NanoString Technologies Inc
Form 10-Q
August 08, 2013
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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 June 30, 2013

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, Suite 2000

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 ¨ No x

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 x 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 ¨
Non-accelerated filer x (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 x

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date:

The number of shares of registrant s common stock outstanding as of August 5, 2013 was 14,613,939

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NANOSTRING TECHNOLOGIES, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED JUNE 30, 2013

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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)

	June 30, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 10,755	$ 21,692
Accounts receivable, net	4,779	3,322
Inventory	5,627	5,380
Prepaid expenses and other	2,533	1,320
Total current assets	23,694	31,714
Restricted cash	180	180
Deferred offering costs	3,384	1,765
Property and equipment, net	3,028	3,674
Other assets	204	73
Total assets	$ 30,490	$ 37,406
Liabilities, Mandatorily Redeemable Convertible Preferred Stock and Stockholders Deficit		
Current liabilities:		
Accounts payable	$ 2,727	$ 2,865
Accrued liabilities	5,689	4,481
Deferred revenue, current portion	1,086	878
Deferred rent, current portion	610	764
Long-term debt, current portion	2,675	2,789
Total current liabilities	12,787	11,777
Deferred revenue, net of current portion	489	362
Deferred rent, net of current portion	1,684	1,903
Long-term debt, net of current portion	15,047	9,970
Preferred stock warrant liability	2,513	3,532
Total liabilities	32,520	27,544
Mandatorily redeemable convertible preferred stock, $0.0001 par value per share, 8,979 shares authorized; 8,118 shares issued and outstanding	108,275	103,622
Stockholders deficit		
Common stock, $0.0001 par value, 11,713 shares authorized; 583 and 411 shares issued and outstanding, respectively		
Accumulated deficit	(110,305)	(93,760)

Total stockholders deficit	(110,305)	(93,760)
Total liabilities, mandatorily redeemable convertible preferred stock and stockholders deficit	$ 30,490	$ 37,406

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, except per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	**2012**	**2013**	**2012**
Revenue	$ 7,218	$ 5,943	$ 12,894	$ 10,445
Costs and expenses:				
Cost of revenue	3,522	3,334	6,404	5,990
Research and development	3,626	2,971	6,685	5,168
Selling, general and administrative	6,708	3,251	12,834	6,418
Total costs and expenses	13,856	9,556	25,923	17,576
Loss from operations	(6,638)	(3,613)	(13,029)	(7,131)
Other income (expense):				
Interest income	3	6	6	13
Interest expense	(489)	(220)	(874)	(332)
Other income (expense)	(9)	185	(13)	172
Revaluation of preferred stock warrant liability	1,638	71	1,156	97
Total other income (expense)	1,143	42	275	(50)
Net loss	(5,495)	(3,571)	(12,754)	(7,181)
Accretion of mandatorily redeemable convertible preferred stock	(2,311)	(1,844)	(4,653)	(3,637)
Net loss attributable to common stockholders	$ (7,806)	$ (5,415)	$ (17,407)	$ (10,818)
Net loss per share basic and diluted	$ (13.69)	$ (16.02)	$ (31.48)	$ (32.49)
Shares used in computing basic and diluted net loss per share	570	338	553	333

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)

	Six Months Ended June 30,	
	2013	**2012**
Operating activities		
Net loss	$ (12,754)	$ (7,181)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	901	974
Amortization of debt discount	110	95
Stock-based compensation	488	417
Revaluation of preferred stock warrant liability	(1,156)	(97)
Interest accrued on long-term notes	99	32
Loss on disposal of property and equipment	1	
Changes in operating assets and liabilities		
Accounts receivable	(1,457)	(590)
Inventory	(247)	(602)
Prepaid expenses and other	(1,213)	10
Other assets	(131)	(11)
Accounts payable	826	(79)
Accrued liabilities	329	321
Deferred revenue	335	(102)
Deferred rent	(373)	(347)
Net cash used in operating activities	(14,242)	(7,160)
Investing activities		
Purchases of property and equipment	(254)	(222)
Increase in restricted cash		(1)
Net cash used in investing activities	(254)	(223)
Financing activities		
Proceeds from issuance of long-term debt	5,000	7,500
Repayment of long-term debt	(109)	(1,603)
Deferred offering costs	(1,705)	
Proceeds from exercise of stock options	373	30
Net cash provided by financing activities	3,559	5,927
Net decrease in cash and cash equivalents	(10,937)	(1,456)
Cash and cash equivalents		
Beginning of period	21,692	10,868
End of period	$ 10,755	$ 9,412

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 Delaware in June 2003 and is headquartered 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, to academic, government, biopharmaceutical and clinical laboratories.

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 the Company s business in accordance with its business plan. The Company s activities have been financed primarily through the sale of equity securities and incurrence of indebtedness, and to a lesser extent, capital leases and other borrowings.

Reverse Stock Split

On June 12, 2013, the Company effected a 1-for-32 reverse stock split of its common stock and preferred stock. All share and per share information has been retroactively adjusted to reflect this reverse stock split.

Initial Public Offering

On June 25, 2013, the Company s registration statement on Form S-1 was declared effective related to its initial public offering, in which the Company sold 5,400,000 shares of common stock at a price of $10.00 per share. The shares began trading on the NASDAQ Global Market on June 26, 2013. The $50.2 million in proceeds from the initial public offering, which is net of underwriting discounts and commissions but before offering expenses, were received at closing on July 1, 2013.

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, NanoString Technologies International, Inc., NanoString Technologies Asia Pacific Limited, NanoString Technologies Europe Limited and NanoString Technologies SAS. The condensed consolidated balance sheet data as of December 31, 2012 were derived from audited financial statements not included in this report. 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 generally accepted accounting principles in the United States of America (GAAP) for unaudited condensed consolidated financial information. Accordingly, they do not include all of the information and footnotes required by 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.

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and accompanying notes included in the prospectus that forms a part of the Company s Registration Statement on Form S-1 (File No. 333-188704), which prospectus was filed with the SEC pursuant to Rule 424 promulgated under the Securities Act of 1933 on June 26, 2013.

The preparation of financial statements in conformity with 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 six month periods ended June 30, 2013 are not necessarily indicative of the results to

be expected for the full year or for any other period.

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Revenue Recognition

The Company recognizes revenue when (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 revenue from the sale of products and services. The Company s products consist of its proprietary nCounter Analysis System 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.

Systems product revenue is recognized upon installation and calibration in geographic regions where such services are only available from specialized Company technicians. In these regions, systems and related installation and calibration are considered to be one unit of accounting, as systems are required to be professionally installed and calibrated before use. In certain geographic regions, installation and calibration services are available from other vendors, and in such regions they are considered separate revenue elements. Consumables are considered to be separate units of accounting as they are sold separately. Consumables product revenue is recognized upon shipment.

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

The Company allocates the contract consideration at the inception of the contract 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 median 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.

Recent Accounting Pronouncements

The Company has reviewed recent accounting pronouncements and concluded that they are either not applicable to the business, or that no material effect is expected on the consolidated financial statements as a result of future adoption.

3. Net Loss Per Share

Net loss attributable to common stockholders per share is computed by dividing the net loss allocable to common stockholders by the weighted average number of shares of common stock outstanding. Outstanding stock options, warrants and preferred stock have not been included in the calculation of the diluted net loss attributable to common stockholders 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 outstanding options, warrants and preferred stock were excluded from the computation of basic and diluted net loss per share for the six month periods presented because their effect would have been anti-dilutive (in thousands):

	2013	2012
Options to purchase common stock	1,796	1,623
Convertible preferred stock (as converted)	8,631	7,567
Convertible preferred stock warrants (as converted)	618	554
Common stock warrant		2

4. Concentration of Risks

Financial instruments that potentially expose the Company to concentrations of credit risk consist principally of cash and cash equivalents and accounts receivable. The Company has credit risk related to the collectability of its accounts receivable. The Company performs initial and ongoing evaluations of its customers financial position and generally extends credit on account without collateral.

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The Company had no customers that individually represented more than 10% of total revenue during the six months ended June 30, 2013 or 2012. In addition, the Company had one customer that represented more than 10% of total accounts receivable as of June 30, 2013 and none as of December 31, 2012.

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. A change in suppliers, however, could cause a delay in manufacturing and a possible loss of sales, which would adversely affect operating results.

5. Deferred Offering Costs

Deferred offering costs represent legal, accounting and other direct costs related to the Company s efforts to raise capital through an initial public offering of the Company s common stock. These costs have been deferred through the completion of the initial public offering and on the closing date of July 1, 2013, will be reclassified to additional paid-in capital as a reduction of the proceeds. The Company recorded approximately $3.4 million and $1.8 million of deferred offering costs as a non-current asset in the accompanying balance sheets as of June 30, 2013 and December 31, 2012, respectively.

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:

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 and cash equivalents, 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.

As of June 30, 2013, the Company had mandatorily redeemable convertible preferred stock which contained certain redemption provisions which precluded equity classification. Accordingly, warrants to purchase this mandatorily redeemable convertible preferred stock were classified as liabilities for the periods presented. These preferred stock warrants were subject to remeasurement at each balance sheet date and any change in fair value was recognized as a component of other income (expense).

