)	(15)
Total other income (expense), net	$(1,584)	$(1,023)	55	$(4,122)	$(3,107)	33

For the three and nine months ended September 30, 2016, interest expense increased primarily due to an increase in outstanding long-term debt borrowings, from $31.2 million as of September 30, 2015 to $47.5 million as of September 30, 2016.

Liquidity and Capital Resources

As of September 30, 2016, we had cash, cash equivalents and short-term investments totaling $53.6 million. We believe our existing cash, cash equivalents and short-term investments, together with additional funding available to us under our existing term loan agreement, 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: the nature and timing of any additional companion diagnostic development collaborations we may establish; market acceptance of our products; 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.

If we require additional funds in the future, 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 collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets, or delay, reduce the scope of or eliminate some or all of our development programs. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or

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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.

Sources and Uses of Funds

Since inception, we have financed our operations primarily through the sale of equity securities and, to a lesser extent, from borrowings. We generated cash from operations for the nine months ended September 30, 2016 as a result of receipts under our collaboration agreements. However, the timing and amount of such receipts in the future are unpredictable and therefore we expect to require cash to fund our operations for at least the next several years.

In May 2015, 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 total sales proceeds. Under the sales agreement, we sold 960,400 shares during 2015 for net proceeds of $12.5 million. In October 2016, we sold 1,062,330 shares for net proceeds of approximately $20.4 million. The sales agreement allows us to set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales may be made, limits on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Following the October 2016 issuance, approximately $5.8 million of common stock is available to be sold under the “at the market” equity offering program. We cannot guarantee that we will be able to sell the remaining available shares under the sales agreement under favorable market conditions.

In April 2014, we entered into a term loan agreement under which we may borrow up to $45.0 million, including an option to defer payment of a portion of the interest that would accrue on the borrowing under the term loan agreement. Upon initial closing, we borrowed $20.0 million and in October 2014, we borrowed an additional $10.0 million under the term loan agreement.

In October 2015, we amended our term loan agreement to, among other provisions, increase the maximum borrowing capacity to $60.0 million (excluding accrued interest), reduce the applicable interest rate from 12.5% to 12.0%, extend the interest-only period through March 2021, and extend the final maturity to March 2022. Under the amended agreement, borrowings accrue interest at 12.0% annually, 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. We have elected to exercise the option to defer a portion of the interest and we have recorded $2.5 million of deferred interest through September 30, 2016. In December 2015, we borrowed an additional $10 million under the terms of the amended agreement and in June 2016, we borrowed an additional $5 million. At our option, we may borrow up to an additional $15 million through December 31, 2016. Total borrowings under the amended term loan agreement were $47.5 million as of September 30, 2016.

Under the amended term loan agreement, we may pay interest-only for the first seven years of the term and principal payments are due in four equal installments during the eighth year of the term. We have the option to prepay the term loan, in whole or part, at any time subject to payment of a redemption fee of up to 4%, which declines 1% annually, with no redemption fee payable if prepayment occurs after the fourth year of the loan. In addition, a facility fee equal to 2.0% of the amount borrowed plus any deferred interest is payable at the end of the term or when the loan is repaid in full. A long-term liability of $1.1 million is being accreted using the effective interest method for the facility fee over the term of the loan agreement. Obligations under the term loan agreement are collateralized by substantially all of our assets.

The term loan agreement contains customary conditions to borrowings, events of default and negative covenants, including 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 term loan agreement also includes a $2.0 million minimum liquidity covenant and minimum revenue-based financial requirements, specifically $70.0 million for 2016 with annual increases of $15 million for each subsequent fiscal year thereafter. If our actual revenue are 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 revenue and the minimum revenue requirement. We were in compliance with our covenants as of September 30, 2016.

