GENOMIC HEALTH INC
Form 10-Q
May 07, 2014
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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 March 31, 2014

Or

o 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: 000-51541

GENOMIC HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0552594**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

301 Penobscot Drive

Redwood City, California 94063

(Address of principal executive offices, including Zip Code)

(650) 556-9300

(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 x NO o

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 o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES o NO x

The number of outstanding shares of the registrant s Common Stock, $0.0001 par value, was 31,242,188 as of April 30, 2014.

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PART 1: FINANCIAL INFORMATION

Item 1. Financial Statements

GENOMIC HEALTH, INC.

Condensed Consolidated Balance Sheets

(In thousands)

(Unaudited)

	March 31, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,241	$ 33,279
Short-term marketable securities	72,621	72,071
Accounts receivable (net of allowance for doubtful accounts; 2014 - $1,932, 2013 - $1,907)	28,901	29,446
Prepaid expenses and other current assets	10,125	10,196
Total current assets	139,888	144,992
Long-term marketable securities	1,285	
Property and equipment, net	18,065	18,290
Other assets	14,099	13,752
Total assets	$ 173,337	$ 177,034
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 7,562	$ 5,160
Accrued compensation	11,399	12,776
Accrued license fees	2,300	2,554
Accrued expenses and other current liabilities	9,958	8,464
Deferred revenues	8	586
Other current liabilities	192	292
Total current liabilities	31,419	29,832
Other liabilities	2,136	2,221
Commitments and contingencies		
Stockholders equity:		
Common stock	3	3
Additional paid-in capital	347,582	345,345
Accumulated other comprehensive income, net	21	12
Accumulated deficit	(177,714)	(170,269)
Treasury stock, at cost	(30,110)	(30,110)
Total stockholders equity	139,782	144,981
Total liabilities and stockholders equity	$ 173,337	$ 177,034

See accompanying notes.

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GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2014	**2013**
Revenues:		
Product revenues	$ 67,002	$ 62,709
Contract revenues		385
Total revenues	67,002	63,094
Operating expenses:		
Cost of product revenues	12,055	9,746
Research and development	14,681	13,663
Selling and marketing	32,732	27,439
General and administrative	14,728	13,135
Total operating expenses	74,196	63,983
Loss from operations	(7,194)	(889)
Interest income	50	65
Other income (expense), net	(226)	(6)
Loss before income taxes	(7,370)	(830)
Income tax expense	75	53
Net loss	$ (7,445)	$ (883)
Basic and diluted net loss per share	$ (0.24)	$ (0.03)
Shares used in computing basic and diluted net loss per share	31,087	30,099

See accompanying notes.

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GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Comprehensive Income (Loss)

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2014	**2013**
Net loss	$ (7,445)	$ (883)
Other comprehensive income		
Unrealized gain on available-for-sale marketable securities, net of tax	9	18
Comprehensive loss	$ (7,436)	$ (865)

See accompanying notes.

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GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2014	**2013**
Operating activities		
Net loss	$ (7,445)	$ (883)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,757	1,545
Employee stock-based compensation	4,356	4,359
Outside director restricted stock awarded in lieu of fees	50	50
(Gain) loss on disposal of property and equipment	33	(4)
Impairment of assets held for sale	265	
Changes in assets and liabilities:		
Accounts receivable	545	(4,792)
Prepaid expenses and other assets	(315)	(771)
Accounts payable	2,367	(898)
Accrued compensation	(1,377)	(1,832)
Accrued expenses and other liabilities	468	2,049
Deferred revenues	(578)	(321)
Net cash provided by (used in) operating activities	126	(1,498)
Investing activities		
Purchases of property and equipment	(1,169)	(2,217)
Purchases of marketable securities	(23,326)	(18,289)
Maturities of marketable securities	21,500	20,387
Net cash used in investing activities	(2,995)	(119)
Financing activities		
Net proceeds from issuance of common stock under stock plans	996	3,158
Withholding taxes related to restricted stock units net share settlement	(3,165)	(2,434)
Repurchase of common stock		(15)
Net cash provided by (used in) financing activities	(2,169)	709
Net decrease in cash and cash equivalents	(5,038)	(908)
Cash and cash equivalents at the beginning of the period	33,279	18,005
Cash and cash equivalents at the end of the period	$ 28,241	$ 17,097
Supplemental disclosure of cash flow information		
Cash paid for income taxes	$ 218	$ 108
Non-cash investing and financing activities		
Accrued purchase of property and equipment	$ 1,750	$ 1,372

See accompanying notes.

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GENOMIC HEALTH, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2014

(Unaudited)

Note 1. Organization and Summary of Significant Accounting Policies

The Company

Genomic Health, Inc. (the Company) is a global healthcare company that provides actionable genomic information to personalize cancer treatment decisions. The Company develops and globally commercializes genomic-based clinical laboratory services that analyze the underlying biology of cancer, allowing physicians and patients to make individualized treatment decisions. The Company was incorporated in Delaware in August 2000. The Company s first product, the Onco*type* DX invasive breast cancer test, was launched in 2004 and is used for early stage invasive breast cancer patients to predict the likelihood of breast cancer recurrence and the likelihood of chemotherapy benefit. In January 2010, the Company launched its second product, the Onco*type* DX colon cancer test, which is used to predict the likelihood of colon cancer recurrence in patients with stage II disease. In December 2011, the Company made Onco*type* DX available for patients with ductal carcinoma in situ (DCIS), a pre-invasive form of breast cancer. This test provides a DCIS score that is used to predict the likelihood of local recurrence. In June 2012, the Company began offering the Onco*type* DX colon cancer test for use in patients with stage III disease treated with oxaliplatin-containing adjuvant therapy. In May 2013, the Company launched the Onco*type* DX prostate cancer test. The test provides a Genomic Prostate Score, or GPS, to predict disease aggressiveness in men with low risk disease. This test is used to improve treatment decisions for prostate cancer patients, in conjunction with the Gleason score, or tumor grading.

Principles of Consolidation

The condensed consolidated financial statements include all the accounts of the Company and its wholly-owned subsidiaries. The Company had three wholly-owned subsidiaries at March 31, 2014: Genomic Health International Sarl, which was established in Switzerland in 2009, and Genomic Health International Holdings, LLC, which was established in Delaware in 2010, both of which support the Company s international sales and marketing efforts; and Oncotype Laboratories, Inc., which was established in 2003, and is inactive. Genomic Health International Holdings, LLC has nine wholly-owned subsidiaries. The functional currency for the Company s wholly-owned subsidiaries incorporated outside the United States is the U.S. dollar. All significant intercompany balances and transactions have been eliminated.

Basis of Presentation and Use of Estimates

The accompanying interim period condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The condensed consolidated balance sheet as of March 31, 2014, and the condensed consolidated statements of operations, comprehensive income (loss) and cash flows for the three months ended March 31, 2014 and 2013 are

unaudited, but include all adjustments, consisting only of normal recurring adjustments, which the Company considers necessary for a fair presentation of its financial position, operating results and cash flows for the periods presented. The condensed consolidated balance sheet at December 31, 2013 has been derived from audited financial statements, but it does not include certain information and notes required by GAAP for complete consolidated financial statements.

The preparation of financial statements in conformity with GAAP requires management to make judgments, assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures in the Company s condensed consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

The accompanying interim period condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2013.

Revenue Recognition

The Company derives its revenues from product sales and contract research arrangements. The majority of the Company s historical product revenues have been derived from the sale of the Onco*type* DX breast cancer test. The Company generally bills third-party payors upon generation and delivery of a patient report to the physician. As such, the Company takes assignment of benefits and the risk of collection with the third-party payor. The Company usually bills the patient directly for amounts owed after multiple requests for payment have been denied or only partially paid by the insurance carrier. The Company pursues case-by-case reimbursement where policies are not in place or payment history has not been established.

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The Company s product revenues for tests performed are recognized when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Criterion (1) is satisfied when the Company has an arrangement to pay or a contract with the payor in place addressing reimbursement for the Onco*type* DX test. In the absence of such arrangements, the Company considers that criterion (1) is satisfied when a third-party payor pays the Company for the test performed. Criterion (2) is satisfied when the Company performs the test and generates and delivers to the physician, or makes available on its web portal, a patient report. Determination of criteria (3) and (4) are based on management s judgments regarding whether the fee charged for products or services delivered is fixed or determinable, and the collectability of those fees under any contract or arrangement. When evaluating collectability, the Company considers whether it has sufficient history to reliably estimate a payor s individual payment patterns. Based upon at least several months of payment history, the Company reviews the number of tests paid against the number of tests billed and the payor s outstanding balance for unpaid tests to determine whether payments are being made at a consistently high percentage of tests billed and at appropriate amounts given the contracted payment amount. To the extent all criteria set forth above are not met when test results are delivered, product revenues are recognized when cash is received from the payor.

The Company has exclusive distribution agreements for one or more of its Onco*type* DX tests with approximately 20 distributors covering more than 90 countries. The distributor generally provides certain marketing and administrative services to the Company within its territory. As a condition of these agreements, the distributor generally pays the Company an agreed upon fee per test and the Company processes the tests. The same revenue recognition criteria described above generally apply to tests received through distributors. To the extent all criteria set forth above are not met when test results are delivered, product revenues are generally recognized when cash is received from the distributor.

From time to time, the Company receives requests for refunds of payments, generally due to overpayments made by third-party payors. Upon becoming aware of a refund request, the Company establishes an accrued liability for tests covered by the refund request until such time as the Company determines whether or not a refund is due. Accrued refunds were $1.2 million and $770,000 at March 31, 2014 and December 31, 2013, respectively, and included in accrued expenses and other current liabilities.

Contract revenues are generally derived from studies conducted with biopharmaceutical and pharmaceutical companies. The specific methodology for revenue recognition is determined on a case-by-case basis according to the facts and circumstances applicable to a given contract. Under certain contracts, the Company s input, measured in terms of full-time equivalent level of effort or running a set of assays through its clinical reference laboratory under a contractual protocol, triggers payment obligations, and revenues are recognized as costs are incurred or assays are processed. Certain contracts have payments that are triggered as milestones are completed, such as completion of a successful set of experiments. Milestones are assessed on an individual basis and revenue is recognized when these milestones are achieved, as evidenced by acknowledgment from collaborators, provided that (1) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (2) the milestone payment is non-refundable. Where separate milestones do not meet these criteria, the Company typically defaults to a performance-based model, such as revenue recognition following delivery of effort as compared to an estimate of total expected effort.

Advance payments received in excess of revenues recognized are classified as deferred revenue until such time as the revenue recognition criteria have been met.

Allowance for Doubtful Accounts

The Company accrues an allowance for doubtful accounts against its accounts receivable based on estimates consistent with historical payment experience. Bad debt expense is included in general and administrative expense on the Company s condensed consolidated statements of

operations. Accounts receivable are written off against the allowance when the appeals process is exhausted, when an unfavorable coverage decision is received or when there is other substantive evidence that the account will not be paid. The Company s allowance for doubtful accounts at both March 31, 2014 and December 31, 2013 was $1.9 million. Write-offs for doubtful accounts of $1.5 million and $1.0 million were recorded against the allowance during the three months ended March 31, 2014 and 2013, respectively. Bad debt expense was $1.5 million and $1.3 million for the three months ended March 31, 2014 and 2013, respectively.

Research and Development Expenses

Research and development expenses are comprised of costs incurred to develop technology and carry out clinical studies and include salaries and benefits, reagents and supplies used in research and development laboratory work, infrastructure expenses, including allocated facility occupancy and information technology costs, contract services, and other outside costs. Research and development expenses also include costs related to activities performed under contracts with biopharmaceutical and pharmaceutical companies. Research and development costs are expensed as incurred.

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The Company enters into collaboration and clinical trial agreements with clinical collaborators and records these costs as research and development expenses. The Company records accruals for estimated study costs comprised of work performed by its collaborators under contract terms. Advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as expense as the goods are delivered or the related services are performed.

Income Taxes

The Company uses the liability method for income taxes, whereby deferred income taxes are provided on items recognized for financial reporting purposes over different periods than for income tax purposes. Valuation allowances are provided when the expected realization of tax assets does not meet a more-likely-than-not criterion.

The Company accounts for uncertain income tax positions using a benefit recognition model with a two-step approach, a more-likely-than-not recognition criterion and a measurement attribute that measures the position as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement, in accordance with the accounting guidance for uncertain tax positions. If it is not more likely than not that the benefit will be sustained on its technical merits, no benefit is recorded. Uncertain tax positions that relate only to timing of when an item is included on a tax return are considered to have met the recognition threshold. The Company recognizes accrued interest and penalties related to unrecognized tax benefits in income tax expense when and if incurred. See Note 8, Income Taxes, for additional information regarding unrecognized tax benefits.

Investments in Privately Held Companies

The Company determines whether its investments in privately held companies are debt or equity based on their characteristics, in accordance with accounting guidance for investments. The Company also evaluates the investee to determine if the entity is a variable interest entity (VIE) and, if so, whether the Company is the primary beneficiary of the VIE, in order to determine whether consolidation of the VIE is required in accordance with accounting guidance for consolidations. If consolidation is not required and the Company owns less than 50.1% of the voting interest of the entity, the investment is evaluated to determine if the equity method of accounting should be applied. The equity method applies to investments in common stock or in-substance common stock where the Company exercises significant influence over the investee, typically represented by ownership of 20% or more of the voting interests of an entity. If the equity method does not apply, investments in privately held companies determined to be equity securities are accounted for using the cost method. Investments in privately held companies determined to be debt securities are accounted for as available-for-sale or held-to-maturity securities, in accordance with accounting guidance for investments.

In December 2010, the Company invested $500,000 in the preferred stock of a private company representing 21% of the entity s outstanding voting shares. The Company determined that it was not the primary beneficiary of this VIE and, accordingly, applied the equity method of accounting. In June 2012, the Company invested an additional $400,000 in the preferred stock of this company as part of a new equity financing, reducing the Company s holdings to approximately 16%. As of June 30, 2012, as a result of the Company s ownership falling below 20% and not having the ability to exercise influence over the investee entity, the Company changed its method of accounting for this investment to the cost method. Each of the Company s equity investments is reviewed at least annually for impairment or whenever events or changes in circumstances indicate that the carrying value of the investment might not be recoverable. At December 31, 2013, the Company concluded that the indicators of impairment of its investment in this privately held company were other than temporary and wrote off the remaining asset balance of $643,000. Therefore, the net carrying value of this investment was $0 at March 31, 2014 and December 31, 2013.