The Company s preferred stock warrants are categorized as Level 3 because they were valued based on unobservable inputs and management judgment due to the absence of quoted market prices, inherent lack of liquidity and the long-term nature of such financial instruments. The Company performed a fair value assessment of the preferred stock warrant inputs on a quarterly basis using the Black-Scholes option pricing model. The assumptions used in the Black-Scholes option pricing model are inherently subjective and involve significant judgment. Any change in fair value was recognized as a component of other income (expense) in the condensed consolidated statements of comprehensive loss.

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The following information summarizes the carrying value of the warrants to purchase shares of the Company s previously outstanding preferred stock (in thousands):

Balance at December 31, 2012	$ 3,532
Issuance of preferred stock warrants	
Warrant revaluation	482
Balance at March 31, 2013	4,014
Issuance of preferred stock warrants	137
Warrant revaluation	(1,638)
Balance at June 30, 2013	$ 2,513

Upon the closing of the Company s initial public offering, all warrants to purchase preferred stock were converted to common stock. After July 1, 2013, these warrants will not be remeasured to fair value at each reporting date.

7. Inventory

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

	June 30, 2013	December 31, 2012
Raw materials	$ 2,465	$ 2,120
Work in process	1,082	962
Finished goods	2,080	2,298
	$ 5,627	$ 5,380

8. Reserve for Product Warranties

The Company generally provides a one-year warranty on its nCounter Analysis Systems and establishes an accrual based on historical product failure rates and actual warranty costs incurred. Warranty expense is recorded as a component of cost of revenue in the condensed consolidated statements of comprehensive loss.

The following information reconciles changes in the Company s warranty reserve and related costs (in thousands):

Warranty reserve, December 31, 2012	$ 248
Cost of warranty claims	(63)
Warranty accrual	43
Warranty reserve, March 31, 2013	228
Cost of warranty claims	(24)
Warranty accrual	52
Warranty reserve, June 30, 2013	$ 256

9. Long-term Debt and Obligations

In March 2012, the Company entered into a loan and security agreement (the credit facility), pursuant to which it incurred $13.0 million in term loan borrowings in 2012 and subsequently incurred an additional $5.0 million in term loan borrowings in April 2013, for an aggregate principal amount of $18.0 million. All of such borrowings accrue interest at a rate of 8.89%. Through January 2014, the Company is required to pay interest only on such term loan borrowings. Following the expiration of the interest only payment period, the Company is required to pay principal and interest in 30 equal monthly installments, plus an end of term payment equal to 5.5% of the amount borrowed, or $990,000, at maturity in July 2016. The Company may at its option prepay all of the term loan borrowings by paying the lender, among other things, all principal and accrued interest, the end of term payment plus a premium of up to 3% of the amount borrowed. Pursuant to the credit facility, from time to time the Company can also incur revolver borrowings of up to the lesser of $2.0 million or a borrowing base tied to the amount of eligible accounts receivable. Interest on revolver borrowings accrues at a floating rate equal to the prime rate plus 3.70% (subject to a floor of 6.95%) and is payable monthly. The Company is also required to pay a fee of 0.075% per month on the unused portion of the revolver borrowings.

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The credit facility contains customary conditions to borrowing, events of default and covenants, including covenants that restrict the Company s ability to dispose of assets, merge with or acquire other entities, incur indebtedness, incur encumbrances, make distributions to holders of the Company s capital stock, make investments or engage in transactions with its affiliates. In addition, the Company must comply with a financial covenant based on life sciences revenue. This financial covenant is measured monthly on a trailing three month basis. The Company is in compliance with all covenants as of June 30, 2013. The Company s obligations under the credit facility are secured by substantially all of its assets other than intellectual property.

Pursuant to an office building lease, the owner of the building financed a portion of tenant improvements under an arrangement in which the Company is obligated to pay the amount financed over the term of the lease. The amount financed totaled $843,000 and is being repaid over the five-year term of the lease, which expires in August 2016. Interest accrues on the unpaid balance at a rate of 10% per annum.

Borrowings, including current portion, consisted of the following (in thousands):

	June 30, 2013	December 31, 2012
Landlord payable	$ 145	$ 235
Term loans payable	18,195	13,115
	18,340	13,350
Less: Unamortized debt discount	(618)	(591)
Current portion	(2,675)	(2,789)
Non-current portion	$ 15,047	$ 9,970

Scheduled future payments for principal obligations under outstanding debt facilities were as follows at June 30, 2013 (in thousands):

Long-term debt:	
2013	$ 101
2014	6,192
2015	7,295
2016	4,752
	$ 18,340

10. Segment Reporting

Operating segments are defined as components of an enterprise for which separate financial information is available and evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance.

The Company develops, manufactures and sells products that unlock genetic information from very small amounts of tissue. Products, consisting of instruments, consumables and related services, are currently provided to researchers in the life sciences industry and will be provided to clinical laboratories providing diagnostic testing. The Company is organized as, and operates in, two reportable segments: life sciences segment and diagnostics segment. The life sciences business provides instruments, consumables and services efficiently profiling the activity of hundreds of genes from a single tissue sample. The diagnostics business provides molecular diagnostic kits to pathology labs enabling complex molecular testing on a distributed basis.

The Company s chief operating decision maker is the chief executive officer. The chief operating decision maker reviews financial information presented on a total Company basis, accompanied by information about segment revenue and certain direct sales and marketing expenses by segment. The chief operating decision maker does not review segment information related to cost of revenue, research and development or other selling, general and administrative expenses. The Company s chief operating decision maker evaluates performance based on these two measures.

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Operating results for each segment and a reconciliation of segment profit to loss from operations are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Product revenue:				
Instruments	$ 2,320	$ 2,579	$ 3,959	$ 4,079
Consumables	4,305	3,054	8,004	5,757
Service revenue	390	310	728	609
Total life sciences segment	7,015	5,943	12,691	10,445
Diagnostics segment				
Instruments	203		203	
Total diagnostics segment	203		203	
Total revenue	7,218	5,943	12,894	10,445
Selling, general, and administrative expenses:				
Life sciences segment	2,642	1,759	4,845	3,274
Diagnostics segment	1,240	176	2,680	517
Life sciences segment profit	4,373	4,184	7,846	7,171
Diagnostics segment loss	(1,037)	(176)	(2,477)	(517)
Total segment profit	3,336	4,008	5,369	6,654
Adjustments:				
Cost of revenue	(3,522)	(3,334)	(6,404)	(5,990)
Research and development expenses	(3,626)	(2,971)	(6,685)	(5,168)
Unallocated selling, general and administrative expenses	(2,826)	(1,316)	(5,309)	(2,627)
Loss from operations	$ (6,638)	$ (3,613)	$ (13,029)	$ (7,131)

The following table is based on the geographic location of distributors or end users who purchased products and services. For sales to distributors, their geographic location may be different from the geographic locations of the ultimate end user. Revenue by geography was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
North America	$ 5,218	$ 3,898	$ 9,695	$ 7,060
Europe & Middle East	1,494	1,006	2,110	1,998
Asia Pacific	506	1,039	1,089	1,387
Total revenue	$ 7,218	$ 5,943	$ 12,894	$ 10,445

Total revenue in the United States was $4.3 million, $3.8 million, $7.9 million and $6.6 million for the three and six month periods ended June 30, 2013 and 2012, respectively.

The Company s assets are primarily located in the United States and not allocated to any specific segment or geographic region. Substantially all of the Company s long-lived assets are located in the United States.

11. Subsequent Events

On July 1, 2013, the Company completed its initial public offering of 5,400,000 shares of common stock, at $10.00 per share. The proceeds from the initial public offering were $50.2 million net of underwriting discounts and commissions, but before offering expenses. As of June 30, 2013, the Company had incurred $3.4 million of deferred offering costs, which will be offset against the net proceeds received from the sale of common stock.

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On July 1, 2013, all outstanding shares of the Company s mandatorily redeemable convertible preferred stock converted into shares of the Company s common stock in connection with the initial public offering. Following the initial public offering, there were no shares of preferred stock outstanding. The shares of common stock issued upon conversion of the preferred stock were as follows (in thousands):

	Shares of Preferred Stock	Shares of Common Stock
Series A	557	781
Series B	516	805
Series C	3,551	3,551
Series D	2,430	2,430
Series E	1,064	1,064
	8,118	8,631

Until the conversion of the preferred stock, the Company recorded preferred stock accretion using an effective interest method to reach a value equal to the redemption value pursuant to the terms of the preferred stock set forth in the Company s certificate of incorporation.

In addition, on July 1, 2013, concurrent with completion of the initial public offering, all outstanding preferred stock warrants converted into warrants to purchase an aggregate of 617,605 shares of common stock with a weighted average exercise price of $8.78 per share.

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

Forward-Looking Statements

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. This discussion contains certain 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, seek and other similar expressions. You should read these statements car 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 ability to successfully commercialize Prosigna, our first product for which we have obtained a CE mark in the European Union;
- our ability to secure regulatory clearance or approval, domestically and internationally, for the clinical use of our products, including a version of Prosigna in the United States;
- the implementation of our business model and strategic plans for our business;
- the regulatory regime for our products, domestically and internationally;
- our strategic relationships, including with patent holders of our technologies, manufacturers and distributors of our products, and third parties who conduct our clinical studies;
- our intellectual property position;
- our expectations regarding the market size and growth potential for our life sciences and diagnostic businesses;
- any estimates regarding expenses, future revenues, capital requirements, and stock performance; and
- our ability to sustain and manage growth, including our ability to develop new products and enter new markets.