Our principal use of cash is funding our operations, and other working capital requirements. 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 growing our existing research business and in developing Prosigna and preparing it for commercialization. Through December 31, 2015, our cash used in operating activities increased from previous years. For the nine months ended September 30, 2016, we generated operating cash from receipts under our collaboration agreements, however, the timing and amount of such receipts in the future are unpredictable

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and therefore we expect to require cash to fund our operations. Our operating cash requirements may increase in the future as we (1) increase sales and marketing activities to expand the installed base of our nCounter Analysis Systems among research customers and clinical laboratories and continue to promote consumable usage, including Prosigna, (2) commercialize, and conduct studies to expand the clinical utility of Prosigna and develop new diagnostic tests and (3) develop new applications, chemistry and instruments for our nCounter platform, and we cannot be certain our revenue will grow sufficiently to offset our operating expense increases.

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,	
	2016	2015
Cash provided by (used in) operating activities	$351	$(38,762)
Cash (used in) provided by investing activities	(18,705)	24,201
Cash provided by financing activities	6,967	14,010

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 generally outweighed 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 as we have expanded our business in the United States and other markets and this will likely continue for the foreseeable future.

For the nine months ended September 30, 2016, we had net cash provided by operating activities due primarily to $40.2 million in payments received from our collaborators, Merck and Medivation and Astellas. Net cash provided by operating activities consisted of our net loss of $35.5 million, which was more than offset by $25.9 million of changes in our operating assets and liabilities and $9.9 million of net non-cash items, such as stock-based compensation, depreciation and amortization, deferred interest converted to principal for the term loan, and amortization of premium on short-term investments.

Net cash used in operating activities for the nine months ended September 30, 2015 largely consisted of our net loss of $36.8 million and $9.3 million of changes in our operating assets and liabilities. These uses were partially offset by $7.3 million of net non-cash items, such as depreciation and amortization, amortization of premium on short-term investments, deferred interest converted to principal for the term loan and stock-based compensation.

Investing Cash Flows

Our most significant investing activities for the nine months ended September 30, 2016 and 2015 were related to the purchase and sale of short-term investments. Because we manage our cash balances and usage based on the total of our cash, cash equivalents and short-term investments, we do not consider cash flows solely related to our short-term investments to be important to an understanding of our liquidity and capital resources.

In the nine months ended September 30, 2016 and 2015, we purchased $2.7 million and $1.8 million, respectively, of property and equipment 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 the incurrence of indebtedness.

Net cash provided by financing activities for the nine months ended September 30, 2016 consisted of proceeds of $5.0 million under the amended term loan agreement, Employee Stock Purchase Plan proceeds of $1.5 million and $0.7 million of proceeds from the exercise of stock options. These proceeds were partially offset by the repayment of lease financing obligations of $0.2 million.

Net cash provided by financing activities for the nine months ended September 30, 2015 consisted of net proceeds of $12.5 million from the sale of our common stock, Employee Stock Purchase Plan proceeds of $1.3 million and $0.5 million of

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proceeds from the exercise of stock options. These proceeds were partially offset by the repayment of lease financing obligations of $0.2 million and deferred offering costs of $0.1 million.

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 generally accepted accounting principles in the United States of America, or U.S. 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 U.S. 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 significant 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, 2016 compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC on March 11, 2016.

Recent Accounting Pronouncements

As an “emerging growth company” the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies.

In May 2014, the Financial Accounting Standards Board, or FASB issued an accounting standards update entitled, or ASU, “ASU 2014-09, Revenue from Contracts with Customers.” The standard requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to a customer. This guidance will replace most existing revenue recognition guidance and will become effective for us in fiscal year 2018, including interim periods within that reporting period, based on the FASB decision in July 2015 (ASU 2015-14, Revenue from Contracts with Customers - Deferral of the Effective Date) to delay the effective date of the new revenue recognition standard by one year, but providing entities a choice to adopt the standard as of the original effective date. In March 2016, the FASB issued “ASU 2016-08, Principal vs Agent Considerations (Reporting Revenue Gross versus Net)” which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued “ASU 2016-10, Identifying Performance Obligations and Licensing” which clarifies the implementation guidance on identifying performance obligations and the licensing implementation guidance. In May 2016, the FASB issued “ASU 2016-12, Narrow-Scope Improvements and Practical Expedients” which provides practical expedient for contract modifications and clarification on assessing the collectability criterion, presentation of sales taxes, measurement date for noncash consideration and completed contracts at transition. These standards permit

the use of either the retrospective or cumulative effect transition method. We have not selected a transition method and we are currently evaluating the impact these standards will have on our consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

In August 2014, FASB issued "ASU 2014-15, Presentation of Financial Statements – Going Concern." The standard requires entities to evaluate for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). The standard will become effective for us beginning January 1, 2017.