In March 2011, the Company invested $2.3 million in the redeemable preferred stock of a private company representing 21% of the entity s outstanding voting shares. The Company determined that the investment was a held-to-maturity debt security and that the investee was not subject to consolidation. In August 2012, the Company participated in the first tranche of a second preferred stock financing of this private company and purchased $1.0 million of preferred stock with no redemption privileges. In connection with this financing, the terms of the Company s initial redeemable preferred stock investment were modified to become preferred stock with no redemption privileges. As a result of this transaction, the Company s ownership interest was reduced to approximately 19% and the investment held by the Company is considered to be an investment in non-marketable equity securities. In October 2012, the Company participated in the second tranche of the second financing and purchased an additional $3.6 million of preferred stock, resulting in an ownership percentage of approximately 18%. In May 2013, the investee completed an additional round of financing to new investors. In November 2013, the Company participated in the second tranche of the fourth financing and purchased an additional $5.0 million of preferred stock. At both March 31, 2014 and December 31, 2013, the Company s ownership percentage was approximately 12%. The investee is not consolidated because the Company owns less than 20% of the investee, and the Company does not have the ability to exercise significant influence over the investee. As a result, the Company will continue to use the cost method of accounting for this investment. The carrying value of this investment was $11.9 million at both March 31, 2014 and December 31, 2013, and no impairment has been recognized for this investment through March 31, 2014.

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Recently Issued Accounting Pronouncements

The Company has implemented all new accounting pronouncements that are in effect and that may impact its financial statements and does not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on its financial position or results of operations.

Note 2. Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing net income (loss) for the period by the weighted-average number of common shares outstanding for the period without consideration of potential common shares. Diluted net income (loss) per share is calculated by dividing net income (loss) by the weighted-average number of common shares outstanding for the period and dilutive potential common shares for the period determined using the treasury-stock method. For purposes of this calculation, options to purchase common stock and restricted stock unit awards are considered to be potential common shares and are not included in the calculation of diluted net loss per share because their effect is anti-dilutive.

Options to purchase 1.2 million shares of the Company s common stock and 140,000 restricted stock units were outstanding at March 31, 2014, but were not included in the computation of diluted net loss per share because their effect is anti-dilutive. Options to purchase 1.4 million shares of the Company s common stock and 112,000 restricted stock units were outstanding at March 31, 2013, but were not included in the computation of diluted net loss per share because their effect is anti-dilutive.

Note 3. Fair Value Measurements

The Company measures certain financial assets, including cash equivalents and marketable securities, at their fair value on a recurring basis. The fair value of these financial assets was determined based on a hierarchy of three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

Level 1: Quoted prices in active markets for identical assets or liabilities;

Level 2: Observable inputs other than Level 1 inputs, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company s assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The Company did not have any non-financial assets or liabilities that were measured or disclosed at fair value on a recurring basis at March 31, 2014 and December 31, 2013, respectively. The following tables set forth the Company s financial instruments that were measured at fair value on a recurring basis at March 31, 2014 and December 31, 2013 by level within the fair value hierarchy:

	Actively Quoted Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Balance at March 31, 2014
		(In thousands)		
As of March 31, 2014:				
Assets				
Money market deposits	$ 10,841	$	$	$ 10,841
Commercial paper		41,644		41,644
Corporate debt securities		36,261		36,261
Total	$ 10,841	$ 77,905	$	$ 88,746

	Actively Quoted Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Balance at December 31, 2013
		(In thousands)		
As of December 31, 2013:				
Assets				
Money market deposits	$ 15,690	$	$	$ 15,690
Commercial paper		37,643		37,643
Corporate debt securities		35,428		35,428
Total	$ 15,690	$ 73,071	$	$ 88,761

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The Company s debt securities of U.S. government-sponsored entities, commercial paper and corporate bonds are classified as Level 2 as they are valued using multi-dimensional relational pricing models that use observable market inputs, including benchmark yields, reported trades, broker-dealer quotes, issuer spreads, benchmark securities, bids, offers and reference data. Not all inputs listed are available for use in the evaluation process on any given day for each security evaluation. In addition, market indicators, industry and economic events are monitored and may serve as a trigger to acquire further corroborating market data. There were no transfers between Level 1 and Level 2 categories during the three months ended March 31, 2014 and 2013, respectively.

All of the Company s marketable securities are classified as available-for-sale. The following tables illustrate the Company s available-for-sale marketable securities as of the dates indicated:

	March 31, 2014			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(In thousands)			
Commercial paper	$ 37,620	$ 24	$	$ 37,644
Corporate debt securities	36,265	1	(5)	36,261
Total	$ 73,885	$ 25	$ (5)	$ 73,905

	December 31, 2013			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(In thousands)			
Commercial paper	$ 36,625	$ 18	$	$ 36,643
Corporate debt securities	35,434	3	(9)	35,428
Total	$ 72,059	$ 21	$ (9)	$ 72,071

The Company had no realized gains or losses on available-for-sale marketable securities for the three months ended March 31, 2014 and 2013, respectively.

The following table summarizes the Company s portfolio of available-for-sale marketable securities by contractual maturity as of the dates indicated:

	March 31, 2014		December 31, 2013	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
	(In thousands)			
Due in one year or less	$ 72,600	$ 72,620	$ 72,059	$ 72,071
Due in more than one year but less than five years	1,285	1,285		
Total	$ 73,885	$ 73,905	$ 72,059	$ 72,071

Note 4. Collaboration and Commercial Technology Licensing Agreements

The Company has entered into a variety of collaboration and specimen transfer agreements relating to its development efforts. The Company recorded collaboration expenses of $1.2 million and $459,000 for the three months ended March 31, 2014 and 2013, respectively, relating to services provided in connection with these agreements. In addition to these expenses, some of the agreements contain provisions for royalties from inventions resulting from these collaborations. The Company has specified options and rights relating to joint inventions arising out of the collaborations.

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In August 2013, the Company entered into a collaboration agreement to conduct an additional large DCIS clinical study to validate the relationship between the Oncotype DX DCIS score and the likelihood of local recurrence in patients with DCIS. The agreement, which is estimated to be completed in 2017, includes a study fee and milestone payments dependent on the completion of certain key milestones. In 2013, the Company capitalized the milestone payments of $392,000 related to this agreement. During the three months ended March 31, 2014, the Company recorded collaboration expenses related to this agreement for $237,000. All future milestone payments are contingent on certain accomplishments, and therefore the timing for any related payments cannot be estimated.

In November 2013, the Company entered into an exclusive license agreement to develop and commercialize a test to predict benefit from DNA damage-based chemotherapy drugs, such as anthracycline-based regimens, in high risk breast cancer. The Company made an up-front payment of $9.0 million, which was recognized in research and development expense in the fourth quarter of 2013, and will make milestone payments as certain clinical and commercial endpoints are achieved in the future. All future milestone payments are contingent on certain milestone accomplishments, and therefore the timing for future milestone payments cannot be estimated. With successful commercialization of a test, the Company will be obligated to pay royalties.

In January 2014, the Company entered into a collaboration agreement to conduct a prostate study with a goal to determine the association between the Genomic Prostate Score, or GPS provided by the assay and the likelihood of experiencing disease progression while on active surveillance. In February 2014, the Company capitalized a milestone payment of $367,000 related to this agreement which is included in the other assets in the accompanying condensed consolidated balance sheets. All future milestone payments to be received under this agreement are contingent on certain accomplishments, and therefore the timing for any related payments cannot be estimated.

The Company is a party to various agreements under which it licenses technology on a non-exclusive basis in the field of human diagnostics. Access to these licenses enables the Company to process its Onco*type* DX tests. While certain agreements contain provisions for fixed annual payments, license fees are generally calculated as a percentage of product revenues, with rates that vary by agreement and may be tiered, and payments that may be capped at annual minimum or maximum amounts. The Company recognized costs recorded under these agreements totaling $2.3 million and $2.1 million for the three months ended March 31, 2014 and 2013, respectively, which were included in cost of product revenues.

At March 31, 2014, fixed future annual payments, exclusive of royalty payments, relating to the launch and commercialization of the Onco*type* DX colon cancer test and the Onco*type* DX prostate cancer test totaled $650,000 and are payable as follows:

		Fixed Future Annual Payments (In thousands)
Payment Due:		
2014 (remainder of year)	$	100
2015		550
Total	$	650

These payments are recorded in cost of product revenues as license fees. Expense for payments included in the table above is recorded ratably over the year before the relevant payment is due. If at any time the Company discontinues the sale of the products covered by the agreement, no future annual payments will be payable and the Company will have no further obligation under the applicable agreement.

Contract Research Arrangements

In November 2007, the Company entered into a Collaborative Diagnostic Development Agreement with Pfizer Inc. to provide research and development services for the development of a diagnostic product for renal cell cancer. The Company received an initial payment of $1.5 million and was initially eligible to receive a payment of $2.2 million upon joint agreement on a gene identification plan, $5.0 million in additional payments upon the earlier of Pfizer s election to initiate the next phase of development or a specified number of months from the date the Company received the sample set and related clinical data necessary to conduct the first phase of development, and a final payment of $1.5 million upon completion of clinical validation. Completion of clinical validation represented a substantive milestone and the Company recognized the $1.5 million payment upon completion in December 2013. The Company did not recognize any revenue related to substantive milestones under this agreement during the quarter ended March 31, 2013.

All other payments were not considered substantive milestones as they are not based solely on the Company s past performance. Such payments are recognized using a performance-based model and revenue is recognized following delivery of effort as compared to an estimate of total expected effort.

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Note 5. Commitments

Lease Obligations

In September 2005, the Company entered into a non-cancelable lease for 48,000 square feet of laboratory and office space that the Company currently occupies in Redwood City, California. In November 2010, the Company executed an amendment to extend the term of the lease through March 2019, with an option for the Company to extend the term of the lease for an additional five years. The agreement included lease incentive obligations of $834,000 that are being amortized on a straight line basis over the life of the lease.

In January 2007, the Company entered into a non-cancelable lease for an additional 48,000 square feet of laboratory and office space in a nearby location. In November 2010, the Company executed an amendment to extend the term of the lease through March 2018, with an option for the Company to extend the lease for an additional five years. The agreement included lease incentive obligations totaling $283,000 that are being amortized on a straight line basis over the life of the lease.

In October 2009, the Company entered into a non-cancelable agreement to lease an additional 30,500 square feet of office space near the locations the Company occupied. The lease expires in March 2018, with an option for the Company to extend the term of the lease for an additional five years. The agreement includes lease incentive obligations of $307,000 that are being amortized on a straight line basis over the life of the lease.

In August 2013, the Company entered into a non-cancelable agreement to lease an additional 18,400 square feet of laboratory and office space near the locations the Company currently occupies. The lease expires in March 2019, with an option for the Company to extend the term of the lease for an additional five years. In addition, there is an additional 5,500 square feet that may become available during the initial term of the lease, which the Company has agreed to lease on the same terms. The agreement includes lease incentive obligations of $276,000 which are being amortized on a straight line basis over the life of the lease.

In May 2010, the Company s European subsidiary entered into a non-cancelable lease for approximately 2,500 square feet of office space in Geneva, Switzerland. The lease expires in May 2015. Additionally, the Company has offices in Germany, Ireland and the United Kingdom with short term rental agreements.

Future non-cancelable commitments under these operating leases at March 31, 2014 were as follows:

	Annual Payments (In thousands)
Years Ending December 31,	
2014 (remainder of year)	$ 2,724
2015	3,540

2016		3,597
2017		3,706
2018		2,310
2019 and thereafter		462
Total minimum payments	$	16,339

Note 6. Stock-Based Compensation

Stock Option Grants

The Company granted options to purchase 372,010 shares and 317,500 shares of common stock to employees during the three months ended March 31, 2014 and 2013, respectively. For the three months ended March 31, 2014, the Company issued 94,309 shares of common stock in connection with the exercise of stock options with a weighted-average exercise price of $10.56 per share. For the three months ended March 31, 2013, the Company issued 195,524 shares of common stock in connection with the exercise of stock options with a weighted-average exercise price of $16.15 per share.

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Restricted Stock Units

During the three months ended March 31, 2014, the Company awarded 331,253 restricted stock units (RSUs) with a grant-date fair value equal to $9.7 million. During the three months ended March 31, 2013, the Company awarded 254,598 RSUs with a grant-date fair value equal to $7.3 million. Each RSU entitles the recipient to receive one share of the Company s common stock upon vesting. RSUs awarded to employees generally vest as to one-third of the total number of shares awarded annually over a three-year period. During the three months ended March 31, 2014, the Company issued 164,532 shares of common stock in connection with the vesting of RSUs with a weighted-average grant date fair value of $27.98 per share. During the three months ended March 31, 2013, the Company issued 117,434 shares of common stock in connection with the vesting of RSUs with a weighted-average grant date fair value of $26.44 per share.

Performance-Based Vesting Restricted Stock Units

In March 2014, the Company approved awards of performance-based restricted stock units (PVRSUs) for certain senior officers of the Company under its 2005 Stock Incentive Plan. The awards are subject to the approval of the 2005 Stock Incentive Plan, as amended and restated by the Board of Directors on March 24, 2014, at the 2014 Annual Meeting of Stockholders. The amount potentially available under a PVRSU shall be subject to the attainment of pre-established, objective performance goals over a specified period.

During the three months ended March 31, 2014, the Company awarded 44,630 PVRSUs with a grant date fair value of $1.2 million. The PVRSUs awarded to employees vest base on achievement of a revenue milestone, weighted from 0% to 100%, a tests delivered milestone, weighted from 0% to 100%, and a reimbursement-related milestone, weighted from 0% to 33 1/3%, not to exceed 100% in the aggregate. In addition, the awards also have a service vesting criteria following the achievement of performance criteria through February 2016.

The Company recognizes the fair value of these awards to the extent the achievement of the related performance criteria is estimated to be probable. If a performance criteria is subsequently determined to not be probable of achievement, any related expense is reversed in the period such determination is made. As March 31, 2014, the achievement of the performance criteria is estimated not to be probable. Changes in the Company s assessment of the probability of achievement of performance criteria could have a material effect on the results of operations in future periods.

Restricted Stock in Lieu of Directors Fees

Outside members of the Company s Board of Directors may elect to receive fully-vested restricted stock in lieu of cash compensation for services as a director. During the three months ended March 31, 2014, the Company issued 1,705 shares of restricted stock to outside directors, with a grant date fair value of $50,000, and a weighted-average grant date fair value of $29.27 per share. During the three months ended March 31, 2013, the Company issued 1,835 shares of restricted stock to outside directors, with a grant date fair value of $50,000, and a weighted-average grant date fair value of $27.24 per share.

Employee Stock Purchase Plan

During the three months ended March 31, 2014 and 2013, no shares were issued under the employee stock purchase plan (ESPP). A total of 1,250,000 shares of common stock have been reserved for issuance under the ESPP, of which 951,056 shares were available for issuance as of December 31, 2013. As of March 31, 2014, there was $178,000 of unrecognized compensation expense related to the ESPP, which is expected to be recognized over an estimated weighted-average period of two months.