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.

Overview

We develop, manufacture and sell robust, intuitive products that unlock scientifically valuable and clinically actionable genomic information from minute amounts of tissue. Our nCounter Analysis System directly profiles 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 systems and related consumables to researchers in academic, government, and biopharmaceutical laboratories for use in understanding fundamental biology and the molecular basis of disease. As researchers discover how genomic information can be used to improve clinical decision-making, we seek to selectively translate their discoveries into molecular diagnostic products. In September 2012, we received European Union regulatory

clearance for our first molecular diagnostic product, the Prosigna Breast Cancer Assay, or Prosigna, an assay providing an assessment of a patient s risk of recurrence for breast cancer and the intrinsic subtype of the patient s tumor. In February 2013, we commercially launched Prosigna in Europe and Israel. In December 2012, we submitted an application, known as a 510(k), to the FDA seeking clearance in the United States for a version of Prosigna providing an assessment of a patient s risk of recurrence for breast cancer.

We are organized as, and operate in, two reportable segments: our life sciences business and our diagnostics business. Until recently, we have sold products exclusively through our life sciences business, providing research use only tools to scientific researchers for efficiently profiling the activity of hundreds of genes simultaneously from a single tissue sample. We derive a substantial majority of our life sciences revenue from the sale of products, which consist of our nCounter instruments and related proprietary consumables. 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.

Our diagnostics business provides nCounter instruments and consumables in the form of molecular diagnostic kits, initially our Prosigna assay, to pathology labs enabling complex molecular testing on a decentralized basis. In September 2012, we obtained a CE mark for Prosigna and, in February 2013, we commercially launched Prosigna in Europe and Israel. In December 2012, we submitted an application, known as a 510(k), to the FDA seeking clearance in the United States for a version of Prosigna providing an assessment of a patient s risk of recurrence for breast cancer and have had a number of subsequent communications with the FDA. We

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are currently planning for United States commercial launch in the first quarter of 2014 and are establishing a dedicated oncology diagnostics sales force. As a result, we expect sales and marketing expenses and operating losses to increase as we market the product in Europe and other countries outside of the United States, and to increase further upon the launch in the United States following clearance from the FDA. We expect sales in Europe to grow gradually as more systems are installed and Prosigna gains market acceptance and reimbursement by third-party payors becomes more broadly available.

We use third-party contract manufacturers to produce the two instruments comprising the nCounter Analysis System. 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 products and solutions. We invested $6.7 million and $5.2 million for the six months ended June 30, 2013 and 2012, respectively, in research and development and intend to continue to make significant investments in research and development.

Our total revenue has increased to $12.9 million for the six months ended June 30, 2013 from $10.4 million for the first six months of 2012, which was driven by the sale of additional nCounter Analysis Systems and consumables for use on our growing installed base of instruments. 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 $12.8 million and $7.2 million for the six months ended June 30, 2013 and 2012, respectively, and as of June 30, 2013 our accumulated deficit was $110.3 million.

Recent Developments

On July 1, 2013, the Company completed its initial public offering of 5,400,000 shares of common stock, at $10.00 per share. The proceeds from the initial public offering were $50.2 million net of underwriting discounts and commissions, but before offering expenses.

Key Financial Metrics

Revenue

Our products consist of our nCounter Analysis System and related consumables. Our nCounter Analysis System typically consists of one nCounter Digital Analyzer and one nCounter Prep Station. Life sciences consumables include (1) custom CodeSets, which we manufacture to the specific requirements of an individual researcher, (2) panels, which are standard pre-manufactured CodeSets, and (3) Master Kits, which are ancillary reagents, cartridges, tips and reagent plates required to setup and process samples in our instruments. Diagnostic consumables consist of in vitro diagnostic kits, initially for our Prosigna Breast Cancer Assay. Since 2010, our average consumable revenue per system has exceeded $100,000 per year. Product revenue also includes payments for instrument installation. Currently, our life sciences customer base is primarily composed of academic institutions, government laboratories, and biopharmaceutical companies that perform analyses using our nCounter Analysis System and purchase consumables for research use only.

Service revenue consists of fees associated with extended service contracts and conducting proof-of-principle studies. We include a one-year warranty with the sale of our instruments and offer extended service contracts, which are purchased by a majority of our customers. We selectively provide proof-of-principle studies to prospective life sciences customers in order to help them better understand the benefits of the nCounter Analysis System.

We sell our life sciences products through our own sales force in the United States, Canada, Singapore and certain European countries. We sell through distributors in other parts of the world. As we have expanded our European life sciences direct sales force and entered into agreements with distributors of our life sciences products in Europe, the Middle East, Asia Pacific and South America, the amount of revenue generated from geographies outside of North America has generally increased, although there have been significant quarter-to-quarter fluctuations. In the future, we intend to continue to expand our sales force and establish additional distributor relationships outside the United States to better access international markets. The following table reflects product revenue by geography based on the billing address of our customers. North America consists of the United States, Canada and Mexico; and Asia Pacific includes Japan, China, South Korea, Singapore and Australia.

	Three Months Ended June 30,			Six Months Ended June 30,		
	2013	2012	% Change	2013	2012	% Change
North America	$ 5,218	$ 3,898	34%	$ 9,695	$ 7,060	37%
Europe & Middle East	1,494	1,006	49%	2,110	1,998	6%

Asia Pacific	506	1,039	(51)%	1,089	1,387	(21)%
Total	$ 7,218	$ 5,943	21%	$ 12,894	$ 10,445	23%

Most of our revenue has historically been denominated in U.S. dollars. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States. Changes in foreign currency exchange rates have not materially affected us to date; however, they may become material to us in the future as our operations outside of the United States expand.

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Cost of Revenue

Cost of 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 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 and establish a reserve for warranty repairs based on historical warranty repair costs incurred.

We expect the average unit costs of our instruments to decline in future periods as a result of our ongoing efforts to develop a lower-cost nCounter Analysis System to expand our market opportunity among smaller laboratories. We expect the unit costs of consumable products to decline as a result of our ongoing efforts to improve our manufacturing processes and expected increases in production volume and yields. Although the unit costs of our custom CodeSets vary, they are generally higher as a percentage of the related revenue than our panels and in vitro diagnostic kits.

Operating Expenses

Research and Development

Research and development expenses consist primarily of salaries and benefits, occupancy, laboratory supplies, consulting fees and related costs, 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 for both our life sciences and diagnostics businesses. We believe that our continued investment in research and development is essential to our long-term competitive position and expect these expenses 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. The following table shows the composition of total research and development expense by functional area for the periods indicated.

	Three Months Ended June 30,			Six Months Ended June 30,		
	2013	2012	% Change	2013	2012	% Change
Core nCounter platform technology	$ 817	$ 302	171%	$ 1,429	$ 616	132%
Manufacturing process development	358	274	31%	736	570	29%
Life sciences products and applications	665	473	41%	1,401	936	50%
Diagnostic product development	1,375	1,453	(5)%	2,313	2,101	10%
Facility allocation	411	469	(12)%	806	945	(15)%
Total	$ 3,626	$ 2,971	22%	$ 6,685	$ 5,168	29%

Selling, General and Administrative

Selling, general and administrative expenses consist primarily of costs for our sales and marketing, finance, 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 expenses to increase in future periods as the number of sales, technical support and marketing and administrative personnel grows and we continue to introduce new products, broaden our customer base and grow our business. In particular, the commercial launch of Prosigna requires us to establish a dedicated oncology diagnostics sales force which will increase selling and marketing expenses significantly. We also expect legal, accounting and compliance costs to increase after becoming a public company.

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Results of Operations

Revenue; Cost of Revenue; Gross Profit

	Three Months Ended June 30,			Six Months Ended June 30,		
	2013	2012	% Change	2013	2012	% Change
Product revenue:						
Instruments						
Life sciences	$ 2,320	$ 2,579	(10)%	$ 3,959	$ 4,079	(3)%
Diagnostics	203			203		
Total instrument revenue	2,523	2,579	(2)%	4,162	4,079	2%
Consumables	4,305	3,054	41%	8,004	5,757	39%
Service revenue	390	310	26%	728	609	20%
Total revenue	7,218	5,943	21%	12,894	10,445	23%
Cost of revenue	3,522	3,334	6%	6,404	5,990	7%
Gross profit	$ 3,696	$ 2,609	42%	$ 6,490	$ 4,455	46%
Gross margin	51%	44%		50%	43%	

Instrument revenue was relatively consistent from year to year for both the three and six month periods ended June 30, 2013. Instrument revenue included approximately $200,000 from our diagnostics segment; all other revenue was from our life sciences segment. The increase in consumable revenue for both periods was driven by growth in our installed base of instruments. The increase in service revenue for both the three month and six month periods was primarily related to an increase in the number of instruments covered by service contracts.

The increase in cost of revenue was largely related to the increased volume of consumables sold. Gross margin increased primarily due to a shift in product mix towards consumables, which on average have higher margins than instruments. Increased production volume also lowered costs as a percentage of revenue.