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In July 2015, FASB issued “ASU 2015-11, Inventory – Simplifying the Measurement of Inventory.” The standard requires entities to measure inventory at the lower of cost and net realizable value. The standard will become effective for us beginning January 1, 2017. We do not anticipate the adoption will have a material impact on our consolidated results of operations, financial condition, cash flows, and financial statement disclosures.
In November 2015, FASB issued “ASU 2015-17 - Balance Sheet Classification of Deferred Taxes.” The standard required deferred income tax liabilities and assets be classified as noncurrent in our consolidated balance sheet. The standard is effective for us beginning January 1, 2018. We do not anticipate the adoption will have a material impact on our consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

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. The standard requires lessors to classify leases as either sales-type, finance or operating. A sales-type lease occurs if the lessor transfers all of the risks and rewards, as well as control of the underlying asset, to the lessee. If risks and rewards are conveyed without the transfer of control, the lease is treated as a financing lease. If the lessor does not convey risks and rewards or control, an operating lease results. The standard will become effective for us beginning January 1, 2019. We are currently assessing the impact adoption of this standard will have on our consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

In March 2016, FASB issued “ASU 2016-09, Improvements to Employee Share-Based Payment Accounting” which amends Accounting Standard Codification Topic 718, “Compensation – Stock Compensation”. The standard includes provisions intended to simplify various aspects related to the accounting and presentation for stock-based payments in the financial statements, including the income tax effects of stock-based payments, minimum withholding requirements upon award settlement, and the method of calculating forfeitures in the recognition of stock compensation expense. The standard will become effective for us beginning January 1, 2018. We do not anticipate adoption of the standard will have a material impact on our consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to various market risks, including changes in interest rates and foreign currency exchange 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 1% decline in interest rates, occurring on October 1, 2016 and sustained throughout the period ended September 30, 2017, would not be material.

As of September 30, 2016, the principal outstanding under our term borrowings was $47.5 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

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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.

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.

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, our disclosure controls and procedures were, in design and operation, effective.

(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, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent limitation on the effectiveness of internal control.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, 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. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

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.

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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 $35.5 million and $36.8 million for the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, we had an accumulated deficit of $257.9 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. In addition, 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. Our products 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.

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 a short period of time. We may not achieve similar growth rates in future periods. 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, development and commercialization of the Prosigna Breast Cancer Assay, or Prosigna, and other future diagnostic products worldwide are key elements of our growth strategy and have required us to hire and retain additional sales and marketing, medical, regulatory, manufacturing and quality assurance personnel. If we do not successfully generate demand for our diagnostic products 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.

Our current customer base is primarily composed of academic and government research laboratories, biopharmaceutical companies and clinical 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. Furthermore, 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. Attracting new customers and introducing new applications requires substantial time and expense. Any failure to expand our existing customer base, or launch new applications, would adversely affect our ability to improve our operating results.

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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;
- market-driven pressures to consolidate operations and reduce costs; and
- market acceptance of relatively new technologies, such as ours.

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. 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. Furthermore, from time-to-time, we may lease instruments or place instruments under reagent rental agreements, wherein a customer does not purchase an instrument upfront but instead pays a rental fee associated with each purchase of reagents. An increase in instruments placed under these lease or reagent rental agreements may reduce the number of instruments we would otherwise sell in any period. 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.

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 exclusive distribution agreements for our nCounter Analysis Systems and related consumable products within parts of Europe, the Middle East, Africa, Asia Pacific and South America. 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 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.

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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 intend to 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 health care 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, 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.