Employee Stock-Based Compensation Expense

The Company recognized employee stock-based compensation expense of $4.4 million for both the three months ended March 31, 2014 and 2013. Employee stock-based compensation expense includes expense related to stock option grants, RSU awards to employees, restricted stock issued in lieu of outside director fees and stock purchased under the Company s Employee Stock Purchase Plan (ESPP). Stock-based compensation expense is calculated based on options and RSUs ultimately expected to vest and has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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Valuation Assumptions

The Company values its stock option grants using the Black-Scholes option valuation model. Option valuation models require the input of highly subjective assumptions that can vary over time. The Company s assumptions regarding expected volatility are based on the historical volatility of the Company s common stock. The expected life of options granted is estimated based on historical option exercise data and assumptions related to unsettled options. The risk-free interest rate is estimated using published rates for U.S. Treasury securities with a remaining term approximating the expected life of the options granted. The Company uses a dividend yield of zero as it has never paid cash dividends and does not anticipate paying cash dividends in the foreseeable future. The weighted-average fair values and assumptions used in calculating such values during each period are as follows:

	Three Months Ended March 31,	
	2014	2013
Expected volatility:		
Stock options	44%	46%
ESPP	34%	51%
Risk-free interest rate:		
Stock options	1.98%	1.26%
ESPP	0.10%	0.14%
Expected life in years:		
Stock options	6.66	6.65
ESPP	0.50	0.50
Weighted-average grant date fair value:		
Stock options	$ 14.42	$ 13.19
ESPP	$ 8.12	$ 7.50

Note 7. Segment Information

The Company operates in one business segment, which primarily focuses on the development and global commercialization of genomic based clinical laboratory services that analyze the underlying biology of cancer, allowing physicians and patients to make individualized treatment decisions. As of March 31, 2014, the majority of the Company s product revenues have been derived from sales of one product, the Onco*type* DX breast cancer test.

The following table summarizes total revenues from customers and collaboration partners by geographic region. Product revenues are attributed to countries based on ship-to location. Contract revenues are attributed to countries based on the location of the collaboration partner.

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
United States	$ 55,468	$ 54,562
Outside of the United States	11,534	8,532
Total revenues	$ 67,002	$ 63,094

Note 8. Income Taxes

The Company recorded income tax expense of $75,000 and $53,000 for the three months ended March 31, 2014 and 2013, respectively, which was computed using the discrete (or cut-off) method and was principally comprised of state income taxes and foreign taxes. The difference between the income tax expense actually recorded and the statutory rate applied to the Company s income (loss) before income taxes was primarily due to the impact of nondeductible stock-based compensation expenses and nondeductible meals and entertainment for the three months ended March 31, 2014 and March 31, 2013.

Based on all available objective evidence, the Company believes that it is more likely than not that its net deferred tax assets will not be fully realized. Accordingly, the Company maintained a valuation allowance against all of its federal and state net deferred tax assets as of both March 31, 2014 and December 31, 2013. The Company will continue to maintain a full valuation allowance until there is sufficient evidence to support recoverability of its deferred tax assets.

The Company had $2.2 million of unrecognized tax benefits at both March 31, 2014 and December 31, 2013. The Company does not anticipate a material change to its unrecognized tax benefits over the next twelve months that would affect the company s effective tax rate. Unrecognized tax benefits may change during the next twelve months for items that arise in the ordinary course of business.

Accrued interest and penalties related to unrecognized tax benefits are recognized as part of the Company s income tax provision in its condensed consolidated statements of operations. The statute of limitations remain open for the years 2000 through 2014 in U.S. federal and state jurisdictions, and for the years 2009 through 2014 in foreign jurisdictions.

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When used in this report, the words expects, anticipates, intends, estimates, plans, believes, and similar expressions are intended to identify forward-looking statements. These are statements that relate to future periods and include statements about our expectation that, for the foreseeable future, a significant amount of our revenues will be derived from Oncotype DX for invasive breast cancer; the factors that may impact our financial results; our ability to achieve sustained profitability; our business strategy and our ability to achieve our strategic goals; our expectations regarding product revenues and the sources of those revenues; the amount of future revenues that we may derive from Medicare patients or categories of patients; our belief that we may become more dependent on Medicare reimbursement in the future; our plans to pursue reimbursement on a case-by-case basis; our ability, and expectations as to the amount of time it will take, to achieve reimbursement from third-party payors and government insurance programs for new indications of tests, new tests or in new markets; the potential impact of changes in reimbursement levels for our tests; our expectations regarding our international expansion and opportunities; our expectations for reimbursement in international markets; our intent to enter into additional foreign distribution arrangements; our beliefs with respect to the benefits and attributes of our tests or tests we may seek to develop in the future; the factors we believe drive demand for our tests and our ability to sustain or increase such demand; our success in increasing patient and physician demand as a result of our direct sales approach and our sales forces capacity to sell our tests; our plans with respect to increasing our sales force; plans for, and the timeframe for the development or commercial launch of, future tests or enhancements to address different patient populations of breast, colon or prostate cancer, other types of cancer or specific cancer treatments; our ability to compete with new or existing market participants; the factors that we believe will drive reimbursement and the establishment of coverage policies; the capacity of our clinical reference laboratory to process tests and our expectations regarding capacity; our expectations regarding expansion of our clinical reference laboratory; our dependence on collaborative relationships to develop tests and the success of those relationships; whether any tests will result from our collaborations or license agreements; the applicability of clinical results to actual outcomes; our estimates and assumptions with respect to disease incidence and potential market opportunities; the occurrence, timing, outcome or success of clinical trials or studies; our plans with respect to additional studies; our expectations regarding timing of the announcement or publication of research results; the benefits of our technology platform; the economic benefits of our tests to the healthcare system; the ability of our tests to impact treatment decisions; our beliefs regarding our competitive position; our expectations regarding new and future technologies, including next generation sequencing and non-invasive test technology, and their potential benefits; our belief that multi-gene analysis provides better analytical information; our beliefs regarding the benefits of genomic analysis in various patient populations; our expectations regarding clinical development processes future tests may follow; our beliefs regarding the benefits of individual gene reporting; our expectation that our research and development, general and administrative and sales and marketing expenses will increase and our anticipated uses of those funds; our expectations regarding capital expenditures; our ability to comply with the requirements of being a public company; our expectations regarding future levels of bad debt expense and billing and collections fees; our ability to attract and retain experienced personnel; the adequacy of our product liability insurance; our anticipated cash needs and our estimates regarding our capital requirements; our need for additional financing; our expected future sources of cash; our expectations regarding incurrence of debt; our compliance with federal, state and foreign regulatory requirements; the potential impact resulting from the regulation of our tests by the U.S. Food and Drug Administration, or FDA, and other similar non-U.S. regulators; our belief that our tests are properly regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA; the impact of new or changing policies, regulation or legislation, or of judicial decisions, on our business and reimbursement for our tests; the impact of seasonal fluctuations and economic conditions on our business; our belief that we have taken reasonable steps to protect our intellectual property; the impact of changing interest rates; our beliefs regarding our unrecognized tax benefits or our valuation allowance; the impact of accounting pronouncements and our critical accounting policies, judgments, estimates, models and assumptions on our financial results; the impact of the economy on our business, patients and payors; and anticipated trends and challenges in our business and the markets in which we operate.

Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those expected. These risks and uncertainties include, but are not limited to, those risks discussed in Item 1A of this report, as well as our ability to develop and commercialize new products and product enhancements; the risk of unanticipated delays in research and development efforts; the risk that we may not obtain or maintain reimbursement for our existing tests or any future tests we may develop; the risk that reimbursement pricing or coverage may change; the risks and uncertainties associated with the regulation of our tests by the FDA or regulatory agencies outside of the U.S.; the success of our new technology; the results of clinical studies; the applicability of clinical results to actual outcomes; the impact of new legislation or regulations, or of judicial decisions, on our business; our ability to compete against third parties; our ability to obtain capital when needed; the economic environment; and our history of operating losses. These forward-looking statements speak only as of the date hereof. We expressly disclaim any obligation or undertaking to update any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

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This report contains statistical data attributable to both the Kantar Health, Inc. s CancerMPact database (February 2013) and the Globocan 2008 Data published by the International Agency for Research on Cancer (IARC) 2008, or data that we derived from these sources. These sources generally indicate that they believe their information is reliable but do not guarantee the accuracy and completeness of their information. Although we believe that the sources are reliable, we have not independently verified their data.

In this report, all references to Genomic Health, we, us, or our mean Genomic Health, Inc.

Genomic Health, the Genomic Health logo, Oncotype, Oncotype DX, Recurrence Score and DCIS Score are trademarks or registered trademarks of Genomic Health, Inc. We also refer to trademarks of other corporations and organizations in this report.

Business Overview

We are a global healthcare company that provides actionable genomic information to personalize cancer treatment decisions. We develop and globally commercialize genomic-based clinical laboratory services that analyze the underlying biology of cancer, allowing physicians and patients to make individualized treatment decisions. We offer our Onco*type* DX tests as a clinical laboratory service, where we analyze the expression levels of genes in tumor tissue samples and provide physicians with a quantitative gene expression profile expressed as a single quantitative score, which we call a Recurrence Score for invasive breast cancer and colon cancer, a DCIS Score for ductal carcinoma in situ, or DCIS, and a Genomic Prostate Score, or GPS, for prostate cancer.

In January 2004, we launched our first Onco*type* DX test, which is used to predict the likelihood of cancer recurrence and the likelihood of chemotherapy benefit in early stage invasive breast cancer patients. In January 2010, we launched our second Onco*type* DX test, the first multigene expression test developed to assess risk of recurrence in stage II colon cancer patients. In late December 2011, we made Onco*type* DX available for patients with DCIS, a pre-invasive form of breast cancer. In June 2012, we extended our offering of the Onco*type* DX colon cancer test to patients with stage III disease treated with oxaliplatin-containing adjuvant therapy. In May 2013, we launched our Onco*type* DX prostate cancer test, which is used to predict disease aggressiveness in men with low risk disease. Effective July 1, 2013, the list price of our Onco*type* DX breast cancer test increased from $4,290 to $4,380 and the list price of our Onco*type* DX colon cancer test increased from $3,640 to $4,030. The list price of our Onco*type* DX prostate cancer test is $3,820. The majority of our historical revenues have been derived from the sale of Onco*type* DX breast cancer tests ordered by physicians in the United States.

For the three months ended March 31, 2014, more than 23,080 Onco*type* DX test reports were delivered for use in treatment planning, compared to more than 20,350 test reports delivered for the three months ended March 31, 2013. All of our tests are conducted at our clinical reference laboratory in Redwood City, California. Our clinical reference laboratory processing capacity is currently approximately 100,000 tests annually, and has significant expansion capacity with incremental increases in laboratory personnel and equipment. The Onco*type* DX breast, colon, and prostate cancer tests analyze different genes. However, all of the tests are based on a similar Onco*type* DX RT-PCR platform. We believe that we currently have sufficient capacity to process all of our tests.

In connection with the May 2013 launch of our prostate cancer test, we have expanded our clinical laboratory processing capacity. We expect our initial commercialization efforts of our prostate cancer test will result in increased costs for laboratory testing, including staffing-related costs, incremental sales and marketing staffing to introduce our product to a new group of physicians and patients, costs for clinical utility

studies and costs associated with obtaining reimbursement coverage.

We depend upon third-party payors, both public and private, to provide reimbursement for our tests. Accordingly, we have and expect to continue to focus substantial resources on obtaining reimbursement coverage from third-party payors.

We have continued to expand our business, both in the United States and internationally. We plan to continue to use essentially the same business model internationally as we use in the United States, however, there are significant differences between countries that need to be considered. For example, different countries may have a public healthcare system, a combination of public and private healthcare system or a cash-based payment system. We have a direct commercial presence with employees in Canada, France, Germany, Ireland, Italy, Sweden, Switzerland and the United Kingdom. Additionally, we entered into exclusive distribution agreements for the sale of our breast and colon cancer tests with approximately 20 distributors covering more than 90 countries outside of the United States.

We expect that international sales of our Onco*type* DX tests will be heavily dependent on the availability of reimbursement and sample access. In many countries, governments are primarily responsible for reimbursing diagnostic tests. Governments often have significant discretion in determining whether a test will be reimbursed at all, and if so, how much will be paid. In addition, certain countries, such as China, have prohibitions against exporting tissue samples which will limit our ability to offer our tests in those countries without local facilities or a method of test delivery which does not require samples to be transported to our U.S. facility.

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The majority of our international Onco*type* DX breast and colon cancer test revenues come from direct payor reimbursement, payments from our distributors, patient self-pay, and clinical collaborations in various countries. We have obtained some coverage for our breast cancer test outside of the United States, including in Argentina, Canada, the Czech Republic, Germany, Greece, Ireland, Israel, Saudi Arabia, Spain, Switzerland and the United Kingdom. In September 2013, we announced that the National Institute for Health and Care Excellence (NICE) in the United Kingdom issued its final guidance recommending Onco*type* DX as the only multi-gene breast cancer test for use in clinical practice to guide chemotherapy treatment decisions for patients with early-stage, hormone receptor-positive, invasive breast cancer. In April 2014, we announced that the Gynecologic Oncology Working Group (AGO) in Germany also updated their guidelines to recommend Oncotype DX as the only breast cancer gene expression test to predict chemotherapy benefit in early-stage, hormone receptor-positive invasive breast cancer. We expect that it will take several years to establish broad coverage and reimbursement for our Onco*type* DX breast, colon and prostate cancer tests with payors in countries outside of the United States and there can be no assurance that our efforts will be successful.

Oncotype DX Breast Cancer Test

We expect to continue to focus substantial resources on pursuing global adoption of and reimbursement for our Onco*type* DX breast cancer test. We believe increased demand for our Onco*type* DX breast cancer test resulted from our ongoing commercial efforts, expanded utility for new breast cancer patient groups, continued publication of peer-reviewed articles on studies we sponsored, conducted or collaborated on that support the use of and reimbursement for the test, clinical presentations at major symposia, and the inclusion of our breast cancer test in clinical practice guidelines for node negative, or N-, estrogen receptor positive, or ER+, invasive disease. However, this increased demand is not necessarily indicative of future growth rates, and we cannot provide assurance that this level of increased demand can be sustained or that publication of articles, future appearances or presentations at medical conferences, increased commercial efforts or expansion of utility to new breast cancer patient groups will have a similar impact on demand for our breast cancer test in the future. Sequential quarterly demand for our breast cancer test may also be impacted by other factors, including the economic environment and continued high unemployment levels, seasonal variations that have historically impacted physician office visits, our shift in commercial focus to our Onco*type* DX colon and prostate cancer tests or any future products we may develop, patient enrollment in Onco*type* DX clinical studies and the number of clinical trials in process by cooperative groups or makers of other tests conducting experience studies.

Most national and regional third-party payors in the United States, along with the designated regional Medicare contractor for our tests, have issued positive coverage determinations for our Onco*type* DX breast cancer test for patients with N-, ER+, invasive disease through contracts, agreements or policy decisions. The local carrier with jurisdiction for claims submitted by us for Medicare patients also provides coverage for our breast cancer test for ER+ patients with node positive, or N+, disease (up to three positive lymph nodes) and invasive breast cancer patients where a lymph node status is unknown or not accessible due to a prior surgical procedure, or when the test is used to guide a neoadjuvant treatment decision. Additionally, some payors provide policy coverage for the use of our test in ER+ patients with N+ disease, including lymph node micro-metastasis (greater than 0.2 mm, but not greater than 2.0 mm in size). In July 2011, the *American Journal of Managed Care* published results of an economic assessment suggesting use of Onco*type* DX in breast cancer patients with 1-3 positive nodes may improve health outcomes without adding incremental cost. However, we may not be able to obtain reimbursement coverage from other payors for our test for breast cancer patients with N+, ER+ disease.