Research and Development Expense

	Three Months Ended June 30,			Six Months Ended June 30,		
	2013	2012	% Change	2013	2012	% Change
Research and development expense	$ 3,626	$ 2,971	22%	$ 6,685	$ 5,168	29%

The increases reflected $0.8 million and $1.5 million increases in personnel-related expenses, for the three and six month periods, respectively, to support the advancement of our nCounter technology and clinical development of Prosigna. The increase for the three month period was partially offset by a $0.4 million decrease in Prosigna clinical study costs after completion of the ABCSG8 study in late 2012.

Selling, General and Administrative Expense

	Three Months Ended June 30,			Six Months Ended June 30,		
	2013	2012	% Change	2013	2012	% Change
	$ 6,708	$ 3,251	106%	$ 12,834	$ 6,418	100%

Selling, general and administrative expense

The increase for the three-month period was primarily attributable to $1.2 million of increased staffing and personnel-related costs to support sales and marketing and administration; $1.0 million of increased external marketing and other consulting costs related to the commercial launch of Prosigna; and $0.9 million of increased corporate professional fees.

The increase for the six-month period was primarily attributable to $2.5 million of increased staffing and personnel-related costs to support sales and marketing and administration; $1.7 million of increased external marketing and other consulting costs related to the commercial launch of Prosigna; and $1.0 million of increased corporate professional fees.

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Other Income (Expense), Net

	Three Months Ended June 30,			Six Months Ended June 30,		
	2013	2012	% Change	2013	2012	% Change
Interest income	$ 3	$ 6	(50)%	$ 6	$ 13	(54)%
Interest expense	(489)	(220)	122%	(874)	(332)	163%
Other income (expense)	(9)	185	(105)%	(13)	172	(108)%
Revaluation of preferred stock warrant liability	1,638	71	2,207%	1,156	97	1,092%
Total other income (expense), net	$ 1,143	$ 42	2,621%	$ 275	$ (50)	(650)%

The increases in interest expense for both periods were driven by increased borrowing under our existing credit facility during 2012 and 2013, from $7.5 million in March 2012 to $18.0 million as of June 30, 2013.

The increase in other income from the revaluation of the preferred stock warrant liability for both the three and six month periods resulted from a re-measurement of the fair value of preferred stock warrants using the Black-Scholes option pricing model, which was primarily impacted by a decrease in the valuation of the underlying stock.

Liquidity and Capital Resources

As of June 30, 2013, we had cash and cash equivalents of $10.8 million, which consisted of highly-liquid investments with an original maturity of three months or less. We received $50.2 million of proceeds, net underwriting discounts and commissions but before offering expenses, from our initial public offering. The initial public offering closed on July 1, 2013 and, accordingly, such proceeds are not reflected on our cash and cash equivalents at June 30, 2013.

Sources of Funds

Since inception, we have financed our operations primarily through the sale of equity securities and, to a lesser extent, from borrowings. In April 2013, we incurred $5.0 million of term loan borrowings, increasing our aggregate term loan borrowings to $18.0 million, and amended our credit facility to allow for the incurrence of the remaining $5.0 million in term loan borrowings on or before June 30, 2013. In consideration of the completion of our initial public offering in June, no further term loan borrowings were incurred.

We believe our existing cash and cash equivalents including the net proceeds from our initial public offering, will be sufficient to meet our working capital and capital expenditure needs for at least the next 12 months. However, we may need to raise additional capital to expand the commercialization of our products, fund our operations and further our research and development activities. Our future funding requirements will depend on many factors, including: market acceptance 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.

We may require additional funds in the future and we may not be able to obtain such funds on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or additional equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through 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 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.

Credit Facility

In March 2012, we entered into a loan and security agreement, which we refer to as our credit facility, pursuant to which we have incurred $18.0 million in term loan borrowings, all of which accrue interest at a rate of 8.89%. Through January 2014, we are required to pay interest only on our term loan borrowing. Following the expiration of the interest only payment period, we are required to pay principal and interest in 30 equal monthly installments, plus an end of term payment equal to 5.5% of the amount borrowed, or $990,000, at maturity in July 2016. We may at our option prepay all of the term loan borrowings by paying the lender, among other things, all principal and accrued interest, the end of term payment plus a premium of up to 3% of the amount borrowed. Pursuant to the credit facility, from time to time we can also incur revolver borrowings of up to the lesser of $2.0 million or a borrowing base tied to the amount of eligible accounts receivable. Interest on revolver borrowings accrues at a floating rate equal to the prime rate plus 3.70% (subject to a floor of 6.95%) and is payable monthly. We are also required to pay a fee of 0.075% per month on the unused portion of the revolver borrowings.

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The credit facility contains customary conditions to borrowing, events of default and covenants, including covenants that restrict our ability to dispose of assets, merge with or acquire other entities, incur indebtedness, incur encumbrances, make distributions to holders of our capital stock, make investments or engage in transactions with our affiliates. In addition, we must comply with a financial covenant based on life sciences revenue. This financial covenant is measured monthly on a trailing three month basis. We were in compliance with all covenants as of June 30, 2013. Our obligations under the credit facility are secured by substantially all of our assets other than intellectual property.

Use of Funds

Our principal uses of cash are funding our operations, satisfaction of our obligations under our debt instruments, 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 life sciences business and in developing Prosigna and preparing it for commercialization. As a result, our cash used in operating activities has either remained relatively constant or increased. We expect our operating cash requirements to increase in the future as we (1) increase sales and marketing activities to expand the installed base of our nCounter Analysis Systems among life sciences research customers, (2) commercialize, and conduct studies to expand the clinical utility of, Prosigna, and (3) develop new applications, chemistry and instruments for our nCounter platform.

Historical Cash Flow Trends

The following table shows a summary of our cash flows for the periods indicated:

	Six Months Ended June 30,	
	2013	**2012**
Cash used in operating activities	$ (14,242)	$ (7,160)
Cash used in investing activities	(254)	(223)
Cash provided by financing activities	3,559	5,927

Operating Cash Flows

We derive operating cash flows from cash collected from the sale of our products and services. These cash flows received are 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.

Net cash used in operating activities for the six months ended June 30, 2013 consisted of our net loss of $12.8 million and $1.9 million of cash used for working capital purposes. These uses were partially offset by $0.4 million of net non-cash income and expense items, such as depreciation and amortization, stock-based compensation and change in the fair value of preferred stock warrants.

Net cash used in operating activities for the six months ended June 30, 2012 consisted of our net loss of $7.2 million and $1.4 million of cash used for working capital purposes. These uses were partially offset by $1.4 million of non-cash expense items, such as depreciation and amortization and stock-based compensation.

Investing Cash Flows

Net cash used in investing activities for each of the periods presented was primarily for the purchase of laboratory, manufacturing and computer equipment and software to support our expanding infrastructure. Other than the purchase of nCounter Analysis Systems for loan or rental to clinical laboratories in support of Prosigna commercialization in jurisdictions where we have regulatory authorization, we have no major capital expenditures planned for the remainder of 2013.

Financing Cash Flows

Net cash provided by financing activities for the six months ended June 30, 2013 consisted of proceeds from term loan borrowings of $5.0 million and proceeds from exercise of stock options of $0.4 million. These proceeds were partially offset by payments for deferred offering costs of $1.7 million and repayments of borrowings of $0.1 million.

Net cash provided by financing activities for the six months ended June 30, 2012 consisted of $7.5 million of borrowing under our existing credit facility, which was partially offset by repayments of borrowings under a previous loan agreement of $1.6 million.

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Contractual Obligations

The following table reflects a summary of our contractual obligations as of December 31, 2012.

	Payments due by period				
Contractual Obligations[1]	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
			(In thousands)		
Operating lease obligations[2]	$ 7,295	$ 2,009	$ 3,950	$ 1,336	$
Long-term debt obligations[3]	13,993	3,009	10,984		
Inventory purchase obligations[4]	2,604	2,604			
Total	$ 23,892	$ 7,622	$ 14,934	$ 1,336	$

(1) Excludes royalty obligations based on net sales of products, including royalties payable to the Institute for Systems Biology, as any such amounts are not currently determinable.
(2) Operating lease costs are primarily for office, laboratory and manufacturing space at our headquarters.
(3) Includes principal and interest on long-term debt obligations.
(4) Purchase obligations consist of contractual and legally binding commitments under outstanding purchase orders to purchase long lead time inventory items

Critical Accounting Policies and Significant Estimates

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

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

revenue recognition;

stock-based compensation;

inventory valuation;

fair value measurements; and

income taxes.

Revenue Recognition

We generate revenue from sales of our products and services. Our products consist of our proprietary nCounter Analysis Systems and related consumables. Services consist of extended service contracts and service fees for assay processing.

Revenue is recognized when all of the following criteria are met: (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 evaluation of these revenue recognition criteria requires significant management judgment. For instance, we use judgment to assess collectability based on factors such as the customer s creditworthiness and past collection history, if applicable. If we determine that collection of a payment is not reasonably assured, revenue recognition is deferred until receipt of payment. We also use judgment to assess whether a price is fixed or determinable including but not limited to, reviewing contractual terms and conditions related to payment terms.

Systems product revenue is recognized upon installation and calibration in geographic regions where such services are only available from our specialized technicians. In these regions, systems and related installation and calibration are considered to be one unit of accounting, as systems are required to be professionally installed and calibrated before use. In certain geographic regions, installation and calibration services are available from other vendors, and in such regions they are considered separate revenue elements. Consumables are considered to be separate units of accounting as they are sold separately. Consumables product revenue is recognized upon shipment.