Our strategy to seek to enter into strategic collaborations and licensing arrangements with third parties to develop diagnostic tests 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. 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 collaborations with Merck and Medivation Inc. and Astellas Pharma Inc. to develop companion diagnostic tests, our partners have licensed the technology for such tests to us. We intend to enter into more such arrangements with our research customers and other researchers, including biopharmaceutical companies, for development of future diagnostic products. However, there is no assurance that we will be successful in doing so. 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. 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. Potential collaborators or licensors may elect not to work with us based upon their assessment of our financial, regulatory or intellectual property position. Even if we establish new relationships, they may never result in the successful development or commercialization of future tests.

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 we develop.

Few research and development projects result in successful commercial products, and success in early clinical studies often is not replicated in later studies. For example, even though the results of our clinical studies of Prosigna were favorable, there is no guarantee that any future studies will be successful. 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 March 2014, we entered into our first companion diagnostic collaboration with Celgene Corporation to develop an in vitro diagnostic assay to be used for subtyping certain lymphoma patients. In May 2015, we entered into a clinical research collaboration agreement with Merck to develop an assay that could become the subject of an additional companion diagnostic collaboration. In February 2016, we expanded our collaboration with Merck by entering into a new development collaboration agreement to clinically develop and commercialize a novel diagnostic test, based on an optimized gene expression signature, to predict response to KEYTRUDA in multiple tumor types. In January 2016, we announced a companion diagnostic

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collaboration with Medivation Inc. and Astellas Pharma Inc. to modify our Prosigna Breast Cancer Assay for potential use as a companion diagnostic test for enzalutamide for triple negative breast cancer. We intend to enter into additional similar collaborations over time. The success of the development programs for such assays will be dependent on the success of the related drug trials conducted by our collaborators. There is no guarantee that those clinical trials will be successful and, as a result, we may expend considerable time and resources developing in vitro diagnostic assays that cannot gain regulatory approval. Although we expect such collaborations to provide funding to cover our costs of development, failure of these clinical trials would reduce our prospects for introducing new diagnostic products and would adversely impact our growth prospects and future operating results.

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, 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 acquire or invest in businesses, products and technologies, including new licensing arrangements for new products.

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, our stockholders may experience dilution. For example, we have a sales agreement with Cowen that permits sales of up to $40.0 million worth of shares of our common stock, from time to time, through an “at the market” equity offering program under which Cowen acts as sales agent. As of October 2016, we have sold an aggregate of 2,022,730 shares of common stock for total gross proceeds of $34.2 million (including the sale in October 2016 of 1,062,330 shares for gross proceeds of $21.2 million) and have approximately $5.8 million worth of shares of our common stock remained available for sale under the “at the market” equity offering program. 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 collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we do not have, or are 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.

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 September 2015, the Department of Health and Human

Services, or HHS, issued a proposed rule that would modify informed consent requirements. This proposed rule, if finalized as drafted, could make it more expensive and difficult to obtain banked specimens. If we are not able 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.

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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 diagnostics 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, or qPCR, as well as newer technologies such as next generation sequencing. We believe our principal competitors in the life sciences research market are Agilent Technologies, Becton-Dickinson, Bio-Rad, Bio-Techne, Fluidigm, HTG Molecular Diagnostics, Illumina, Luminex, Merck Millipore, O-Link, Perkin Elmer, Qiagen, RainDance Technologies, Roche Applied Science, Thermo Fisher Scientific, and WaferGen Biosystems. In addition, there are a number of new market entrants in the process of developing novel technologies for the life sciences market.

We also compete with commercial diagnostics 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 NeoGenomics, which also offer services by means of centralized laboratories that profile gene or protein expression in breast cancer. In Europe, we also face regional competition from Myriad Genetics, which recently acquired Sividon Diagnostics and its product EndoPredict, a distributed test for breast cancer recurrence. Myriad Genetics has announced its intent to begin selling EndoPredict in the United States after obtaining any necessary regulatory approvals.

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
- 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. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

We have limited experience in marketing and selling our diagnostic products to clinical laboratories, and if we are unable to successfully commercialize our products, our business may be adversely affected.