In December 2011, we made the Onco*type* DX breast cancer test available for patients with DCIS, a pre-invasive form of breast cancer. The launch of Onco*type* DX for DCIS patients was based upon presented positive results from a clinical validation study of the Onco*type* DX breast cancer test in patients with DCIS, conducted by the Eastern Cooperative Oncology Group, or ECOG, a clinical trials cooperative group supported by the National Cancer Institute. The study met its primary endpoint by demonstrating that a pre-specified Onco*type* DX DCIS Score derived from the Onco*type* DX breast cancer test outperforms traditional clinical and pathologic measures to predict the risk of local recurrence, defined as either the development of a new invasive breast cancer or the recurrence of DCIS in the same breast. In May 2013, our Onco*type* DX DCIS clinical validation study was published online in the *Journal of National Cancer Institute.* Following the publication of the results of this study, the Medicare contractor for our Onco*type* DX breast cancer test expanded coverage to include patients with DCIS. Additionally, the Veterans Administration, Department of Defense hospital facilities and some private payors provide coverage for the Onco*type* DX DCIS test. We expect that it may take several years to establish coverage with a majority of public and private payors for use of our test in DCIS patients

and we may not be able to obtain such coverage.

In September 2013, we began receiving samples for a second Onco*type* DX DCIS clinical validation study to confirm and extend the observations of the published ECOG E5194 DCIS clinical validation study. We anticipate completing this study and reporting top line results in mid-2014.

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Oncotype DX Colon Cancer Test

We expect to continue to focus resources on pursuing global adoption of and reimbursement for our Onco*type* DX colon cancer test. We believe the key factors that will drive further adoption of this test include results from additional studies we sponsor, conduct or collaborate on that support the use of and increased coverage and reimbursement for the test, clinical presentations at major symposia, publications and our ongoing commercial efforts. In June 2011, at the American Society of Clinical Oncology, or ASCO, Annual Meeting, a second large study confirming that the Onco*type* DX colon cancer test independently predicts individualized recurrence risk for stage II colon cancer was presented. In November 2011, positive results from the QUASAR clinical validation study were published online by the *Journal of Clinical Oncology*. Current or future studies of our colon cancer test may lead to inclusion of the test in clinical guidelines and as standard of care for indicated patients.

Effective September 18, 2011, the designated regional Medicare contractor for our tests established a formal coverage policy for our Onco*type* DX colon cancer test for patients with stage II colon cancer. Additionally, the Veterans Administration, Department of Defense hospital facilities and some private payors provide coverage for the Onco*type* DX colon cancer test.

In June 2012, based on the positive results of the landmark randomized NSABP C-07 validation study, we began offering the Onco*type* DX colon cancer test for use in patients with stage III disease treated with oxaliplatin-containing adjuvant therapy. In September 2012, at the European Society for Medical Oncology Congress, we presented these positive results from the NSABP C-07 study, including prediction of risk of recurrence, disease-free survival and overall survival in stage II and stage III colon cancer patients. In November 2013, the *Journal of Clinical Oncology* published positive results of the third successful validation of the Onco*type* DX colon cancer test in patients with stage II disease and the first validation study in patients with stage III disease.

We are working with additional public and private payors and health plans to secure coverage for our colon cancer test based upon clinical evidence showing the utility of the test, and we have obtained reimbursement coverage for our Onco*type* DX colon cancer test from certain other third-party payors. As a relatively new test, our colon cancer test may be considered investigational by payors and therefore may not be covered under their reimbursement policies. Consequently, we intend to pursue case-by-case reimbursement and expect that this test will continue to be reviewed on this basis until policy decisions have been made by individual payors. We believe it may take several years to achieve reimbursement with a majority of third-party payors for our colon cancer test. However, we cannot predict whether, at what rate, or under what circumstances, payors will reimburse for this test. Based upon our experience in obtaining adoption of and reimbursement for our Onco*type* DX breast cancer test, we do not expect product revenues from our colon cancer test to comprise more than 10% of our total revenues for at least the next year or more.

In November 2013, the *Current Medical Research & Opinion* published positive results from the Partnership for Health Analytic Research clinical utility analysis of the Onco*type* DX colon cancer test, demonstrating that use of the assay changes treatment recommendations in 29% of stage II colon cancer patients.

In an exploratory component of the NSABP C-07 clinical trial, researchers analyzed 735 genes and identified 16 genes as being predictive of oxaliplatin benefit when added to adjuvant therapy for use in patients with stage III colon cancer. In September 2013, we delayed our plan to utilize these results and initiate a validation study in 2013. The decision to delay was based on analytical performance during the pre-validation phase that did not meet our standards for a subset of the candidate predictive genes.

Oncotype DX Prostate Cancer Test

In February 2011, at the ASCO Genitourinary Cancer Symposium and the United States and Canadian Academy of Pathology meeting, we presented positive full results from our prostate cancer gene identification study. The study, which applied the same reverse transcription polymerase chain reaction, or RT-PCR, technology used in our Onco*type* DX breast and colon cancer tests, identified 295 genes strongly associated with clinical recurrence of prostate cancer following radical prostatectomy. In June 2012, we presented results of our first development study in prostate tissue obtained from needle biopsies. The study, an analysis of biopsy samples from men with conventionally defined low/intermediate risk prostate cancer, showed that genes and biological pathways associated with clinically-aggressive prostate cancer in radical prostatectomy specimens can be reliably measured by quantitative RT-PCR from fixed prostate needle biopsies. Based on the results of this and multiple prior studies, we initiated a large clinical validation study in early 2012.

In September 2012, we announced positive top line results from this clinical validation study of our biopsy-based prostate cancer test. As a result of this clinical validation study meeting its primary end point, we launched our Onco*type* DX prostate cancer test in May 2013 and made the test commercially available worldwide. The test provides a Genomic Prostate Score, or GPS, that predicts disease aggressiveness in men with low risk disease. This test may be used to improve treatment decisions for prostate cancer patients, in conjunction with the Gleason score, or tumor grading.

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We expect to invest substantial resources related to continued clinical studies and the global adoption of our prostate cancer test. We expect our commercialization efforts for our prostate cancer test will result in further increased costs for laboratory testing, including staffing-related costs, incremental sales and marketing staffing to introduce this product to a new group of physicians and patients, costs for clinical utility studies and costs associated with obtaining reimbursement coverage.

In September 2013, we began receiving samples for a second Onco*type* DX prostate cancer clinical study to reinforce the value of our test in predicting adverse pathology, and to further demonstrate its role in predicting biochemical recurrence, a longer-term outcome also associated with aggressive disease. We anticipate completing this study and reporting top line results in mid-2014.

Based upon our experience in obtaining adoption and reimbursement for our Onco*type* DX breast and colon cancer tests, we do not expect product revenues from our prostate cancer test to comprise more than 10% of our total revenues for at least a year or more following its launch.

Product Development Opportunities

In addition to developing products to address new cancer areas, we continually look to expand the clinical utility and addressable patient populations for our existing cancer tests. These developments efforts may lead to a wide variety of possible new products covering various treatment decisions, including:

- Risk assessment;
- Screening and prevention;
- Early disease diagnosis;
- Adjuvant and/or neoadjuvant disease treatment;
- Metatastic disease treatment selection; and
- Treatment monitoring.

Potential new products may address a specific clinical need or guide a targeted therapy decision and may also leverage our next generation sequencing, or NGS capabilities to expand our product opportunities. Additionally, potential new products may use non-invasive tests that can be performed on blood and urine to quantify the presence and burden of cancer as well as the sensitivity or resistance to specific drug therapies.

Technology

Our commercially available tests utilize RT-PCR technology to quantify gene expression in patient tumor samples. We are also incorporating new technologies, such as high-throughput NGS, in our research and development laboratory. With NGS technology, we can sequence millions of ribonucleic acids, or RNAs, map them back to their respective genes based on their sequence and then count the number of copies and compare the relative expression between different genes.

We have selected NGS to be our primary technology for future biomarker discovery and have begun using NGS for future clinical development in tandem with our existing RT-PCR based approach. NGS technologies parallelize the sequencing process, producing thousands or millions of sequences at once, and are intended to provide nucleic acid sequence information at lower cost than standard methods. We have created proprietary methods for NGS analysis of fixed paraffin embedded, or FPE, tissue nucleic acids, created bioinformatics programs, and infrastructure for data storage and analysis and plan to rely on NGS as the technology source of new biomarkers in the future.

We have begun to further advance our research and development pipeline with proprietary platforms that incorporate emerging molecular technologies in order to develop non-invasive tests that can be performed on blood or urine. While early-stage cancer continues to represent a significant opportunity with near-term potential, we now have the opportunity to expand our business further along the patient s cancer journey. Expanding our focus beyond early-stage treatment decision support toward later-stage disease includes opportunities to monitor progression and response to therapeutics for patients who are diagnosed with later stage or recurrent disease who can also benefit from precision medicine.

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Economic Environment

Continuing concerns over prolonged high unemployment levels, entitlement and health care reform efforts, regulatory changes and taxation issues, and geopolitical issues have contributed to uncertain expectations both for the U.S. and global economies. These factors, combined with uncertainties in business and consumer confidence, continued concerns regarding the stability of some European Union member countries and slowing growth in China, have contributed to the expectations of slower domestic and global economic growth in the near term. We periodically evaluate the impact of the economic environment on our cash management, cash collection activities and volume of tests delivered.

As of the date of this report, we have not experienced a loss of principal on any of our short-term marketable securities, and we expect that we will continue to be able to access or liquidate these investments as needed to support our business activities. We periodically monitor the financial position of our significant third-party payors, which include Medicare and managed care companies. As of the date of this report, we do not expect the current economic environment to have a material negative impact on our ability to collect payments from third-party payors in the foreseeable future. The economic environment continued to impact product payment cycles, growth in tests delivered and product revenue generated during the three months ended March 31, 2014. Specifically, the economic impact of the recent implementation of healthcare reform and the sequester resulting from the Budget Control Act of 2011, discussed below, resulted in a negative impact on our product revenues for three months ended March 31, 2014. We intend to continue to assess the impact of the economic environment on our business activities. If the economic environment does not improve or deteriorates, our business including our patient population, government and third-party payors and our distributors and suppliers could be negatively affected, resulting in a negative impact on our product revenues.

U.S. Healthcare Environment

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or, collectively, the ACA, enacted in March 2010, makes changes that are expected to significantly impact the pharmaceutical and medical device industries and clinical laboratories. The ACA contains a number of provisions designed to generate the revenues necessary to fund expanded health insurance coverage, including new fees or taxes on certain health related industries, including medical device manufacturers. Beginning in 2013, each medical device manufacturer must pay sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices that are listed with the Food and Drug Administration, or FDA. Although the FDA has contended that clinical laboratory tests that are developed and validated by a laboratory for its own use, referred to as LDTs, such as our Onco*type* DX breast, colon and prostate cancer tests, are medical devices, none of our products are currently listed with the FDA. We cannot assure you that the tax will not be extended to services such as ours in the future. The ACA also establishes a board that is charged with reducing the per capita rate of growth in Medicare spending. We are monitoring the impact of the ACA in order to enable us to determine the trends and changes that may be necessitated by the legislation that may potentially impact on our business over time.

Under the Budget Control Act of 2011, which went into effect for dates of service on or after April 1, 2013, Medicare payments to providers, including clinical laboratories, are reduced by 2% due to implementation of the automatic expense reductions (sequester).

In 2012 and again in 2013, the Centers for Medicare and Medicaid Services, or CMS, issued a preliminary determination for the Medicare Clinical Laboratory Fee Schedule, or CLFS, which proposed not to recognize Multi-Analyte codes with Algorithmic Analyses, or MAAAs. However, in its final determination in 2013, CMS determined that reimbursement rates could be set using rates established by local Medicare Administrative Contractors for those MAAA codes covered.

In April 2014, the President signed the Protecting Access to Medicare Act of 2014, or PAMA, which included a substantial new payment system for clinical laboratory tests under the CLFS. Under PAMA, laboratories that receive the majority of their Medicare revenues from payments made under the CLFS or the Physician Fee Schedule would report, beginning January 1, 2016, and then on an every three year basis thereafter (or annually for advanced diagnostic laboratory tests), private payor payment rates and volumes for their tests. CMS will use the rates and volumes reported by laboratories to develop Medicare payment rates for the tests equal to the volume-weighted median of the private payor payment rates for the tests. The payment rates calculated under PAMA will be effective starting January 1, 2017. Any reductions to payment rates resulting from the new methodology are limited to 10% per test per year in each of the years 2017 through 2019 and to 15 percent per test per year in each of 2020 through 2022. Although CMS has not yet issued regulations to implement PAMA, we believe our Onco*type* DX tests each would be considered an advanced diagnostic laboratory test. The initial payment rate (for a period not to exceed nine months) for an advanced diagnostic laboratory test will be set at the actual list charge for the test as reported by the laboratory. Insofar as the actual list charge substantially exceeds private payor rates (by more than 30%), CMS will have the ability to recoup excess payments made during the initial nine-month payment period.

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PAMA codified coverage rules for laboratory tests by requiring any local coverage determination to be made following the established procedures for development and appeals of local coverage determinations. PAMA also authorizes CMS to consolidate coverage policies for clinical laboratory tests among one to four laboratory-specific MACs. These same contractors may also be designated to process claims if CMS determines that such a model is appropriate.

In addition to changes adopted by PAMA, in 2013 CMS announced plans to bundle payments for clinical laboratory tests together with other services performed during hospital outpatient visits under the Hospital Outpatient Prospective Payment System. CMS exempted molecular diagnostic tests from this packaging provision at this time. Although our tests are generally not paid in the hospital outpatient setting, it is possible that this proposal could impact payment for some portion of our tests in the future.

In November 2013, we applied for a specific laboratory billing code from the American Medical Association, the AMA, for our Onco*type* DX breast cancer test under the Current Procedural Terminology, or CPT, category of MAAAs. In March 2014, the AMA posted the Summary of Panel Actions taken by the CPT Editorial Panel, which included acceptance of our application for a test-specific Category I CPT code, which means that the Onco*type* DX breast cancer test met certain utilization and evidence requirements. We expect the new code will be considered for review in July 2014 by Medicare at their annual public meeting seeking input on rate setting for new codes under the CLFS. Under Medicare law, Medicare must establish a reimbursement rate for new codes either by a crosswalk or gapfill process. Under the crosswalk process, Medicare assigns a rate for a new test by reference to an existing reimbursement rate for a similar test. If there is no test considered similar, the gapfill process allows the local MAC to establish rates in 2015 from which a national limitation amount will be established for 2016. We do not know for certain whether this will impact our current payment rate for our Onco*type* DX breast cancer test. However, under PAMA, CMS is required to continue to use the methods for pricing, coding, and coverage of advanced diagnostic laboratory tests that were in effect prior to enactment of PAMA through December 31, 2016, including crosswalking or gapfill methods. Regardless of the rate established for our test under the new code and the ratesetting process in 2015, the payment policies and procedures under PAMA will apply to our tests beginning 2017.