Some of our sales arrangements involve the delivery or performance of multiple products or services. Significant interpretation is sometimes required to determine the appropriate accounting, including whether the deliverables specified in a multiple element arrangement should be treated as separate units of accounting for revenue recognition purposes, and, if so, how the related sales price

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should be allocated among the elements, when to recognize revenue for each element, and the period over which revenue should be recognized. Revenue recognition for arrangements with multiple deliverables is based on the individual units of accounting determined to exist in the arrangement. A delivered element is considered a separate unit of accounting when the delivered element has value to the customer on a stand-alone basis. Elements are considered to have stand-alone value when they are sold separately or when the customer could resell the element on a stand-alone basis.

For multiple-element arrangements, we allocate arrangement consideration at the inception of the arrangement to the deliverables based on the relative selling price method. The selling price used for each deliverable is based on vendor-specific objective evidence, or VSOE, if available, third-party evidence, or TPE, if VSOE is not available, or best estimated selling price, or BESP, if neither VSOE nor TPE is available. BESP is determined in a manner consistent with that used to establish the price to sell the deliverable on a stand-alone basis. To date, selling prices have been established by reference to VSOE based on stand-alone sales transactions for each deliverable. VSOE 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 we have defined to be plus or minus 15% of the median sales price of actual stand-alone sales transactions. Allocated revenue is only recognized for each deliverable when the revenue recognition criteria have been met.

Revenue from the sales of our products that are not part of multiple element arrangements is recognized when no significant obligations remain undelivered and collection of the receivables is reasonably assured, which is generally when delivery has occurred.

Accruals for estimated warranty expenses are made at the time that the associated revenue is recognized. We use judgment to estimate these accruals and, if we were to experience an increase in warranty claims or if costs of servicing our products under warranty were greater than our estimates, our cost of revenue could be adversely affected in future periods.

Revenue from the sales of our services is recognized when no significant obligations remain undelivered and collection of the receivables is reasonably assured, which is generally when delivery has occurred. We offer extended service contracts on our nCounter Analysis Systems for periods ranging from 12 to 36 months after the end of the standard 12-month warranty period. Revenue from extended service contracts is deferred and recognized in income on a straight-line basis over the contract period.

Stock-based Compensation

For those periods covered by this report, we granted stock options at exercise prices believed to be equal to the fair value of the common stock underlying such options as determined by the board of directors, with input from management, on the date of grant. Because such grants occurred prior to the public trading of our common stock, the board of directors exercised significant judgment in determining the fair market value of our common stock. The valuations were consistent with the guidance and methods outlined in the AICPA Practice Aid *Valuation of Privately-Held-Company Equity Securities Issued as Compensation,* or AICPA Practice Aid, for all option grant dates.

We account for stock-based compensation at fair value. Stock-based compensation costs are recognized based on their grant date fair value estimated using the Black-Scholes option pricing model. Stock-based compensation expense recognized in the statement of operations is based on options ultimately expected to vest and has been reduced by an estimated forfeiture rate based on our historical and expected forfeiture patterns. We use the straight-line method of allocating compensation cost over the requisite service period of the related award.

Determining the fair value of stock-based awards at the grant date under the Black-Scholes option pricing model requires judgment, including estimating the value per share of our common stock, risk-free interest rate, expected term and dividend yield and volatility. The assumptions used in calculating the fair value of stock-based awards represent our best estimates based on management judgment and subjective future expectations. These estimates involve inherent uncertainties. If any of the assumptions used in the Black-Scholes option pricing model significantly change, stock-based compensation for future awards may differ materially from the awards granted previously.

The expected term of options granted is based on historical experience of similar awards and expectations of future employee behavior. The risk-free interest rate for the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of grant. We have not paid and do not anticipate paying cash dividends on our common stock; therefore, the expected dividend yield is assumed to be zero. We based our estimate of volatility on the estimated volatility of similar companies whose share prices are publicly available.

Inventory Valuation

Inventory consists of raw materials, certain component parts to be used in manufacturing our products and finished goods. Inventory is stated at the lower of cost or market. Cost is determined using a standard cost system, whereby the standard costs are updated periodically to reflect current costs and market represents the lower of replacement cost or estimated net realizable value. We record adjustments to inventory for

potentially excess, obsolete, slow-moving or impaired items. The business environment in which we operate is subject to rapid changes in technology and customer demand. We regularly review inventory for excess and obsolete products and components, taking into account product life cycle and development plans, product expiration and quality issues, historical experience and our current inventory levels. If actual market conditions are less favorable than anticipated, additional inventory adjustments could be required.

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Fair Value Measurements

We record preferred stock warrant liability at fair value. We establish fair value using the price that would be received to sell an asset or paid to transfer a financial liability in an orderly transaction between market participants at the measurement date. A fair value hierarchy is used to measure fair value. The three levels of the fair value hierarchy are as follows:

Level 1 Quoted prices in active markets for identical assets and liabilities.

Level 2 Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.

Level 3 Valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

Whenever possible, we use observable market data and rely on unobservable inputs only when observable market data are not available. Preferred stock warrant liability is categorized as Level 3 because it was valued based on unobservable inputs and our judgment due to the absence of quoted market prices, inherent lack of liquidity and the long-term nature of such financial instruments. We perform a fair value assessment of the preferred stock warrant inputs on a quarterly basis using the Black-Scholes option pricing model. The assumptions used in the Black-Scholes option pricing model are inherently subjective and involve significant judgment. Changes in our judgments could have a material impact on our results of operations and financial position. Any change in fair value is recognized as a component of other income (expense) on the statements of operations.

Income Taxes

We use the liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to the differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to be in effect when such assets and liabilities are recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the year that includes the enactment date. We determine deferred tax assets including net operating losses and liabilities, based on temporary differences between the book and tax bases of assets and liabilities. We believe that it is currently more likely than not that our deferred tax assets will not be realized, and as such, a full valuation allowance is required.

We utilize a two-step approach for evaluating uncertain tax positions. Step one, recognition, requires us to determine if the weight of available evidence indicates that a tax position is more likely than not to be sustained upon audit, including resolution of related appeals or litigation processes, if any. If a tax position is not considered more likely than not to be sustained, no benefits of the position are recognized. If we determine that a position is more likely than not to be sustained, then we proceed to step two, measurement, which is based on the largest amount of benefit which is more likely than not to be realized on effective settlement. This process involves estimating our actual current tax exposure, including assessing the risks associated with tax audits, together with assessing temporary differences resulting from the different treatment of items for tax and financial reporting purposes. If actual results differ from our estimates, our net operating loss and credit carryforwards could be materially impacted.

At December 31, 2012, we had federal net operating loss carryforwards, or NOLs, of approximately $62.2 million and federal research and experimentation credit carryforwards of approximately $1.0 million, which may be used to reduce future taxable income or offset income taxes due. These NOLs and credit carryforwards expire beginning in 2023 through 2032.

Our realization of the benefits of the NOLs and credit carryforwards is dependent on sufficient taxable income in future fiscal years. We have established a valuation allowance against the carrying value of our deferred tax assets, as it is not currently more likely than not that we will be able to realize these deferred tax assets. In addition, utilization of NOLs and credits to offset future income subject to taxes may be subject to substantial annual limitations due to the change in ownership provisions of the Internal Revenue Code of 1986, or the Code, and similar state provisions. 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. We are in the process of determining whether this offering would constitute an ownership change resulting in further limitations on our ability to use our net operating loss and tax credit carryforwards. If an ownership change is deemed to have occurred as a result of this offering, potential near term utilization of these assets could be reduced.

We do not anticipate that the amount of our existing unrecognized tax benefits will significantly increase or decrease within the next 12 months. Due to the presence of NOLs in most jurisdictions, our tax years remain open for examination by taxing authorities back to the inception of the company.

Recent Accounting Pronouncements

We have reviewed recent accounting pronouncements and concluded that they are either not applicable to our business or that no material effect is expected on the consolidated financial statements as a result of future adoption.

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.

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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

The principal market risk we face is interest rate risk. We had cash and cash equivalents of $10.8 million as of June 30, 2013, which consisted of highly-liquid investments with an original maturity of three months or less. The goals of our investment policy are liquidity and capital preservation; we do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short term nature of our cash and cash equivalents. Declines in interest rates, however, would reduce future investment income. A 1% decline in interest rates, occurring on July 1, 2013 and sustained throughout the period ended June 30, 2014, would not be material.

As of June 30, 2013, the principal and accrued interest outstanding under our term borrowings was $18.1 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 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 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. 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 fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. To date, we have not entered into any material foreign currency hedging contracts although we may do so in the future.

Inflation Risk

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

Item 4. Controls and Procedures

(a) *Evaluation of disclosure controls and procedures.* Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this quarterly report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this quarterly report, 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 June 30, 2013 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.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On November 6, 2012, Fluidigm Corporation filed a complaint against us in the U.S. District Court for the Northern District of California, Civil Action No. C-12-5712. The complaint alleges false advertising in violation of the Lanham Act, unfair competition, and unlawful trade practices, and seeks injunctive relief and damages in relation to a marketing campaign based on a comparative study of our nCounter Single Cell Assay with Fluidigm s BioMark system. We filed our answer on January 4, 2013. On April 22, 2013, Fluidigm filed an amended complaint referencing additional NanoString marketing materials that Fluidigm alleges to contain false comparative statements. Our answer to the amended complaint was filed on May 9, 2013. Trial is scheduled to commence on March 24, 2014. We believe that Fluidigm s amended complaint is without merit and intend to vigorously defend ourselves.