We have limited experience marketing and selling our diagnostic products to clinical laboratories. Our sales of Prosigna will depend in large part on our ability to successfully market to oncologists and other healthcare providers. Because we have limited experience in marketing and selling our products in the diagnostics market, our ability to forecast demand, the infrastructure required to support such demand and the sales cycle to diagnostics customers is unproven. In February 2015, we combined our two separate sales teams into a single organization selling our entire suite of products, targeted primarily toward major academic medical centers and biopharmaceutical companies. If we are not able to maintain an efficient and effective

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sales organization targeting these markets, our business and operating results will be adversely affected. If we are unable to market and sell our products effectively to clinical laboratories, our ability to sell diagnostic products, including Prosigna, will be adversely affected.

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 of new products typically requires new scientific discoveries or advancements and complex technology and engineering. 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 or services and satisfactory technical performance of such components or assembled products. If we do not achieve the required technical specifications, successfully manage new product development processes, or development work 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.

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. In July 2015 we commercially launched a new version of our nCounter Analysis System, the nCounter SPRINT Profiler, that is smaller and less expensive than the previous version. 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 very 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 September 2015, we launched our first 3D Biology application, a new product that allows users to simultaneously measure gene and protein expression from a single sample. We plan to launch additional 3D Biology applications in the future that will also include measurement of DNA mutations. 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 methods of genomic analysis. Also, in 2015, we commercially launched a new version of our nCounter Analysis system for research, the nCounter SPRINT Profiler. 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, 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

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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, 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. Any unforeseen manufacturing problems, such as contamination of our facility, equipment malfunction, or failure to strictly follow procedures or meet specifications, could result in delays or shortfalls in production of our consumable products. Identifying and resolving the cause of any such manufacturing 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.

In addition, the introduction of new products may require the development of new manufacturing processes and procedures. For example, our new 3D Biology applications for the simultaneous measurement of gene and protein expression involve a new process for attaching antibodies to our molecular barcodes. While all of our codesets are produced using the same basic processes, significant variations may be required to meet product specifications. Developing new processes can be very time consuming, and any unexpected difficulty in doing so could delay the introduction of a product.

If our Seattle 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. 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. Seattle 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 revenue internationally and are subject to various risks relating to our international activities, which could adversely affect our operating results.

For the nine months ended September 30, 2016 and 2015, approximately 30% and 34%, respectively, of our revenue was generated from sales to customers located outside of North America. We believe that a 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 Great Britain 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

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- 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 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 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, as it did in 2014, in the absence of a corresponding change in local currency prices, our 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 U.K. or European developments stemming from the U.K.'s referendum on membership in the European Union could have a material adverse effect on us.

On June 23, 2016, the United Kingdom held a referendum and voted in favor of leaving the European Union. This has 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 prospectus.

The referendum, and the likely withdrawal of the United Kingdom from the European Union it triggers, has caused and, along with events that could occur in the future as a consequence of the United Kingdom's withdrawal, including the possible breakup of the United Kingdom, 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) 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.

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

As of December 31, 2015, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of approximately $165.4 million, which expire in various years beginning in 2025, if not utilized. A lack of future taxable income would adversely affect our ability to utilize these NOLs. In addition, under Section 382 of the Internal Revenue 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 Internal Revenue Code. Our NOLs may also be impaired under similar provisions of state law. 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 requires 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;

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- 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, 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 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 to acquisition integration challenges;
- 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 acquisition 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 and could harm our reputation. If that occurs, we may 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

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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 and the generation, transportation and storage of waste. We could discover that we or an acquired business are not in material compliance with these regulations. 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.

Risks Related to Government Regulation and Diagnostic Product Reimbursement

Our “research use only” products for the research market could become subject to regulation 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 include clinical or diagnostic claims or directions or support to use as diagnostic products, they are not subject to regulation by the Food and Drug Administration, or FDA, as medical devices. In particular, while the FDA regulations require that RUO products be labeled, “For Research Use Only. Not for use in diagnostic procedures,” 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, 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 FDA could take enforcement action against a manufacturer for distributing dual-use instruments if the company does not follow the restrictions discussed in the guidance document. 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, and the instruments are being promoted off-label. 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.