PAMA also updated the processes by which new laboratory tests are coded by Medicare, such as our Onco*type* DX colon cancer test and any future tests reimbursed by Medicare. CMS is now required to adopt temporary Healthcare Procedure Coding System, or HCPCS, codes to identify new advanced diagnostic laboratory tests and new tests that are cleared or approved by the FDA. These temporary codes will be effective for a period of up to two years pending the adoption of a permanent HCPCS or CPT code. In addition, by 2016, all advanced diagnostic laboratory tests and tests cleared or approved by the FDA which are currently paid under the CLFS without unique codes will be assigned unique HCPCS codes. PAMA also requires CMS to establish unique identifiers for advanced diagnostic laboratory tests or tests cleared or approved by the FDA. Rulemaking implementing the payment, coding, and coverage provisions of PAMA are expected to proceed over the next several years.

These or any future changes in covered benefit determination, bundled reimbursement rates, proposed fees or mandated reductions in payments may apply to some or all of our clinical laboratory tests delivered to Medicare, Medicare Advantage and Medicaid beneficiaries and subsequently influence private payor coverage and reimbursement.

Changes in Medicare Administrative Contractor (MAC) services

On a five year rotational basis, Medicare requests bids for its regional MAC services. In September 2013, the claims processing function transitioned from our current MAC, Palmetto GBA, to Noridian Healthcare Solutions. Operational changes in contractors processing claims have affected providers in the past, in some cases delaying payment for covered services while claims payment systems are brought on line and

fully operational. Palmetto GBA under their MolDx Program is continuing to establish coverage, coding and reimbursement policies for molecular diagnostics located within the jurisdiction applicable to our tests. An elimination of the MolDx Program or a change in the administrator of that program could impact the coverage or payment rates for our current tests and our ability to obtain Medicare coverage for products for which we do not yet have coverage or any products we may launch in the future, or delay payments for our tests.

Critical Accounting Policies and Significant Judgments and Estimates

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as revenues and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from those estimates under different assumptions or conditions.

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We believe the following critical accounting policies reflect our more significant estimates and assumptions used in the preparation of our financial statements.

Revenue Recognition

We determine whether revenue is recognized on an accrual basis when test results are delivered or on a cash basis when cash is received from the payor. Our revenues for tests performed are recognized on an accrual basis when the following criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. We assess whether the fee is fixed or determinable based on the nature of the fee charged for the products or services delivered and existing contractual arrangements. When evaluating collectability, we consider whether we have sufficient history to reliably estimate a payor s individual payment patterns. Based upon at least several months of payment history, we review the number of tests paid against the number of tests billed and the payor s outstanding balance for unpaid tests to determine whether payments are being made at a consistently high percentage of tests billed and at appropriate amounts given the contracted payment amount. To the extent all criteria set forth above are not met, including where there is no evidence of payment history at the time test results are delivered, product revenues are recognized on a cash basis when cash is received from the payor.

We enter into exclusive distribution agreements for the sale of one or more of our Onco*type* DX tests with distributors outside of the United States. In these countries, the distributor generally provides us with certain marketing and administrative services within its territory. As a condition of these agreements, the distributor generally pays us an agreed upon fee per test and we process the tests. The same revenue recognition criteria described above generally apply to tests received through distributors. To the extent all criteria set forth above are not met when test results are delivered, product revenues are generally recognized when cash is received from the distributor.

Test revenue recognized on an accrual basis is recorded upon delivery of each test performed, net of any contractual discount at the amount that we expect to collect. We determine the amount we expect to collect on a per payor, per contract or arrangement basis, based on our analysis of historical average payments. This average amount is typically lower than the agreed upon amount due to several factors, such as the amount of patient co-payments, the existence of secondary payors and claim denials. We typically review our analysis annually, or at the time a contractual price change is implemented or when information comes to our attention that leads us to believe an adjustment may be warranted.

As of March 31, 2014, amounts outstanding for tests delivered, net of write-downs and adjustments, which were not recognized as revenue upon delivery because our accrual revenue recognition criteria were not met and which had not been collected, totaled approximately $52 million. We cannot provide any assurance as to when, if ever, and to what extent these amounts will be collected.

From time to time, we receive requests for refunds of payments, generally due to overpayments made by third-party payors. Upon becoming aware of a refund request, we establish an accrued liability for tests covered by the refund request until such time as we determine whether or not a refund is due. If we determine that a refund is due, we credit cash and reduce the accrued liability. Accrued refunds were $1.2 million and $770,000 at March 31, 2014 and December 31, 2013, respectively.

Contract revenues are generally derived from studies conducted with biopharmaceutical and pharmaceutical companies and are recognized on a contract-specific basis. Under certain contracts, revenues are recognized as costs are incurred or assays are processed. We may exercise

judgment when estimating full-time equivalent level of effort, costs incurred and time to project completion. For certain contracts, we utilize the performance-based method of revenue recognition, which requires that we estimate the total amount of costs to be expended for a project and recognize revenue equal to the portion of costs expended to date. The estimated total costs to be expended are necessarily subject to revision from time-to-time as the underlying facts and circumstances change.

Accounts Receivable

We accrue an allowance for doubtful accounts against our accounts receivable based on estimates consistent with historical payment experience. Our allowance for doubtful accounts is evaluated quarterly and adjusted when trends or significant events indicate that a change in estimate is appropriate. Historically, the amounts of uncollectible accounts receivable that have been written off have been consistent with management s expectations. We cannot assure you that we will not experience higher than expected write-offs in the future. As of March 31, 2014 and December 31, 2013, our allowance for doubtful accounts was $1.9 million and $1.9 million, respectively. See Liquidity and Capital Resources for additional information, including a summary of accounts receivable aging by payor mix.

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Research and Development Expenses

We enter into collaboration and clinical trial agreements with clinical collaborators and record these costs as research and development expenses. We record accruals for estimated study costs comprised of work performed by our collaborators under contract terms. The financial terms of these agreements are subject to negotiation, may vary from contract to contract, and may result in uneven payment flows. We determine our estimates through discussion with internal clinical development personnel and outside service providers as to the progress or stage of completion of services provided and the agreed upon fee to be paid for such services. Advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed.

All potential future product programs outside of breast, colon and prostate cancer are in the research or development phase. Although we have estimated the time frame in which some of these products may be brought to market, the timing is uncertain given the technical challenges and clinical variables that exist between different types of cancers. We maintain information regarding costs incurred for activities performed under certain contracts with biopharmaceutical and pharmaceutical companies. However, we do not generally record or maintain information regarding costs incurred in research and development on a program-specific basis. Our research and development staff and associated infrastructure resources are deployed across several programs. Many of our costs are thus not attributable to individual programs. As a result, we are unable to determine the duration and completion costs of our research and development programs or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product.

Stock-based Compensation Expense

We measure all stock-based payments to employees and directors, including grants of stock options, based on their relative fair values. Fair values of awards granted under our stock option plans and Employee Stock Purchase Plan, or ESPP, were estimated at grant or purchase rights offering dates using a Black Scholes option valuation model. Stock-based compensation expense related to stock option grants is estimated at the date of grant and stock-based compensation expense related to ESPP purchases is estimated at the beginning of each offering period based on these fair value calculations. The expense is recognized ratably over the requisite service period. The application of option valuation models requires significant judgment and the use of estimates, particularly surrounding assumptions used in determining fair value. The Black Scholes option valuation model requires the use of estimates such as stock price volatility and expected option lives to value stock-based compensation. Our assumptions regarding expected volatility are based on the historical volatility of our common stock. The expected life of options is estimated based on historical option exercise data and assumptions related to unsettled options. The expected life of stock issuable pursuant to the ESPP is six months, or the duration of the purchase period. Expected forfeiture rates for stock option grants are based on historical data, and compensation expense is adjusted for actual results. We do not include expected forfeiture rates when calculating stock-based compensation expense for stock issuable pursuant to the ESPP due to the short duration of the purchase period; however, we do adjust the expense for actual results.

Stock-based compensation expense related to restricted stock unit, or RSU, awards is based on the market value of our common stock at the date of grant and is recognized as expense ratably over the requisite service period. Expected forfeiture rates for RSUs are based on historical data, and compensation expense is adjusted for actual results.

We review our valuation assumptions on an ongoing basis, and, as a result, our assumptions used to value stock awards granted in future periods may change. See Note 6, Stock-Based Compensation, in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information.

Deferred Tax Assets

We are required to reduce our deferred tax assets by a valuation allowance if it is more likely than not that some or all of our deferred tax assets will not be realized. We must use judgment in assessing the potential need for a valuation allowance, which requires an evaluation of both negative and positive evidence. The weight given to the potential effect of negative and positive evidence should be commensurate with the extent to which it can be objectively verified. In determining the need for and amount of our valuation allowance, if any, we assess the likelihood that we will be able to recover our deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical cumulative losses and, based on all available evidence, we believe it is more likely than not that our recorded net deferred tax assets will not be realized. Accordingly, we recorded a valuation allowance against all of our net deferred tax assets at both March 31, 2014 and December 31, 2013. We will continue to maintain a full valuation allowance on our deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of this allowance.

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Results of Operations

Three Months Ended March 31, 2014 and 2013

We recorded a net loss of $7.4 million for the three months ended March 31, 2014 compared to net loss of $883,000 for the three months ended March 31, 2013. On a basic and diluted per share basis, net loss per share was $0.24 for the three months ended March 31, 2014 compared to net loss per share was $0.03 for the three months ended March 31, 2013. We may incur net losses in future periods due to future spending and fluctuations in our business, and we may not achieve or maintain sustained profitability in the future.

Revenues

We derive our revenues primarily from product sales and, to a lesser extent, from contract research arrangements. We operate in one industry segment. As of March 31, 2014, substantially all of our product revenues have been derived from the sale of our Onco*type* DX breast cancer test. Payors are billed upon generation and delivery of test results to the physician. Product revenues are recorded on a cash basis unless a contract or arrangement to pay is in place with the payor at the time of billing and collectability is reasonably assured. Contract revenues are derived from studies conducted with biopharmaceutical and pharmaceutical companies and are recorded as contractual obligations are completed.

	For the Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Product revenues	$ 67,002	$ 62,709
Contract revenues		385
Total revenues	$ 67,002	$ 63,094
Quarter over quarter dollar increase in product revenues	$ 3,908	
Quarter over quarter percentage increase in product revenues	7%	

The increase in product revenues for the three months ended March 31, 2014 compared to the three months ended March 31, 2013 resulted, in part, from increased adoption, as evidenced by a 13% period over period increase in test volume. We also experienced an increase in revenues recorded on an accrual basis. Approximately $49.3 million, or 74%, of product revenues for the three months ended March 31, 2014 were recorded on an accrual basis and recognized at the time the test results were delivered, compared to $45.9 million, or 73%, for the three months ended March 31, 2013. For both periods, the balance of product revenues was recognized upon cash collection as payments were received. The timing of recognition of revenues related to third-party payments may cause fluctuations in product revenues from period to period.

Product revenues related to Medicare patients for the three months ended March 31, 2014 were $13.7 million, or 20%, of product revenues, compared to $13.4 million, or 21%, of product revenues for the three months ended March 31, 2013. There were no other third-party payors comprising product revenues of 10% or more for those periods. International product revenues increased to $11.5 million, or 17% of product revenues, for the three months ended March 31, 2014, from $8.5 million, or 14% of product revenues, for the three months ended March 31, 2013.

Contract revenues were $0 and $385,000 for the three months ended March 31, 2014 and 2013, respectively. Contract revenues represented studies assessing our gene expression technology or collaborative work in gene selection and protocol design with our pharmaceutical partners. The decrease in contract revenues for the 2014 period compared to the 2013 period was due to a decrease in activities with collaboration partners. We expect that our contract revenues will continue to fluctuate based on the number and timing of studies being conducted.

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Cost of Product Revenues

	For the Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Tissue sample processing costs	$ 9,640	$ 7,485
Stock-based compensation	129	135
Total tissue sample processing costs	9,769	7,620
License fees	2,286	2,126
Total cost of product revenues	$ 12,055	$ 9,746
Quarter over quarter dollar increase	$ 2,309	
Quarter over quarter percentage increase	24%	

Cost of product revenues represents the cost of materials, direct labor, equipment and infrastructure expenses associated with processing tissue samples (including sample accessioning, histopathology, anatomical pathology, paraffin extraction, RT-PCR, quality control analyses and shipping charges to transport tissue samples) and license fees. Infrastructure expenses include allocated facility occupancy and information technology costs. Costs associated with performing our tests are recorded as tests are processed. Costs recorded for tissue sample processing represent the cost of all the tests processed during the period regardless of whether revenue was recognized with respect to that test. Royalties for licensed technology calculated as a percentage of product revenues and fixed annual payments relating to the launch and commercialization of Onco*type* DX tests are recorded as license fees in cost of product revenues at the time product revenues are recognized or in accordance with other contractual obligations. While license fees are generally calculated as a percentage of product revenues, the percentage increase in license fees does not correlate exactly to the percentage increase in product revenues because certain agreements contain provisions for fixed annual payments and other agreements have tiered rates and payments that may be capped at annual minimum or maximum amounts. License fees represent a significant component of our cost of product revenues and are expected to remain so for the foreseeable future.

Tissue sample processing costs increased $2.2 million, or 29%, for the three months ended March 31, 2014 compared to the three months ended March 31, 2013 due to an increase in test volume. The $160,000, or 8%, increase in license fees primarily resulted from a 7% period over period increase in product revenue. We expect the cost of product revenues to increase in future periods to the extent we process more tests.

Research and Development Expenses

	For the Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Personnel-related expenses	$ 8,911	$ 7,306
Stock-based compensation	1,239	1,180
Reagents and laboratory supplies	819	624
Collaboration expenses	1,221	459
Allocated information technology, facilities and other costs	834	2,861
Other expenses	1,657	1,233
Total research and development expenses	$ 14,681	$ 13,663
Quarter over quarter dollar increase	$ 1,018	
Quarter over quarter percentage increase	7%	

Research and development expenses represent costs incurred to develop our technology, such as NGS, our proprietary liquid platform and continuous process improvement, and carry out clinical studies, primarily related to our ongoing work in breast, colon and prostate cancer. Research and development expenses include personnel-related expenses, reagents and supplies used in research and development laboratory work, infrastructure expenses, including allocated overhead and facility occupancy costs, contract services and other outside costs. Research and development expenses also include costs related to activities performed under contracts with biopharmaceutical and pharmaceutical companies.