On April 5, 2013, Fluidigm Corporation and its subsidiary Fluidigm Singapore Pte Ltd, filed a complaint against us in the High Court of Singapore, Case No. S 282/2013, alleging substantially the same advertising claims as were asserted in the U.S. case in addition to a separate claim for trademark infringement. Although, as of the date of this report, we have not been served with the complaint in this case, we may be served at any time.

Item 1A. Risk Factors

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

Risks Related to our Business and Strategy

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

We have incurred losses since we were formed and expect to incur losses in the future. We incurred net losses of $12.8 million and $7.2 million for the six months ended June 30, 2013 and 2012, respectively. As of June 30, 2013, we had an accumulated deficit of $110.3 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 development and commercialization of our technology. We also expect that our selling, general and administrative expenses will continue to increase due to the additional costs associated with establishing a dedicated oncology diagnostics sales force and the increased administrative costs associated with being a public company. 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, 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 decreases 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.

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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, commercialization of the Prosigna Breast Cancer Assay, or Prosigna, in Europe and development and commercialization of this test and other diagnostic products worldwide are key elements of our growth strategy and will require us to hire and retain additional sales and marketing, regulatory, manufacturing and quality assurance personnel. If we do not successfully forecast the timing of regulatory clearance or approval for product marketing and subsequent 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 institutions, government laboratories and biopharmaceutical companies that perform analyses using our nCounter Analysis System for research use only. Our success will depend, in part, upon our ability to increase our market penetration among these customers and to expand our market by developing and marketing new life sciences applications, developing a lower cost instrument that would be attractive to more researchers, and introducing diagnostic products into clinical laboratories after obtaining regulatory authorization. For example, we must convince physicians and third-party payors that our diagnostic products, such as Prosigna, are cost effective in obtaining prognostic information that can inform treatment decisions and that our nCounter Analysis System could enable an equivalent or superior approach that lessens reliance on centralized laboratories. 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. 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.

Our life sciences 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 our revenue will be derived primarily from sales of our nCounter Analysis Systems to academic institutions, governmental laboratories and biopharmaceutical companies worldwide for research 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 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.

For example, in the United States, automatic across-the-board cuts in government spending, or sequestration, took effect on March 1, 2013. These cuts will impact the budgets of government agencies, such as the National Institutes of Health, which provide significant funding for cancer research and other diseases, however, as of the date of this report the full impact of the cuts is unknown. We believe that the uncertainty

regarding the availability of research funding, including the potential impact of sequestration, has adversely affected our historical operating results and any continuing uncertainty may adversely affect sales to customers or potential customers that rely on government funding. 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. In addition, any failure to meet customer expectations could result in customers choosing to retain their existing systems or to purchase systems other than ours.

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Our reliance on distributors for sales of our life sciences systems outside of the United States could limit or prevent us from selling our diagnostic tests in foreign markets and impact our revenue.

We have established exclusive distribution agreements for our nCounter Analysis System in the life sciences research market within parts of Europe, the Middle East, Asia Pacific and South America. We intend to continue to grow our business internationally, and to do so we must attract additional distributors to maximize the commercial opportunity for our products. There is no guarantee, if we do seek to enter into such arrangements, that we will be successful in attracting 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.

If we do not obtain regulatory clearance or approval to market our products for diagnostic purposes, we will be limited to marketing our products for research use only. In addition, if regulatory limitations are placed on our diagnostic products our business and growth will be harmed.

We have obtained a CE mark for our first diagnostic product, Prosigna, which permits us to market that assay for diagnostic purposes in Europe, and we intend to seek regulatory authorization in other countries outside of the United States. In Europe, Prosigna can be used to provide a subtype classification based on the fundamental biology of an individual s breast tumor, as well as a prognostic score that indicates the probability of cancer recurrence over 10 years. In February 2013, we commercially launched Prosigna in Europe and Israel, but we do not have regulatory clearance or approval to market any other product for diagnostic purposes or to market Prosigna for diagnostic purposes in any other market. 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 any diagnostic or clinical claims. We intend to seek regulatory authorizations in other jurisdictions to market Prosigna for diagnostic purposes; however, we cannot assure investors that we will be successful in doing so. In December 2012, we submitted an application, known as a 510(k), to the FDA seeking clearance in the United States for a version of Prosigna providing an assessment of a patient s risk of recurrence for breast cancer and have had a number of subsequent communications; however, we cannot guarantee that we will obtain clearance. For example, even though the results of our clinical studies that used samples from the Arimidex, Tamoxifen, Alone or in Combination (ATAC) study and the Austrian Breast & Colorectal Cancer Study Group 8 (ABCSG8) study were favorable, there is no guarantee that any future studies will be successful or that the FDA will provide clearance of Prosigna based on the studies we have completed. If the FDA requires additional studies, we may be required to expend considerable resources to conduct them, which would greatly increase our costs, divert resources away from other programs and halt or delay the path to commercialization. If we do not obtain such clearance, we will be limited to marketing our products for research use only within the United States. In addition, even if we obtain clearance for Prosigna, the prognostic information ultimately reported could be limited. For example, if we do obtain clearance from the FDA to market Prosigna in the United States, the test may be limited to classifying patients into categories according to the risk of recurrence of breast cancer, such as high/intermediate/low risk or high/low risk. If Prosigna is not cleared by the FDA to indicate a specific risk score or if Prosigna is limited to classifying node-negative patients into high or low risk groups only, the prognostic information provided by Prosigna and our ability to differentiate our test from alternatives may be adversely affected in the United States. Similarly, if we do not obtain regulatory clearance or approval of future products or future indications for diagnostic purposes, for instance approval to allow for reporting of the subtype classification based on the fundamental biology of an individual s breast cancer, if unexpected 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.

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

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, third-party payors and patients that Prosigna provides equivalent or better prognostic information.

In Europe, Prosigna may be used for intrinsic subtyping of breast cancer and in the future we intend to seek approval from the FDA for such use. Intrinsic subtyping will be a new methodology in categorizing breast cancer patients, and we may have to overcome resistance among physicians to adopting it for the marketing of our products to be successful. Even if we are able to obtain regulatory approval from the FDA, the use of intrinsic subtyping and thus Prosigna may not be included in breast cancer treatment guidelines. In addition, breast cancer treatment guidelines recommend that chemotherapy be considered in many cases, in combination with other patient factors. Accordingly, physicians may be reluctant to order a test, such as Prosigna, that may suggest recommending against chemotherapy. Furthermore, our diagnostic tests would be performed

by pathologists in local laboratories, rather than by a vendor in a remote centralized laboratory, which will require us to educate pathologists regarding the benefits of this business model.

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, and thus we may encounter significant difficulty in broadening market acceptance of Prosigna.

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As part of our current business model, we will seek to enter into strategic collaborations and licensing arrangements with third parties to develop diagnostic tests.

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 life sciences research customers engaged in translational research. In addition, in February 2013, we secured an option from The Broad Institute, a leading non-profit molecular medicine institute in Cambridge, Massachusetts, to acquire an exclusive worldwide license for a gene signature that could be used, after appropriate regulatory authorization, for a second molecular diagnostic product focused on hepatocellular carcinoma, or HCC. We intend to enter into more such arrangements with our life sciences customers and other researchers for future diagnostic products. However, there is no assurance that we will be successful in doing so. In particular, our life sciences research 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 that used samples from the ATAC study and ABCSG8 study of postmenopausal women with HR+ early stage breast cancer were favorable, there is no guarantee that the FDA will provide clearance of Prosigna based on the studies we have completed, that any future studies will be successful, or that if the FDA provides clearance, the prognostic information that may be reported will differentiate our test from alternatives in the United States. 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.

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, including the funds we raised in our initial public offering, 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;
- 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.

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. 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 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

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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. 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 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.

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 Affymetrix, Agilent Technologies, Bio-Rad, Exiqon, Fluidigm, High Throughput Genomics, Illumina, Life Technologies, Luminex, Perkin Elmer, Qiagen and Roche Applied Science. In addition, there are a number of new market entrants in the process of developing novel technologies for the life sciences market, including companies such as RainDance Technologies and Wafergen Bio-Systems.

We will also compete with commercial diagnostics companies. We believe our principal competitor in the breast cancer diagnostics market will be 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 expect to face competition from companies such as Agendia, Clarient (a GE Healthcare company), Genoptix (a division of Novartis) and bioMeriéux, which also offer services by means of centralized laboratories that profile gene or protein expression in breast cancer. In Europe, we will also face regional competition from smaller companies such as Sividon Diagnostics, maker of EndoPredict, a distributed test for breast cancer recurrence, and other independent laboratories.

Most of our current competitors are either publicly traded, or are divisions of publicly-traded companies, and 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:

breadth of clinical decisions that can be influenced by information generated by tests;

volume, quality, and strength of clinical and analytical validation data;

availability of reimbursement for testing services; and

economic benefit accrued to customers based on testing services enabled by products.

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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 products, and if we are unable to successfully commercialize our products, our business may be adversely affected.