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, 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 and there are still several large private insurance plans that have not yet issued policies confirming coverage 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 products would be compromised and our revenue would be significantly limited. Even if we do obtain reimbursement for our tests, Medicare, Medicaid and private and other payors may withdraw their

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coverage policies, cancel their contracts with us 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 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. Most recently the Protecting Access to Medicare Act (PAMA) of 2014 revises the Medicare Clinical Laboratory Fee Schedule (CLFS) to base prices on commercial payer rates that are reported to the Centers for Medicare and Medicaid Services (CMS). In June 2016, CMS released the final Clinical Diagnostic Tests Laboratory Payment System regulations, in response to PAMA. The statute applies different reporting and payment requirements to Advanced Diagnostic Laboratory Tests (ADLTs) and to Clinical Diagnostic Laboratory Tests (CDLTs). Under the definitions in the proposed rules, Prosigna would be defined as a CDLT and would be repriced every three years based on a weighted median of commercial payments submitted by labs. As a result, if commercial 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. Reductions in the reimbursement rate of third-party payors have also occurred and may occur in the future. Reductions in the prices at which testing services based on our technology are reimbursed could have a negative impact on our revenue.

In many countries outside of the United States, various coverage, pricing and reimbursement approvals are required. Recently, positive reimbursement decisions for Prosigna have occurred in France, certain regions of Spain and Israel. 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 Elements reagents may be used by clinical laboratories to create Laboratory-Developed Tests, 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.

In February 2014, we launched nCounter Elements reagents, a new digital molecular barcoding chemistry that allows users to design their own customized assays using standard sets of barcodes provided by us with the laboratories' choice of oligonucleotide probes. nCounter Elements reagents may be used by laboratories in conjunction with appropriate analyte specific reagents and general purpose reagents to create diagnostic tests or test systems.

A clinical laboratory can use nCounter Elements 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 its draft guidance documents for LDTs proposing the use of a risk-based approach to regulating LDTs. Further, numerous FDA officials have stated that FDA expects to release the final guidance document on LDTs during the current administration, which would mean FDA would subject LDTs to the medical device regulations, including the requirement to obtain clearance or approval of LDTs prior to marketing. Any restrictions on LDTs by the FDA could decrease demand for our nCounter Elements reagents. Additionally, compliance with additional regulatory burdens could be time consuming and costly for our customers. Similarly, there have been proposals that Congress enact legislation that could result in FDA regulation of some LDTs. If legislation

were enacted, it could adversely affect demand for our nCounter Elements reagents.

If we are unable to obtain additional regulatory clearances 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 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, and we have obtained a CE mark for

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Prosigna which permits us to market that assay for diagnostic purposes in the European Union. We do not have regulatory clearance or approval to market in any additional markets, other than Israel, Canada, Turkey, South Africa, New Zealand, Hong Kong, Australia, Thailand, and Argentina, or to promote Prosigna in the United States for additional indications. Other than with respect to Prosigna in such jurisdictions, 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, as well as 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 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. Some of the compensation we expect to receive pursuant to these collaborations is based on the receipt of such approvals.

We cannot assure investors that we will be successful in obtaining these regulatory clearances or approvals. If we do not obtain additional regulatory clearances 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.

Approval 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, thereby subjecting them to FDA regulation as medical devices, unless an exemption applies, we are required to obtain either prior 510(k) clearance or prior pre-market application approval, or PMA 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. We may pursue additional intended uses for Prosigna that require a PMA approval, which is a more burdensome regulatory process than the 510(k) clearance process. In addition, we are currently collaborating with Celgene, Merck and Medivation and Astellas on companion diagnostics. 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 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), the Agency expects that companion diagnostics usually will require a 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, e.g., diagnostics that do not meet the definition of an IVD companion diagnostic but are nonetheless beneficial for therapeutic product development or clinical decision making. If we developed a diagnostic device that was cleared or approved apart from a therapeutic product, rather than as a companion diagnostic, this may result in potentially reduced revenue for the test as the test would not be necessary for prescribing of the drug.