The $1.0 million, or 7%, increase in research and development expenses for the three months ended March 31, 2014 compared to the three months ended March 31, 2013 included a $1.6 million increase in personnel-related expenses, a $762,000 increase in collaboration expenses, $195,000 increase in reagents and laboratory supplies, and $59,000 increase in stock-based compensation expense, partially offset by a $2.0 million decrease in allocated information technology. The $1.6 million increase in personnel-related expenses was primarily attributable to increases in salaries and benefits due to increased headcount to support the launch of our prostate cancer test, as well as projects related to our product pipeline and ongoing work in NGS and our proprietary liquid platform. The decrease in allocated information technology, facilities and other costs is primarily due to preparing for our prostate cancer product launch during the three months ended March 31, 2013, which included project work from our various information technology groups, allocated based on specific development projects.

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We expect our research and development expenses to increase in future periods due to increased investment in our new product pipeline for breast, colon, prostate, renal and other cancers, along with increased investment in NGS and our proprietary liquid platform.

Selling and Marketing Expenses

	For the Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Personnel-related expenses	$ 16,634	$ 13,861
Stock-based compensation	1,123	1,075
Promotional and marketing materials	4,881	4,249
Travel, meetings and seminars	3,661	3,622
Allocated information technology, facilities and other costs	5,589	3,771
Other expenses	844	861
Total selling and marketing expenses	$ 32,732	$ 27,439
Quarter over quarter dollar increase	$ 5,293	
Quarter over quarter percentage increase	19%	

Our selling and marketing expenses consist primarily of personnel-related expenses, education and promotional expenses, market analysis and development expenses and infrastructure expenses, including allocated facility occupancy and information technology costs. These expenses include the costs of educating physicians, laboratory personnel and other healthcare professionals regarding our genomic technologies, how our Onco*type* DX tests are developed and validated and the value of the quantitative information that our tests provide. Selling and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation and dissemination of scientific and economic publications related to our Onco*type* DX tests. Our sales force compensation includes annual salaries and eligibility for quarterly commissions based on the achievement of predetermined sales goals and other management objectives.

The $5.3 million, or 19%, increase in selling and marketing expenses for the three months ended March 31, 2014 compared to the three months ended March 31, 2013 was due to U.S. and international sales and operations support and included a $2.8 million increase in personnel-related expenses, a $1.8 million increase in allocated information technology, facilities and other costs, and a $632,000 increase in promotional and marketing materials related to the expansion of our international commercial business and executing our prostate cancer product launch. The $2.8 million increase in personnel-related expenses was attributable to increases in salaries, benefits and related expenses due primarily to increased headcount, including new hires related to our launch of our prostate cancer test in May 2013 and annual salary increases. The increase in allocated information technology, facilities and other costs is primarily due to increased selling activities and project work from our various information technology groups, primarily related to our newly established prostate sales and marketing programs, allocated based on specific departmental projects.

We expect selling and marketing expenses will continue to increase in future periods due to our efforts to establish adoption of and reimbursement for our new products, continued investment in our global commercial infrastructure and increases in our sales force.

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General and Administrative Expenses

	For the Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Personnel-related expenses	$ 10,568	$ 9,521
Stock-based compensation	1,865	1,969
Occupancy and equipment expenses	5,005	4,047
Billing and collection fees	2,309	2,048
Bad debt expense	1,542	1,289
Professional fees and other expenses	1,923	2,015
Information technology, facilities and other cost allocations	(8,484)	(7,754)
Total general and administrative expenses	$ 14,728	$ 13,135
Quarter over quarter dollar increase	$ 1,593	
Quarter over quarter percentage increase	12%	

Our general and administrative expenses consist primarily of personnel-related expenses, occupancy and equipment expenses, including rent and depreciation expenses, billing and collection fees, bad debt expense, professional fees and other expenses, including intellectual property defense and prosecution costs, and other administrative costs, partially offset by cost allocations to our commercial laboratory operations, research and development, and sales and marketing functions, including allocated information technology and facility occupancy costs.

The $1.6 million, or 12%, increase in general and administrative expenses for the three months ended March 31, 2014 compared to the three months ended March 31, 2013 included a $1.0 million increase in personnel-related expenses, a $958,000 increase in occupancy and equipment expenses, a $261,000 increase in billing and collection fees, a $253,000 increase in bad debt expense partially offset by a $730,000 increase in information technology, facilities and other costs allocated to other functional areas, a $104,000 decrease in stock-based compensation expenses and a $92,000 decrease in professional fees and other expenses. Of the $1.0 million increase in personnel-related expenses, $710,000 was attributable to annual increases in salaries and benefits expenses, primarily resulting from increased headcount, $169,000 was attributable to higher contract labor and consulting expenses to support growth of our business and $167,000 was attributable to higher bonus payments.

We expect general and administrative expenses to increase in future periods as we hire additional staff and incur other expenses to support the growth of our business, and to the extent we spend more on both billing and collections fees and bad debt expense.

Interest and Other Income

Interest and other income was $50,000 for the three months ended March 31, 2014 compared to $65,000 for the three months ended March 31, 2013. The decrease was primarily due to lower average balances in our investments in marketable securities during the three months ended March 31, 2014. We expect our interest income will remain nominal if the current low interest rate environment continues.

Other Income (Expense), Net

Other expense, net was $226,000 for the three months ended March 31, 2014 compared to $6,000 for the three months ended March 31, 2013. Other expense, net for the three months ended March 31, 2014 was related to $226,000 of net foreign currency transaction losses. We expect other income (expense), net to continue to fluctuate based on fluctuations in exchange rates that impact our foreign exchange transaction gains and losses.

Income Tax Expense

Income tax expense was $75,000 for the three months ended March 31, 2014 compared to $53,000 for the three months ended March 31, 2013. Income tax expense for both periods was principally comprised of state income taxes and foreign taxes and was computed using the discrete, or cut-off , method.

As a result of historical cumulative losses and based on all available evidence, we believe it is more likely than not that our recorded net deferred tax assets will not be realized. Accordingly, we recorded a full valuation allowance on our net deferred tax assets for the three months ended March 31, 2014 and 2013, respectively. We will continue to maintain a full valuation allowance on our deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of this allowance.

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Liquidity and Capital Resources

As of March 31, 2014, we had an accumulated deficit of $177.7 million. We may incur net losses in the future, and we cannot provide assurance as to when, if ever, we will achieve sustained profitability. We expect that our research and development, selling and marketing and general and administrative expenses will increase in future periods and, as a result, we will need to continue to generate significant product revenues to achieve sustained profitability.

	2014	2013
	(In thousands)	
As of March 31:		
Cash, cash equivalents and marketable securities	$ 102,147	$ 96,078
Working capital	108,469	108,134
For the three months ended March 31:		
Cash provided by (used in):		
Operating activities	126	(1,498)
Investing activities	(2,995)	(119)
Financing activities	(2,169)	709
Capital expenditures (included in investing activities above)	(1,169)	(2,217)

Sources of Liquidity

At March 31, 2014, we had cash, cash equivalents and marketable securities of $102.1 million compared to $96.1 million at March 31, 2013. The $6.0 million increase was attributable to increased cash collections from increased sales of our tests offset by investments in the growth of our business, including research and development, U.S. and international expansion, activities related to reimbursement coverage of our tests and investments in privately held companies. In accordance with our investment policy, available cash is invested in short-term and long-term, low-risk, investment-grade debt instruments. Our cash and marketable securities are held in a variety of interest-bearing instruments including money market accounts, U.S. Treasury securities, debt obligations of U.S. government-sponsored entities, and high-grade commercial paper and corporate bonds.

Historically we have financed our operations primarily through sales of our equity securities and cash received in payment for our tests.

In December 2012, we entered into a collared accelerated share repurchase agreement with a financial institution for the purpose of repurchasing up to $30.0 million of our outstanding shares of common stock. Under the terms of this agreement, in December 2012, we paid $30.0 million to a financial institution and received 984,074 shares of our common stock, representing the minimum number of shares deliverable under the agreement. In February 2013, upon termination of the agreement and in accordance with the share delivery provisions of the agreement, we received an additional 77,257 shares of our common stock based on the average of the daily volume weighted-average prices of our common stock during a specified period less a predetermined discount per share. As a result, the average purchase price of our common stock under the accelerated share repurchase program was $28.27 per share.

Accounts Receivable

At March 31, 2014 and December 31, 2013, $28.9 million, or 17%, and $29.4 million, or 17%, respectively, of our total assets consisted of accounts receivable. The $545,000 decrease in accounts receivable from December 31, 2013 to March 31, 2014 was attributable to an increased cash collections partially offset by increased revenues. Days sales outstanding, or DSOs, is a measure of the average number of days it takes for us to collect our accounts receivable, calculated from the date that tests are billed. At March 31, 2014 and December 31, 2013, our weighted average DSOs were 67 days and 72 days, respectively. The timing of our billing and cash collections causes fluctuations in our monthly DSOs and accounts receivable.

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The following tables summarize accounts receivable by payor mix at March 31, 2014 and December 31, 2013:

	March 31, 2014							
	Total	% of Total	Current	31-60 Days	61-90 Days	91-120 Days	121 to 180 Days	Over 180 Days
				(In thousands)				
Managed care and other	$ 25,434	82%	$ 10,580	$ 5,086	$ 2,868	$ 1,712	$ 1,821	$ 3,367
Medicare	5,399	18	4,444	252	145	82	136	340
Total	30,833	100%	$ 15,024	$ 5,338	$ 3,013	$ 1,794	$ 1,957	$ 3,707
Allowance for doubtful accounts	(1,932)							
Net accounts receivable	$ 28,901							

	December 31, 2013							
	Total	% of Total	Current	31-60 Days	61-90 Days	91-120 Days	121 to 180 Days	Over 180 Days
				(In thousands)				
Managed care and other	$ 22,535	72%	$ 10,083	$ 3,513	$ 2,186	$ 1,641	$ 1,988	$ 3,124
Medicare	8,818	28	5,453	1,950	344	372	176	523
Total	31,353	100%	$ 15,536	$ 5,463	$ 2,530	$ 2,013	$ 2,164	$ 3,647
Allowance for doubtful accounts	(1,907)							
Net accounts receivable	$ 29,446							

Cash Flows

Net cash provided by operating activities was $126,000 for the three months ended March 31, 2014, compared to net cash used in operating activities of $1.5 million for the three months ended March 31, 2013. Net cash provided by (used in) operating activities includes net loss adjusted for certain non-cash items and changes in assets and liabilities. Net cash provided by operating activities for the three months ended March 31, 2014 reflected net loss of $7.4 million, adjusted for $6.1 million of stock-based compensation and depreciation and amortization expense, a $2.4 million increase in accounts payable, a $545,000 decrease in accounts receivable and a $468,000 increase in accrued expenses and other liabilities, offset by a $1.4 million decrease in accrued compensation, a $578,000 decrease in deferred revenue and a $315,000 increase in prepaid expenses and other assets. Net cash used in operating activities for the three months ended March 31, 2013 reflected net loss of $883,000, adjusted for $5.9 million of stock-based compensation and depreciation and amortization expense, and a $2.0 million increase in accrued expenses and other liabilities, offset by a $4.8 million increase in accounts receivable, a $1.8 million decrease in accrued compensation, an $898,000 decrease in accounts payable, a $771,000 increase in prepaid expenses and other assets and a $321,000 decrease in deferred revenues.

Net cash used in investing activities was $3.0 million for the three months ended March 31, 2014, compared to $119,000 for the three months ended March 31, 2013. Our investing activities have consisted predominately of purchases and maturities of marketable securities and capital expenditures. Net cash used in investing activities for the three months ended March 31, 2014 included $1.2 million in capital expenditures and $1.8 million in net purchase of marketable securities. Net cash used in investing activities for the three months ended March 31, 2013 included $2.2 million in capital expenditures partially offset by $2.1 million in net maturities of marketable securities.

Net cash used in financing activities was $2.2 million for the three months ended March 31, 2014, compared to net cash provided by financing activities of $709,000 for the three months ended March 31, 2013. Our financing activities have historically included sales of our equity securities. Net cash used in financing activities for the three months ended March 31, 2014 included cash paid for tax withholdings in the amount of $3.2 million related to net share settlements of restricted stock units and awards partially offset by $996,000 in proceeds from the issuance of our common stock upon the exercise of employee stock options. The decrease in proceeds from the issuance of common stock quarter over quarter was partially due to the exercise of options with lower exercise prices, as well as a decrease in the number of options exercised. Net cash provided by financing activities for the three months ended March 31, 2013 included $3.2 million in proceeds from the issuance of our common stock upon the exercise of employee stock options, partially offset by cash paid for tax withholdings in the amount of $2.5 million related to net share settlements of restricted stock units and awards.

Contractual Obligations

The following table summarizes our significant contractual obligations as of March 31, 2014 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(In thousands)		
Non-cancelable operating lease obligations	$ 16,339	$ 3,614	$ 7,161	$ 5,564	$

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Our non-cancelable operating lease obligations are for laboratory and office space. We lease various facilities in Redwood City, California, totaling 144,900 square feet. The lease terms expire between March 2018 and March 2019, each with an option for us to extend the terms of the lease for an additional five years. We also lease 2,500 square feet of space in Geneva, Switzerland. This lease expires in May 2015.

We are required to make a series of fixed annual payments under a collaboration agreement beginning with the January 2010 launch of our Onco*type* DX colon cancer test. We made payments under this agreement of $450,000, $450,000 and $300,000 in 2014, 2013 and 2012, respectively. We are also required to make a series of fixed annual payments under a collaboration agreement beginning with the May 2013 commercial launch of our Onco*type* DX prostate cancer test. We made a payment under this agreement of $150,000 in 2013. As of March 31, 2014, future annual payments under these agreements totaled $650,000, of which $100,000 is due in fiscal year 2014 and $550,000 is due fiscal year 2015. However, because these agreements may be terminated by either party upon 30 days prior written notice, these payments are not included in the table above.

We have also committed to make potential future payments to third parties as part of our collaboration and licensing agreements. Payments under these agreements generally become due and payable only upon achievement of specific project milestones. Because the achievement of these milestones is generally neither probable nor reasonably estimable, such commitments have not been included in the table above.

Operating Capital and Capital Expenditure Requirements

We achieved positive operating cash flow for the three months ended March 31, 2014 and the year ended December 31, 2013. We currently anticipate that our cash, cash equivalents and short-term marketable securities, together with payments for our Onco*type* DX tests, will be sufficient to fund our operations and facilities expansion plans for at least the next 12 months, including the expansion of our research and development programs, our NGS and proprietary liquid platform development efforts, our efforts to expand adoption of and reimbursement for our Onco*type* DX colon, DCIS and prostate cancer tests and our international expansion efforts. We expect to spend approximately $10 million over the next 12 months for planned laboratory equipment, information technology and facilities expansion. We may also use cash to acquire or invest in complementary businesses, technologies, services or products. We expect that our cash, cash equivalents and short term marketable securities will also be used to fund working capital and for other general corporate purposes, such as licensing technology rights, distribution arrangements for our tests both within and outside of the United States or expanding our direct sales capabilities worldwide.