We have limited experience marketing and selling our products. Our nCounter Analysis System was introduced for sale in the life sciences research market in 2008, and was introduced for sale in the diagnostics market in Europe and Israel in connection with the February 2013 commercial launch of Prosigna in those markets. We sell our products through our own sales force in North America and through a combination of our own sales force and distributors in Europe, Middle East, Asia Pacific and South America. In the future, we intend to establish distributor relationships in other parts of the world; however, we may not be able to market and sell our products effectively.

Our future sales of diagnostic products will depend in large part on our ability to successfully establish an oncology diagnostics sales force and to increase the scope of our marketing efforts. Because we have no 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. If we do not build an efficient and effective sales force targeting this market, our business and operating results will be adversely affected.

We may not be able to develop new products or enhance the capabilities of our systems to keep pace with rapidly changing technology and customer requirements, 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, single-cell analysis and copy number variation, as well as potential markets for our diagnostic product candidates, are characterized by rapid technological change and innovation. It is critical to our success that we anticipate changes in technology and customer requirements and to successfully introduce new, enhanced and competitive technologies to meet our customers and prospective customers needs on a timely and cost-effective basis. At the same time, however, we must carefully manage the introduction by us 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. 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 successfully innovate and introduce new technology into our product lines or manage the transitions to new product offerings, our revenues, results of operations and business will be adversely impacted.

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.

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 July 2013, we launched nCounter Elements, a new digital molecular barcoding chemistry that allows users to design their own customized assays using standard sets of barcodes provided by us, and in September 2012, we launched a single cell gene expression application for our nCounter Analysis System, which applies our technology to, amongst other things, improve single cell analytic workflow for gene expression analysis. The future growth of the market for these 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. If the markets for nCounter Elements, single cell analysis or others do not develop as we expect, our business may be adversely affected. In addition, we commercially launched Prosigna in Europe and Israel in February 2013 and we intend to offer Prosigna in other countries outside of the United States. Genomic testing for breast cancer is not widely available outside of the United States 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. Our success in these new markets will depend to a large extent on our ability to successfully market, sell and establish reimbursement for products using our technologies. If we are not able to successfully market and sell our products or to achieve the revenue or margins we expect, our operating results may be harmed and we may not recover our product development and marketing expenditures.

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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 and Korvis LLC of Corvallis, Oregon, to build our nCounter Digital Analyzer. Each of these contract manufacturers are sole suppliers. Since our contracts with these instrument suppliers do not commit them to carry inventory or make available any particular quantities, they may give other customers needs higher priority than ours, and we may not be able to obtain adequate supplies in a timely manner or on commercially reasonable terms. We also rely on sole suppliers for various components we use to manufacture our consumable products. We periodically forecast our needs for such components and enter into standard purchase orders with them. If we were to lose such suppliers, 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 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 that type of product. While all of our codesets are produced using the same basic processes, significant variations may be required to meet product specifications. Developing such a process can be very time consuming, and any unexpected difficulty in doing so could delay the introduction of a product.

If our Seattle facility becomes unavailable or inoperable, we will be unable to continue manufacturing our consumables or process sales orders, and our business will be harmed.

We manufacture our consumable products in our facility in Seattle, Washington. In addition, our Seattle facility is the center for order processing, receipt of our prep station and digital analyzer manufactured by third-party contract manufacturers and shipping products to customers. Our facility 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. The facility 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 tests 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 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.

During the six months ended June 30, 2013 and 2012, approximately 25% and 32%, 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;

potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;

difficulties and costs of staffing and managing foreign operations; and

difficulties protecting or procuring intellectual property rights.

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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, 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.

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.

The enactment of legislation implementing changes in the U.S. taxation of international business activities or the adoption of other tax reform policies could materially impact our future financial position and results of operations.

Recent changes to U.S. tax laws, including limitations on the ability of taxpayers to claim and utilize foreign tax credits and the deferral of certain tax deductions until earnings outside of the United States are repatriated to the United States, as well as changes to U.S. tax laws that may be enacted in the future, could impact the tax treatment of future foreign earnings. Should the scale of our international business activities expand, any changes in the U.S. taxation of such activities could increase our worldwide effective tax rate and harm our future financial position and results of operations.

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

As of December 31, 2012, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of approximately $62.2 million, which expire in various years beginning in 2023, 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, including this or future offerings, 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 credit facility 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;
- pay dividends or make other distributions to holders of our capital stock;

make specified investments;

change certain key management personnel; and

engage in transactions with our affiliates.

These restrictions could inhibit our ability to pursue our business strategies. In addition, we are subject to a financial covenant based on life sciences revenue. If we default under our credit facility, and such event of default was 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.

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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. In particular, the commercial launch of Prosigna requires us to establish a dedicated oncology diagnostics sales force to fully optimize the breast cancer diagnostic market opportunity. 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. Since our current customers use our products for research and may, if cleared or approved, in the future use them for diagnostic applications, disruptions or other performance problems with our products may damage our customers business 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 harm our business and operating results.

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

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

Our operations are subject to complex and stringent environmental, health, safety and other governmental laws and regulations that both public officials and private individuals may seek to enforce. Our activities that are subject to these regulations include, among other things, our use of hazardous materials and the generation, transportation and storage of waste. We could discover that we or an acquired business is 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.

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Risks Related to Government Regulation and Diagnostic Product Reimbursement

Our research use only products for the life sciences 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 life sciences 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 institutions and life sciences laboratories. Because such products are not intended for use in clinical practice in diagnostics, and the products cannot include clinical or diagnostic claims, they are not subject to regulation by the 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. However, in June 2011, the FDA issued a draft guidance document that, if finalized as drafted, could restrict the provision of our RUO products, and it is unclear whether the FDA will issue a final guidance and if so what the contents of the guidance will be. If in the future the FDA modifies its approach to regulating our 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.

Our general purpose reagents may be used by clinical laboratories to create laboratory developed tests, or LDTs, which could in the future be subject to regulation as medical devices, which could materially and adversely affect our life sciences business and results of operations.

Recently, we launched nCounter Elements, 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 are considered general purpose reagents, or GPRs, by the FDA, that are class I medical devices, and we recently listed nCounter Elements with the FDA as GPRs.

A clinical laboratory can use nCounter Elements to create what is called a laboratory developed test, or LDT. LDTs are diagnostic tests that are developed and performed by a laboratory and include genetic tests, tests for rare conditions and companion diagnostics. In June 2013, the Commissioner of the FDA stated that the FDA intends to further regulate LDTs; however, it is unclear whether, when and to what extent the FDA will do so. Restrictions on LDTs by the FDA could restrict the demand for our products, including nCounter Elements. Additionally, compliance with additional regulatory burdens could be time consuming and costly. If the FDA regulates LDTs, such regulation could adversely affect our prospects, results of operations and financial condition.

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 would be required to obtain either prior 510(k) clearance or prior pre-market approval, or PMA, from the FDA. In December 2012, we submitted an application, known as a 510(k), to the FDA seeking clearance in the United States for a version of Prosigna and have had a number of subsequent communications with the FDA. Based on pre-submission interactions with the FDA and the FDA s written response to our 510(k) submission, we expect Agendia s MammaPrint to serve as the legally marketed predicate that, if Prosigna is cleared, would enable us to market a version of Prosigna in the United States to assess a patient s risk of recurrence for breast cancer. In the FDA s written response to our 510(k) submission, the FDA communicated, among other things, that we would need to provide further support before the FDA could determine whether the pending 510(k) application, if cleared, would allow us to include a risk score and three distinct risk groups in patient reports for all patients tested. If Prosigna is not cleared by the FDA to include a specific risk score or if Prosigna is limited to classifying node-negative patients into high or low risk groups only, the prognostic information provided by Prosigna and our ability to differentiate our test from alternatives may be adversely affected in the United States. As with all *in vitro* diagnostic products, the FDA reserves the right to redefine the regulatory path at the time of submission or during the review process, and could require a more burdensome approach, including a PMA. In the future we plan to submit a separate application for approval of Prosigna to report intrinsic subtype, and we expect that this application will require a PMA supported by additional clinical studies. We intend to pursue additional intended uses for Prosigna, which may require more burdensome regulatory processes than the 510(k) clearance process, including PMAs. Even if granted, a 510(k) clearance or PMA approval for any future product would likely place substantial restrictions on how our device is marketed or sold, and the FDA will continue to place considerable restrictions on our products, including, but not limited to, quality system regulations, or QSR, registering manufacturing facilities, listing the products with the FDA, and complying with labeling, marketing, complaint handling, adverse event and medical device reporting requirements and 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. 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 be

permitted to market our product for those uses.

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Sales of our diagnostic products outside the United States will be subject to foreign regulatory requirements governing clinical studies, vigilance reporting, marketing approval, manufacturing, 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 and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA and foreign regulatory authorities could require additional testing. In addition, FDA regulates exports of medical devices. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to commercialize our diagnostic products outside of the United States.

We expect to rely on third parties to conduct any future studies of our diagnostic products that may be required by the FDA or other regulatory authorities, 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 Prosigna. Accordingly, we expect to rely on third parties, such as medical institutions and clinical investigators, 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 prepare, 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.

Even if we are able to obtain regulatory approval or clearance for our diagnostic products, we will continue to be subject to ongoing and extensive regulatory requirements, and our failure to comply with these requirements could substantially harm our business.