Any 510(k) clearance 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 Quality System Regulation, or 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 or approval for diagnostics can be expensive and uncertain, and generally takes from several months to several years, and generally requires detailed and comprehensive scientific and clinical data, as well as compliance with FDA regulations. Notwithstanding the expense, these efforts may never result in FDA approval or clearance. Even if we were to obtain regulatory approval 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 or clearance, and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. Approval 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.

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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 or approval for our diagnostic products, including additional indications for Prosigna. Accordingly, we expect to rely on third parties, such as medical institutions, clinical investigators, consultants, and collaborators to conduct such studies. 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 our study design. Our reliance on third parties that we do not control will not relieve us of any applicable requirement to develop, and ensure compliance with, various procedures required under good clinical practices. 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, our studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our diagnostic products.

In many countries, we are not permitted 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 medical devices, including Prosigna, the nCounter Dx Analysis System and nCounter Elements reagents. Accordingly, we and certain of our contract manufacturers are subject to ongoing International Organization for Standardization, or ISO, and FDA obligations and continued regulatory oversight and review. These include routine inspections by EU Notified Bodies and by the FDA of our manufacturing facilities and our records for compliance with requirements such as ISO 13485 and the QSR, which establish extensive requirements for quality assurance and control as well as manufacturing and change control procedures. 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 complaint, adverse event and malfunction reporting; corrections and removals reporting; 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 EU, recently launched an initiative to determine guidelines for the use of genomic biomarkers in the development and life-cycle of drugs. It is expected that at the end of 2016 the European Union will adopt the IVD Directive Regulation, currently being finalized, which would increase the regulatory requirements applicable to some in vitro diagnostics in the EU and would require that we re-classify and obtain pre-approval for our existing CE-marked IVD products within a 5-year grace period. 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 cleared (or equivalent) indication. 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 U.S. 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 federal and state healthcare fraud and abuse laws and other federal and state laws applicable to our marketing practices. If we are unable to comply, or have not complied, with such laws, we could face substantial penalties.

Our operations are directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal and state anti-kickback statutes and state and federal 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 patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

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- the federal Anti-kickback Law and state anti-kickback prohibitions;
- the federal physician self-referral prohibition, commonly known as the Stark Law, and the 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 civil and criminal penalties and state equivalents; and
- state physician gift bans and state and federal marketing expenditure disclosure laws.

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. Absent further legislative action, the medical device tax would be reinstated January 1, 2018. The tax applies to our listed medical device products, which include the nCounter Dx Analysis System, Prosigna in vitro diagnostic kits and nCounter Elements reagents. 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 this occurs through adjustment to the Clinical Laboratory Fee Schedule. 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 includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. In addition, the ACA establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce health care expenditures, which may have a negative impact on payment rates for services, including our tests. The IPAB proposals may impact payments for clinical laboratory services that our customers use our technology to deliver beginning in 2016 and for hospital services beginning in 2020, and may indirectly reduce demand for our products.

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. Such co-payments by Medicare beneficiaries for laboratory services were discussed as possible cost savings for the Medicare program as part of the debt ceiling budget discussions in mid-2011 and may be enacted in the future. 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 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. The expansion in government’s effect on 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, 2016, we owned

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or licensed 15 issued U.S. patents and approximately 45 pending U.S. patent applications, including provisional and non-provisional filings. We also owned or licensed approximately 185 pending and granted counterpart applications worldwide, including 65 country-specific validations of 6 European patents. 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.

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. 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.

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 recently 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 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 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. 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:

- 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.
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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

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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. 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 and the intellectual property relating to a gene signature for lymphoma subtyping from the National Institutes of Health for use in our collaboration with Celgene Corporation. 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 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.

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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.