The amount and timing of actual expenditures may vary significantly depending upon a number of factors, such as the amount of cash provided by our operations, the progress of our commercialization efforts, product development, regulatory requirements, progress in reimbursement for our tests and available strategic opportunities for acquisition of or investment in complementary businesses, technologies, services or products.

We cannot be certain that our international expansion plans, efforts to expand adoption of and reimbursement for our Onco*type* DX colon and prostate cancer and DCIS tests or the development of future products will be successful or that we will be able to raise sufficient additional funds to see these activities through to a successful result. It may take years to move any one of a number of product candidates in research through development and validation to commercialization.

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

- the rate of progress in establishing and maintaining reimbursement arrangements with domestic and international third-party payors;

- the cost of expanding our commercial and laboratory operations, including our selling and marketing efforts;

- the rate of progress and cost of research and development activities associated with expansion of our Onco*type* DX breast, colon and prostate cancer tests;

- the rate of progress and cost of selling and marketing activities associated with expanding adoption of and reimbursement for our Onco*type* DX colon and prostate cancer and DCIS tests;

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- the rate of progress and cost of research and development activities associated with products in research and development focused on cancers other than breast, colon and prostate;

- the rate of progress and cost of research and development activities associated with NGS and our proprietary liquid platform;

- the cost of acquiring, licensing or investing in technologies, including NGS and our proprietary liquid platform;

- the cost of acquiring or investing in complementary businesses or assets;

- costs related to future product launches;

- the cost of acquiring or achieving access to tissue samples and technologies;

- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

- the effect of competing technological and market developments;

- costs related to international expansion;

- costs and delays in product development as a result of any changes in regulatory oversight applicable to our products or operations;

- the impact of changes in Federal, state and international taxation; and

- the economic and other terms and timing of any collaborations, licensing or other arrangements into which we may enter or investments or acquisitions we might seek to effect.

If we are not able to generate and maintain sustained product revenues to finance our cash requirements, we will need to finance future cash needs primarily through public or private equity offerings, debt financings, borrowings or strategic collaborations or licensing arrangements. If we raise funds by issuing equity securities, dilution to stockholders may result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities or borrowings could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. The credit market and financial services industry have in the past, and may in the future, experience periods of upheaval that could impact the availability and cost of equity and debt financing. If we are not able to secure additional funding when needed, on acceptable terms, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives. In addition, we may have to work with a partner on one or more of our product or market development programs, which could lower the economic value of those programs to us.

Off-Balance Sheet Arrangements

As of March 31, 2014, we had no material off-balance sheet arrangements.

Recently Issued Accounting Pronouncements

We have implemented all new accounting pronouncements that are in effect and that may impact our financial statements and do not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on our financial position or results of operations.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to interest earned on our cash equivalents and marketable securities. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. Our investment policy provides for investments in short-term, low-risk, investment-grade debt instruments. Our investments in marketable securities, which are comprised primarily of money market funds, obligations of U.S. Government agencies and government-sponsored entities, commercial paper and corporate bonds, are subject to default, changes in credit rating and changes in market value. These investments are subject to interest rate risk and will decrease in value if market interest rates increase.

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Our cash, cash equivalents and marketable securities, totaling $102.1 million at March 31, 2014, did not include any auction preferred stock, auction rate securities or mortgage-backed investments. We currently do not hedge interest rate exposure, and we do not have any foreign currency or other derivative financial instruments. The securities in our investment portfolio are classified as available for sale and are, due to their short-term nature, subject to minimal interest rate risk. To date, we have not experienced a loss of principal on any of our investments. Although we currently expect that our ability to access or liquidate these investments as needed to support our business activities will continue, we cannot ensure that this will not change. We believe that, if market interest rates were to change immediately and uniformly by 10% from levels at March 31, 2014, the impact on the fair value of these securities or our cash flows or income would not be material.

Foreign Currency Exchange Risk

Substantially all of our revenues are recognized in U.S. dollars. Certain expenses related to our international activities are payable in foreign currencies. As a result, factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets will affect our financial results. We recognized net foreign exchange transaction losses of $226,000 and $10,000 for the three months ended March 31, 2014 and 2013, respectively. The functional currency of our wholly-owned subsidiaries is the U.S. dollar, so we are not currently subject to gains and losses from foreign currency translation of the subsidiary financial statements. We currently do not hedge foreign currency exchange rate exposure. Although the impact of currency fluctuations on our financial results has been immaterial in the past, there can be no guarantee that the impact of currency fluctuations related to our international activities will not be material in the future.

ITEM 4. CONTROLS AND PROCEDURES.

(a) ***Evaluation of disclosure controls and procedures***. We maintain disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, or Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future condition.

Based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

(b) ***Changes in internal control over financial reporting***. There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS.

We have a history of net losses, we may incur net losses in the future, and we expect to continue to incur significant expenses to develop and market our tests, which may make it difficult for us to achieve sustained profitability.

We have historically incurred substantial net losses. From our inception in August 2000 through March 31, 2014, we had an accumulated deficit of $177.7 million. We expect to continue to invest in our product pipeline, including our current Onco*type* DX tests and future products, and in our global commercial infrastructure, our laboratory operations and next generation sequencing and other technology. For the three months ended March 31, 2014, our research and development expenses were $14.7 million and our selling and marketing expenses were $32.7 million. We expect our expense levels to continue to increase for the foreseeable future as we seek to globally expand the clinical utility of our Onco*type* DX breast cancer test, drive adoption of and reimbursement for our Onco*type* DX colon cancer and prostate cancer tests and develop and commercialize new tests. As a result, we will need to generate significant growth in revenues in order to achieve sustained profitability. Our failure to achieve sustained profitability in the future could cause the market price of our common stock to decline.

Continued weak general economic or business conditions could have a negative impact on our business.

Continuing concerns over prolonged high unemployment levels, entitlement and healthcare reform efforts, regulatory changes and taxation issues, and geopolitical issues have contributed to continued volatility and uncertain expectations for both the U.S. and global economies. These factors, combined with uncertainties in business and consumer confidence, continued concerns regarding the stability of some European Union member countries, and slowing economic growth in China, have contributed to the expectations of slower domestic and global economic growth in the near term. These economic conditions continued to impact product payment cycles, growth in tests delivered and product revenues generated during the three months ended March 31, 2014. If the economic environment does not improve or deteriorates, our business, including our patient population, our suppliers and our third-party payors, could be negatively affected, resulting in a negative impact on our product revenues.

Healthcare policy changes, including recently enacted legislation reforming the U.S. 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 ACA, 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 pays a sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices that are listed with the FDA. Although the FDA has contended that clinical laboratory tests that are developed and validated by a laboratory for its own use, or LDTs, such as our Onco*type* DX breast, colon and prostate cancer tests are medical devices, none of our products are currently listed with the FDA. We cannot assure you that the tax will not be extended to services such as ours in the future.

Other significant measures contained in the ACA include, for example, coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies and new fraud and abuse measures. In addition, the ACA establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB proposals may impact payments for clinical laboratory services beginning in 2016 and for hospital services beginning in 2020. We are monitoring the impact of the ACA in order to enable us to determine the trends and changes that may be necessitated by the legislation that may potentially impact our business over time.

In addition to the ACA, various healthcare reform proposals have also emerged from federal and state governments. Under the Budget Control Act of 2011, which went into effect for dates of service on or after April 1, 2013, Medicare payments are subject to a 2% reduction due to implementation of the automatic expense reductions (sequester).

State legislation on reimbursement applies to Medicaid reimbursement and Managed Medicaid reimbursement rates within that state. Some states have passed or proposed legislation that would revise reimbursement methodology for clinical laboratory payment rates under those Medicaid programs. In October 2011, CMS approved California s plan, to reduce certain Medi-Cal payments by 10% retroactive to June 1, 2011. In February 2012, Medi-Cal began the recoupment process adjusting sporadically payments on new claims. According to the California Department of Health Care Services, the cut would apply to various healthcare providers and outpatient services including laboratory services with certain exceptions. A proposed amendment to the Plan, if approved, could potentially result in an additional 10% reduction to laboratory payments retroactive to July 1, 2012. CMS has not yet issued a response to Medi-Cal s reimbursement reduction recommendation.

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Although recent changes to reimbursement methodology in states outside of California have not changed the payment rate for our tests, we cannot be certain that these or future changes will not affect payment rates in the future. We also 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, cost reduction measures and the expansion in government s role in the U.S. 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. In addition, sales of our tests outside the United States make us subject to foreign regulatory requirements and cost-reduction measures, which may also change over time.

If the FDA were to begin regulating our tests, we could incur substantial costs and time delays associated with meeting requirements for pre-market clearance or approval or we could experience decreased demand for or reimbursement of our tests.

Clinical laboratory tests like ours are regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, as well as by applicable state laws. Diagnostic kits that are sold and distributed through interstate commerce are regulated as medical devices by the FDA. Most LDTs are not currently subject to FDA regulation, although reagents or software provided by third parties and used to perform LDTs may be subject to regulation. We believe that our Onco*type* DX tests are not diagnostic kits and also believe that they are LDTs. As a result, we believe our tests should not be subject to regulation under established FDA policies. The container we provide for collection and transport of tumor samples from a pathology laboratory to our clinical reference laboratory may be a medical device subject to FDA regulation but is currently exempt from pre-market review by the FDA.

At various times since 2006, the FDA has issued guidance documents or announced draft guidance regarding initiatives that may require varying levels of FDA oversight of our tests. Legislative proposals addressing oversight of genetic testing and LDTs were introduced in the previous two Congresses and we expect that new legislative proposals will be introduced from time to time. In October 2011, Congress introduced the Modernizing of Laboratory Standards Act for Patients aimed at confirming CLIA as the appropriate mechanism for improving regulation of laboratory tests such as ours. We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our tests, whether through additional guidance issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law or guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new tests.

In addition, the Secretary of the Department of Health and Human Services, or HHS, requested that its Advisory Committee on Genetics, Health and Society make recommendations about the oversight of genetic testing. A final report was published in April 2008. If the report s recommendations for increased oversight of genetic testing were to result in further regulatory burdens, it could have a negative impact on our business and could delay the commercialization of tests in development.

If pre-market review is required, our business could be negatively impacted until such review is completed and clearance to market or approval is obtained, and the FDA could require that we stop selling our tests pending pre-market clearance or approval. If our tests are allowed to remain on the market but there is uncertainty about our tests, if they are labeled investigational by the FDA, or if labeling claims the FDA allows us to make are very limited, orders or reimbursement may decline. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and submitting a pre-market clearance notice or filing a pre-market approval application with the FDA. If pre-market review is required by the FDA, there can be no assurance that our tests will be cleared or approved on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our tests. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to inspection by and the regulatory requirements of the FDA and penalties for failure to comply with these requirements. We may also decide voluntarily to pursue FDA pre-market review of our tests if we determine that doing so would be appropriate.

In November 2013, the FDA published a list of planned guidance documents that the agency stated it intends to focus on in its fiscal year 2014, including the finalization of previously issued draft guidance which could include guidance documents addressing FDA regulation of laboratory tests such as ours. To date, the FDA has not issued any of these planned guidance documents. We cannot predict the ultimate timing or form of any such guidance or regulation and the potential impact on our existing tests, our tests in development or the materials used to perform our tests. While we qualify all materials used in our tests according to CLIA regulations, we cannot be certain that the FDA might not enact rules or guidance documents which could impact our ability to purchase materials necessary for the performance of our tests. Should any of the reagents obtained by us from suppliers and used in conducting our tests be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of testing or delaying, limiting or prohibiting the purchase of reagents necessary to perform testing.

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If we were required to conduct additional clinical trials prior to continuing to sell our breast, colon and prostate cancer tests or launching any other tests we may develop, those trials could result in delays or failure to obtain necessary regulatory approvals, which could harm our business.

If the FDA decides to regulate our tests, it may require additional pre- market clinical testing prior to submitting a regulatory notification or application for commercial sales. Such pre-market clinical testing could delay the commencement or completion of clinical testing, significantly increase our test development costs, delay commercialization of any future tests, and interrupt sales of our current tests. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial.

We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the trials. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests, or to achieve sustained profitability.

If third-party payors, including managed care organizations and Medicare, do not provide reimbursement, breach, rescind or modify their contracts or reimbursement policies or delay payments for our Oncotype DX tests, or we are unable to successfully renegotiate reimbursement contracts, our commercial success could be compromised.

Physicians and patients may not order our Onco*type* DX tests unless third-party payors, such as managed care organizations as well as government payors such as Medicare and Medicaid and governmental payors outside of the United States, pay a substantial portion of the test price. Reimbursement by a payor may depend on a number of factors, including a payor s determination that tests using our technologies are:

- not experimental or investigational,
- medically necessary,
- appropriate for the specific patient,

- cost-effective,

- supported by peer-reviewed publications, and

- included in clinical practice guidelines.

There is uncertainty concerning third-party payor reimbursement of any test incorporating new technology, including tests developed using our Onco*type* DX platform. Several entities conduct technology assessments of new medical tests and devices and provide the results of their assessments for informational purposes to other parties. These assessments may be used by third-party payors and health care providers as grounds to deny coverage for a test or procedure. Although there are a number of favorable assessments of our Onco*type* DX breast cancer test, the test has received negative assessments in the past and our tests may receive negative assessments in the future. For example, in November 2010, the Medical Advisory Panel of the Blue Cross and Blue Shield Association s Technology Evaluation Center, a technology assessment group, published its conclusion that the existing clinical data in support of our Onco*type* DX breast cancer test did not meet the panel s technology criteria for clinical effectiveness and appropriateness for usage in patients with N+ disease.

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Since each payor makes its own decision as to whether to establish a policy to reimburse our test, seeking these approvals is a time-consuming and costly process. To date, we have positive coverage determinations for our Onco*type* DX breast cancer test for N-, ER+ patients from most third-party payors in the United States through contracts, agreements or policy decisions. We cannot be certain that coverage for this test will be provided in the future by additional third-party payors or that existing contracts, agreements or policy decisions or reimbursement levels, including tests processed as out of network, will remain in place or be fulfilled within existing terms and provisions. From time to time payors change processes that may affect timely payment. These changes may result in uneven cash flow or impact the timing of revenue recognized with these payors.

We have obtained limited reimbursement from private third-party payors in the United States for our Onco*type* DX colon cancer test launched in January 2010. We expect to focus resources on obtaining adoption of and reimbursement coverage for this test. We have obtained limited reimbursement from private third-party payors in the United States for our Onco*type* DX breast cancer test for N+ and DCIS patients launched in 2008 and December 2011, respectively. Until further clinical data is presented, our N+ and DCIS indication for our breast cancer test and our colon cancer test may be considered investigational by payors and therefore may not be covered under their reimbursement policies.

We believe it may take several years to achieve reimbursement with a majority of third-party payors for our N+ and DCIS indication for our breast cancer test and our colon cancer test. In addition, the launch of our test for prostate cancer in May 2013 requires that we expend substantial time and resources in order to drive adoption of and reimbursement for this test. We cannot predict whether, under what circumstances, or at what payment levels payors will reimburse for these tests. If we fail to establish broad adoption of and reimbursement for our colon and prostate cancer tests, our reputation could be harmed and our future prospects and our business could suffer.