If we receive regulatory approval or clearance for our diagnostic products, we will be subject to ongoing FDA obligations and continued regulatory oversight and review, such as compliance with QSRs, inspections by the FDA, continued adverse event and malfunction reporting, corrections and removals reporting, registration and listing, and promotional restrictions, and we may also be subject to additional FDA post-marketing obligations. If we are not able to maintain regulatory compliance, we may not be permitted to market our diagnostic products and/or may be subject to 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.

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, such as Prosigna. 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 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. Reductions in the reimbursement rate of third-party payors have 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. We expect that it will take several years to establish broad coverage and reimbursement for testing services based on our products with payors in countries outside of the United States, and our efforts may not be successful.

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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.

If we obtain FDA approval or clearance for any of our diagnostic product candidates and begin commercializing those products in the United States, our operations will be 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. These laws may impact, among other things, our proposed sales and marketing and education programs. 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:

- 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; and
- the federal False Claims Act civil and criminal penalties and state equivalents.

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 recently enacted 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 Affordability Reconciliation Act, collectively, the PPACA, enacted in March 2010, makes changes that are expected to significantly impact the pharmaceutical and medical device industries and clinical laboratories. Beginning in 2013, each medical device manufacturer will have to pay a sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. We expect that the new tax may apply to some or all of our diagnostic products. The PPACA also mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule of 1.75% for the years 2011 through 2015 and a productivity 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 diagnostics customers use our technology to deliver to Medicare beneficiaries, and may indirectly reduce demand for our diagnostic products.

Other significant measures contained in the PPACA 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 PPACA 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 PPACA 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 future diagnostics customers use our technology to deliver beginning in 2016 and for hospital services beginning in 2020, and may indirectly reduce demand for our diagnostic products.

In addition to the PPACA, 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 taxes imposed by the new federal legislation and 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 July 25, 2013, we owned or exclusively licensed six issued U.S. patents and approximately 22 pending U.S. patent applications, including provisional and non-provisional filings. We also owned or licensed approximately 66 pending and granted counterpart applications worldwide, including 22 country-specific validations of three 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.

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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. 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. Accordingly, this evolving case law in the United States may adversely impact our ability to obtain new patents and may facilitate third-party challenges to our existing owned and licensed patents. One of our main areas of intellectual property, namely patents we license directed to the use of gene expression markers as part of genomic diagnostic tests, may be affected by these decisions.

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

We apply for patents covering our products and technologies and uses thereof, as we deem appropriate. However, we may fail to apply for patents on important products and technologies in a timely fashion or at all.

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

In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. 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, including Prosigna, 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.

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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 and technology relating to Prosigna licensed from Bioclassifier, LLC. 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.

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. Our rights under the licenses are subject to our continued compliance with the terms of the license, including the payment of royalties due under the license. Because of the complexity of our products and the patents we have licensed, determining the scope of the license and related royalty obligation can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the license or termination of the license. If a licensor believed we were not paying the royalties due under the license or were otherwise not in compliance with the terms of the license, the licensor might attempt to revoke the license. If such an attempt were successful, we might be barred from producing and selling some or all of our products.

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

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. 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

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jurisdictions that claim methods of using certain genes that are included in Prosigna. We believe that Prosigna will 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, 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 and other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims against us, including the claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify any of these third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our employees former employers.

Many of our employees were previously employed at universities or other life sciences companies, including our competitors or potential competitors. Although no claims against us are currently pending, we 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.

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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

We expect that our stock price will fluctuate significantly and investors may not be able to resell their shares at or above the initial public offering price.

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

- 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 life sciences research and molecular 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;

expiration of contractual lock-up agreements with our executive officers, directors and security holders;

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 section of the report captioned Risk Factors.

The stock market in general, and market prices for the securities of health technology 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 develop.

Until recently, there has been no public market for our common stock. Although our common stock is listed on The NASDAQ Global Market, an active trading market for our shares may never develop or be sustained in the future. The lack of an active market 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.

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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.

The resale of approximately 9.2 million shares, or 63% of our outstanding shares, are currently prohibited or otherwise restricted as a result of securities law provisions, market standoff agreements entered into by our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters of our initial public offering; however, subject to applicable securities law restrictions, these shares will be able to be sold in the public market beginning December 22, 2013. In addition, the shares subject to outstanding options and warrants, of which options and warrants to purchase 1,326,097 shares and 617,605 shares, respectively, were exercisable as of June 30, 2013, and the shares reserved for future issuance under our stock option and equity incentive plans will become available for sale immediately upon the exercise of such options and the expiration of any applicable market stand-off or lock-up agreements.

Holders of approximately 9.5 million shares (including the shares underlying outstanding warrants), or 65%, of our outstanding shares, will 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 intend to register the offer and sale of all shares of common stock that we may issue under our equity compensation plans. Once we register the offer and sale of shares for the holders of registration rights and option holders, they can be freely sold in the public market upon issuance, subject to any related lock-up agreements.

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 issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

Our executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned approximately 59% of our capital stock as of June 30, 2013. Accordingly, our executive officers, directors and principal stockholders will be able to determine the composition of the board of directors, retain the voting power to approve all matters requiring stockholder approval, including mergers and other business combinations, and continue to have significant influence over our operations. 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.

Our management team has broad discretion to use the net proceeds from our initial public offering and its investment of these proceeds may not yield a favorable return. We may invest the proceeds of our initial public offering in ways with which investors disagree.

We have broad discretion as to how to spend and invest the proceeds from our initial public offering and we may spend or invest these proceeds in a way with which our stockholders disagree. Accordingly, investors will need to rely on our judgment with respect to the use of these proceeds and these uses may not yield a favorable return to our stockholders. In addition, until the net proceeds are used, they may be placed in investments that do not produce significant income or that may lose value.

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 will:

- 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;

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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 will be permitted to amend the bylaws only upon receiving at least two-thirds of the total votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

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

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, or JOBS, Act enacted in April 2012, and, for as long as we continue to be an emerging growth company, we may choose 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 for up to five years following the completion of our initial public offering, 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. We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may 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 will increase 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 will 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 will need to devote a substantial amount of time to compliance with these laws and regulations. These requirements have increased and will 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, we expect these rules and regulations to make it 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, beginning January 1, 2014, Section 404 of the Sarbanes-Oxley Act, or Section 404, will require 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 expect to avail 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

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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 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 controls from our independent registered public accounting firm.

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

(a) Sales of Unregistered Securities

From April 1, 2013 until June 30, 2013, we granted stock options under our 2004 Stock Option Plan to purchase 19,500 shares of our common stock to certain of our employees an exercise price of $8.96 per share. In addition, from April 1, 2013 until June 30, 2013, we granted stock options under our 2013 Equity Incentive Plan to purchase 11,686 shares of our common stock to one of our directors at an exercise price of $10.00 per share. During such period we issued an aggregate of 19,197 shares of common stock that were not registered under the Securities Act to our employees pursuant to the exercise of stock options for cash consideration with aggregate exercise proceeds of approximately $45,000. These issuances were undertaken in reliance upon the exemption from registration requirements available under Rule 701 of the Securities Act.

(b) Use of Proceeds from Public Offering of Common Stock

On June 25, 2013, our registration statement on Form S-1 (No. 333-189883) was declared effective for our initial public offering, and on July 1, 2013 we consummated the initial public offering consisting of 5,400,000 shares of our common stock for $10.00 per share. The underwriters of the offering were J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC, Leerink Swann LLC and Robert W. Baird & Co. Incorporated. Following the sale of the shares in connection with the closing of the initial public offering, the offering terminated. As a result of the offering, we received total net proceeds of approximately $46.8 million, after deducting total expenses of $7.2 million, consisting of underwriting discounts and commissions of $3.8 million and offering-related expenses of approximately $3.4 million. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates.

We intend to use the net proceeds from our initial public offering to: (1) commercialize Prosigna after obtaining regulatory authorization, including establishing a dedicated oncology sales force; (2) expand the clinical utility of Prosigna and to develop other potential diagnostic product opportunities; (3) expand life sciences commercial operations to grow and support the installed base of our nCounter Analysis Systems among life sciences research customers in the United States and internationally; (4) develop new life sciences applications, chemistry and instrumentation for our nCounter technology platform; and (5) for working capital and other general corporate purposes. We may also use a portion of the net proceeds to acquire, license and invest in complementary products, technologies or businesses; however, we currently have no agreements or commitments to complete any such transaction. There has been no material change in the planned use of proceeds from our initial public offering from that described in the final Prospectus filed with the SEC pursuant to Rule 424(b)(4) on June 25, 2013.

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Item 6. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Company
3.2	Amended and Restated Bylaws of the Company
10.1	Third amendment to Loan and Security Agreement among the Company, Oxford Finance LLC and Silicon Valley Bank, dated July 22, 2013
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**	The following financial statements from the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, formatted in XBRL: (i) Consolidated Statements of Cash Flows, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Income (Loss), (iv) Consolidated Balance Sheets, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text and including detailed tags.

* 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.

** Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

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SIGNATURES

Pursuant to the requirements of the Securities 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: August 8, 2013

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

(Principal Executive Officer)

Date: August 8, 2013

By: /s/ James A. Johnson
James A. Johnson
Chief Financial Officer

(Principal Financial and Accounting Officer)

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101**	The following financial statements from the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, formatted in XBRL: (i) Consolidated Statements of Cash Flows, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Income (Loss), (iv) Consolidated Balance Sheets, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text and including detailed tags.

* 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.

** Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.