We may be involved in lawsuits to protect or enforce our patents and proprietary rights, to determine the scope, coverage and validity of others' proprietary rights, or to defend against third-party claims of intellectual property infringement, any of which could be time-intensive and costly and may adversely impact our business or stock price. 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 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 be necessary for us to enforce our patent and proprietary rights 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. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us, and we might not be able to obtain licenses to technology that we require. Even if such licenses are obtainable, they may not be available at a reasonable cost. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products. In addition, 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.

As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. 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. 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. 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 and competitors may assert that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into those markets. Third parties may assert that we are employing their proprietary technology without authorization. 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. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. 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 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

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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 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

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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, commercial relationships or capital commitments;
- 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, 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.

An active trading market for our common stock may not be sustained.

Although our common stock is listed on The NASDAQ Global Market, the market for our shares has demonstrated varying levels of trading activity and the current level of trading may not be sustained in the future. Purchases or sales of large blocks of our shares relative to the trading volume on a given day can have a disproportionate effect on the price of our common stock. The lack of an active market for our common stock or significant and rapid changes in the price of our common stock may impair investors' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable, may reduce the fair market value of their shares and may impair our ability to raise capital.

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. 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.

Holders of approximately 4.0 million shares (including shares underlying outstanding warrants), or approximately 20%, of our outstanding shares as of September 30, 2016, have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also register the offer and sale of all shares of common stock that we

may issue under our equity compensation plans.

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

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

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

Our officers and directors, and their respective affiliates, own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

Our executive officers and directors together with their respective affiliates, own approximately 23% of our outstanding common stock as of September 30, 2016. Accordingly, our executive officers and directors together with their respective affiliates, will be able to exert significant influence over matters submitted to our stockholders for approval, as well as our management and affairs. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material adverse effect on our stock price and may prevent attempts by our stockholders to replace or remove the board of directors or management.

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

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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."

We are an "emerging growth company," and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012, and, for as long as we continue to be an "emerging growth company," we have chosen to take advantage of exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including, but not limited to, not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an "emerging growth company" until December 31, 2018, although, if we have more than $1.0 billion in annual revenue, if the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30 of any year, or we issue more than $1.0 billion of non-convertible debt over a three-year period before the end of that five-year period, we would cease to be an "emerging growth company" as of the following December 31. If some investors find our common stock less attractive as a result of these exemptions, there may be a less active trading market for our common stock and our stock price may be lower and be more volatile.

As an "emerging growth company" the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. We have elected to use this extended transition period under the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make our common stock less attractive to investors.

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, and particularly after we cease to be an "emerging growth company," we incur and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. 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, among other things, that we assess the effectiveness of our internal control over financial reporting annually and 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 potentially to attest to, the effectiveness of our internal control over financial reporting. As an "emerging growth company," we are availing 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 when we cease to be an "emerging growth company." When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, 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. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting

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firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.
Furthermore, investor perceptions of our company may suffer if deficiencies are found, 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 implement these requirements effectively or efficiently, 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.

The SEC adopted its final rule implementing Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act concerning conflict minerals in August 2012. The rule requires us to submit forms and reports to the SEC annually to disclose our determinations and due diligence measures. We have filed Form SD for the year ended December 31, 2015 and included a Conflict Minerals Report as an exhibit to such form. We do not directly purchase any conflict minerals. However, tracing these materials back to their country of origin is a complex task that required us to, among other things, survey suppliers in our supply chain to understand what programs they have in place for tracing the source of minerals supplied to us or used in products supplied to us and to ensure that reasonable due diligence has been performed. However, we have not determined how many, or if any, of our supply chain partners use conflict minerals. Moreover, we may face a limited pool of suppliers who can provide us “conflict-free” components, parts and manufactured products, and we may not be able to obtain conflict-free products or supplies in sufficient quantities or at competitive prices for our operations, and may be required to disclose that our products are not “conflict free.” This could adversely affect our reputation and may harm relationships with business partners and customers, and our stock price could suffer as a result.

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.

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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 4, 2016 By: /s/ R. Bradley Gray
R. Bradley Gray
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 4, 2016 By: /s/ James A. Johnson
James A. Johnson
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

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