Based upon our experience in obtaining adoption and reimbursement for our Onco*type* DX breast and colon cancer tests, we do not expect product revenues from our prostate cancer test to comprise more than 10% of our total revenues for at least a year or more following commercial availability. We may not be able to obtain Medicare reimbursement coverage for our prostate cancer test, or obtain third-party payor reimbursement for patients with colon or prostate cancer or with DCIS that is similar to the coverage we have obtained for our invasive breast cancer test.

If we are unable to obtain or maintain reimbursement from private payors, such as the Blue Cross/Blue Shield family, and public payors, such as Medicare and Medicaid programs, for our existing tests or new tests or test enhancements we may develop in the future, our ability to generate revenues could be limited. We have in the past, and will likely in the future, experience delays and temporary interruptions in the receipt of payments from third-party payors due to modifications in existing contracts or arrangements, contract implementation steps, documentation requirements and other issues, which could cause our revenues to fluctuate from period to period.

If we are unable to obtain or maintain adequate reimbursement for our tests outside of the United States, our ability to expand internationally will be compromised.

The majority of our international Onco*type* DX breast and colon cancer test revenues come from direct payor reimbursement, payments from our distributors, patient self-pay, and clinical collaborations in various countries. 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 our tests with payors in countries outside of the United States, and our efforts may not be successful. Once established, reimbursement levels outside of the United States may vary considerably from the domestic reimbursement amounts we receive. In addition, because we rely on distributors to obtain reimbursement for our tests, to the extent we do not have direct reimbursement arrangements with payors, we may not be able to retain reimbursement coverage in certain countries with a particular payor if our agreement with a distributor is terminated or expires or a

distributor fails to pay us for other reasons. Distributors of our tests may also be negatively affected by the financial instability of, and austerity measures implemented by, several countries in the European Union and elsewhere.

The prices at which our tests are reimbursed may be reduced by Medicare and private and other payors, and any such changes could have a negative impact on our revenues.

Even if we are being reimbursed 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 our revenues. 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. These measures have resulted in reduced payment rates and decreased utilization for the clinical laboratory industry. Noridian Healthcare Solutions and Palmetto GBA (the Medicare Administrative Contractors, or MACs, processing and setting coverage payment policies, respectively, for tests billed by our laboratory) and other MACs review coverage and reimbursement rates annually.

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In April 2014, the President signed the Protecting Access to Medicare Act of 2014, or PAMA, which included a substantial new payment system for clinical laboratory tests under the Clinical Laboratory Fee Schedule, or CLFS. Under PAMA, Medicare payment rates for tests will be equal to the volume-weighted median of the private payor payment rates for the test. The payment rates calculated under PAMA will be effective starting January 1, 2017, and will be reviewed every three years (or annually for advanced diagnostic laboratory tests), based on private payor payment rates and volumes for their tests. Although CMS has not yet issued regulations to implement PAMA, we believe our Onco*type* DX tests each would be considered an advanced diagnostic laboratory test.

In November 2013, we applied for a specific CPT code for our Onco*type* DX breast cancer test. Our application for a test-specific Category I CPT code was accepted, and we expect the new code to be considered for review in July 2014 by Medicare. CMS establishes a reimbursement rate for a new test code either by a crosswalk or gapfill process. Under the crosswalk process, Medicare assigns a rate for a new test by reference to the rate for a similar test. Under the gapfill process, our reimbursement rate would be established first by the local MAC, in 2015 and then a national limitation amount would be established for 2016. The gapfill process is generally applied when no similar test exists. In its final determination for the 2014 CLFS, CMS announced a policy according to which it would apply the gapfill process if the MAC determines the code is payable. However, under PAMA, CMS is required to continue to use the methods for pricing, coding, and coverage of advanced diagnostic laboratory tests that were in effect prior to enactment of PAMA through December 31, 2016, including crosswalk or gapfill methods. Regardless of the rate established for our breast cancer test under the new code and the rate setting process in 2015, the payment determination policies and procedures under PAMA will apply to all of our tests beginning 2017. We do not know whether the rate setting process for a new test-specific CPT code for Onco*type* DX breast cancer test will impact our current payment rate for this test through 2016. While we do not believe the new payment rate system under PAMA will have a negative effect on the current payment rates of our Medicare-covered tests beginning in 2017, regulations implementing PAMA have not yet been promulgated. As a result, there can be no assurance that adequate payment rates will continue to be assigned to our tests.

Additionally, on a five year rotational basis, Medicare requests bids for its regional MAC services. In September 2013, the claims processing function transitioned from our current MAC, Palmetto GBA, to Noridian Healthcare Solutions, however coverage and payment rate determinations for our tests remain with Palmetto GBA at this time. The change in the MAC processing the Medicare claims for our tests delayed reimbursement for a brief period of time. Future changes in the MAC may affect our ability to obtain Medicare coverage and reimbursement for products for which we do not yet have coverage or any products we may launch in the future or delay payments, including payments for our Onco*type* DX prostate cancer test.

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Because of Medicare billing rules, we may not receive reimbursement for all tests provided to Medicare patients.

Under current Medicare billing rules, claims for our Onco*type* DX tests performed on Medicare beneficiaries who were hospital inpatients at the time the tumor tissue samples were obtained and whose tests were ordered less than 14 days from discharge must be incorporated in the payment that the hospital receives for the inpatient services provided. Medicare billing rules also require hospitals to bill for the test when ordered for hospital outpatients less than 14 days following the date of the hospital procedure where the tumor tissue samples were obtained. Accordingly, we are required to bill individual hospitals for tests performed on Medicare beneficiaries during these time frames. Because we generally do not have written agreements in place with these hospitals to pay for these tests, we may not be paid or may have to pursue payment from the hospital on a case-by-case basis. Although we believe patients coming under this rule represent less than 1% of our total testing population, these billing rules may lead to confusion regarding whether Medicare provides adequate reimbursement for our tests, and could discourage Medicare patients from using our test. In addition, a greater proportion of eligible patients for our colon and prostate tests are covered by Medicare. We cannot assure you that Medicare will reverse these billing rules or that Medicare will not extend this limitation in the future and we also cannot ensure that hospitals will agree to arrangements to pay us for Onco*type* DX tests performed on patients falling under these rules.

We depend on Medicare for a significant portion of our product revenues and if Medicare or other significant payors stop providing reimbursement or decrease the amount of reimbursement for our tests, our revenues could decline.

Reimbursement on behalf of patients covered by Medicare accounted for 20% and 21% of our product revenues for the three months ended March 31, 2014 and 2013, respectively. Accounts receivable on behalf of patients covered by Medicare represented 18% and 28% of our net accounts receivable at March 31, 2014 and December 31, 2013, respectively. While there were no other third-party payors representing 10% or more of our product revenues for these periods, there have been in the past, and may be in the future, other payors accounting for 10% or more of our product revenues. Because the majority of stage II and stage III colon cancer patients and prostate cancer patients in the United States are age 65 and over, and thus insured by Medicare, we may become more dependent on Medicare reimbursement in the future. It is possible that Medicare or other third-party payors that provide reimbursement for our tests may suspend, revoke or discontinue coverage at any time, may require co-payments from patients, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues.

Our financial results depend largely on the sales of one test, our Oncotype DX breast cancer test, and we will need to generate sufficient revenues from this and other tests to run our business.

For the near future, we expect to continue to derive a substantial majority of our revenues from sales of one test, our Onco*type* DX test for invasive breast cancer. While we launched our test for colon cancer in January 2010, we do not expect to recognize significant revenues from this test until significant levels of adoption and reimbursement for this test have been established. We have similar expectations for revenue related to our DCIS breast cancer test, which was launched in December 2011, and our prostate cancer test, which was launched in May 2013. We are in various stages of research and development for other tests that we may offer as well as for enhancements to our existing tests. We may not be able to successfully commercialize tests for other cancers or diseases. If we are unable to increase sales of our test for invasive breast cancer, establish adoption of and reimbursement for our colon, or prostate cancer or DCIS tests, or successfully develop and commercialize other tests or enhancements, our revenues and our ability to achieve sustained profitability would be impaired.

Complying with numerous regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations mandate specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We have a current certificate of accreditation under CLIA to perform testing through our accreditation by the College of American Pathologists, or CAP. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratory.

Although we are required to hold a certificate of accreditation or compliance under CLIA that allows us to perform high complexity testing, we are not required to hold a certificate of accreditation through CAP. We could alternatively maintain a certificate of accreditation from another accrediting organization or a certificate of compliance through inspection by surveyors acting on behalf of the CLIA program. If our accreditation under CAP were to terminate, either voluntarily or involuntarily, we would need to convert our certification under CLIA to a certificate of compliance (or to a certificate of accreditation with another accreditation organization) in order to maintain our ability to perform clinical testing and to continue commercial operations. Whether we would be able to successfully maintain operations through either of these alternatives would depend upon the facts and circumstances surrounding termination of our CAP accreditation, such as whether any deficiencies were identified by CAP as the basis for termination and, if so, whether these were addressed to the satisfaction of the surveyors for the CLIA program (or another accrediting organization).

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We are also required to maintain a license to conduct testing in California. California laws establish standards for day-to-day operation of our clinical reference laboratory, including the training and skills required of personnel and quality control. In addition, our clinical reference laboratory is required to be licensed on a product-specific basis by New York State. New York law also mandates proficiency testing for laboratories licensed under New York state law, regardless of whether or not such laboratories are located in New York. Moreover, several other states require that we hold licenses to test specimens from patients in those states. Other states may have similar requirements or may adopt similar requirements in the future. Finally, we may be subject to regulation in foreign jurisdictions as we seek to expand international distribution of our tests, which may require review of our tests in order to offer our services or may have other limitations such as prohibitions on the export of tissue necessary for us to perform our tests that may limit our ability to distribute outside of the United States.

If we were to lose our CLIA accreditation or California license, whether as a result of a revocation, suspension or limitation, we would no longer be able to sell our tests, which would limit our revenues and harm our business. If we were to lose our license in New York or in other states where we are required to hold licenses, we would not be able to test specimens from those states.

We are subject to other regulation in the United States by both the federal government and the states in which we conduct our business, as well as in other jurisdictions outside of the United States, including:

- Medicare billing and payment regulations applicable to clinical laboratories;
- 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;
- the Medicare civil money penalty and exclusion requirements;
- the Federal False Claims Act civil and criminal penalties and state equivalents; and
- the Foreign Corrupt Practices Act, the United Kingdom Anti-bribery Act and the European Data Protection Directive, all of which apply to our international activities.

We have adopted policies and procedures designed to comply with these laws. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance is also subject to governmental review. The growth of our business and sales organization and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

New test development involves a lengthy and complex process, and we may be unable to commercialize on a timely basis, or at all, any new tests we may develop.

We have multiple tests in development and devote considerable resources to research and development. There can be no assurance that our technologies will be capable of reliably predicting the recurrence of cancers other than breast, colon and prostate cancer with the sensitivity and specificity necessary to be clinically and commercially useful, or that our colon or prostate cancer tests will result in commercially successful products. In addition, before we can develop diagnostic tests for new cancers or other diseases and commercialize any new products, we will need to:

- conduct substantial research and development;
- conduct validation studies;
- expend significant funds;

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- develop and scale our laboratory processes to accommodate different tests; and

- develop and scale our infrastructure to be able to analyze increasingly large amounts of data.

Our product development process involves a high degree of risk and may take several years. Our product development efforts may fail for many reasons, including:

- failure of the product at the research or development stage;

- difficulty in accessing archival tissue samples, especially tissue samples with known clinical results; or

- lack of clinical validation data to support the effectiveness of the product.

Few research and development projects result in commercial products, and success in early clinical trials often is not replicated in later studies. At any point, we may abandon development of a product candidate or we may be required to expend considerable resources repeating clinical trials, which would adversely impact the timing for generating potential revenues from those product candidates. In addition, as we develop products, we will have to make significant investments in product development, marketing and selling resources. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study, we might choose to abandon the development of the product or product feature that was the subject of the clinical trial, which could harm our business. For example, in September 2013 we delayed our plan to initiate a validation study in 2013 utilizing results from our NSABP C-07 clinical trial. The decision to delay was based on analytical performance, during the pre-validation phase, that did not meet our standards for a subset of the candidate predictive genes. In addition, competitors may develop and commercialize competing products faster than we are able to do so.

If we are unable to support demand for our tests, including successfully managing the evolution of our technology and manufacturing platforms, our business could suffer.

As our test volume grows, we will need to continue to ramp up our testing capacity, implement increases in scale and related processing, customer service, billing and systems process improvements, and expand our internal quality assurance program, technology and manufacturing platforms to support testing on a larger scale. We will also need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our tests. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available. As additional products are commercialized, such as our prostate cancer test, we will need to bring new equipment on-line, implement new systems, technology, controls and procedures and hire personnel with different qualifications. We cannot assure you that any such efforts will not result in delays. Failure to implement necessary procedures, transition to new equipment or processes or to hire the necessary personnel could result in higher cost of processing or an inability to meet market demand. There can be no assurance that we will be able to perform tests on a timely basis at a level consistent with demand, that our efforts to scale our commercial operations will not negatively affect the quality of test results, or that we will be successful in responding to the

growing complexity of our testing operations. If we encounter difficulty meeting market demand or quality standards for our tests, our reputation could be harmed and our future prospects and our business could suffer.

We may experience limits on our revenues if physicians decide not to order our tests.

If medical practitioners do not order our Onco*type* DX tests or any future tests developed or offered by us, we will likely not be able to create or maintain demand for our products in sufficient volume for us to achieve sustained profitability. To generate demand, we will need to continue to make oncologists, urologists, surgeons and pathologists aware of the benefits of each type of test through published papers, presentations at scientific conferences and one-on-one education by our sales force. In addition, we will need to demonstrate our ability to obtain and maintain adequate reimbursement coverage from third-party payors.

Prior to the inclusion of our Onco*type* DX breast cancer test in clinical guidelines for treatment of N-, ER+ breast cancer, guidelines and practices regarding the treatment of breast cancer recommended that chemotherapy be considered in most cases, including many cases in which our test might indicate that, based on our clinical trial results, chemotherapy would be of little or no benefit. Accordingly, physicians may be reluctant to order a test that may suggest recommending against chemotherapy in treating breast cancer. Moreover, our test provides quantitative information not currently provided by pathologists and it is performed at our facility rather than by the pathologist in a local laboratory, so pathologists may be reluctant to support our test. These facts may make it difficult for us to convince medical practitioners to order our test for their patients, which could limit our ability to generate revenues and achieve sustained profitability.

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Our Onco*type* DX colon cancer test predicts recurrence but, unlike our test for invasive breast cancer, does not predict chemotherapy benefit. Our new Onco*type* DX prostate cancer test provides physicians and patients with a new way to assess the aggressiveness of a patient s prostate cancer. We will need to educate physicians, patients and payors about the benefits and cost-effectiveness of these tests and to establish reimbursement arrangements for these tests with payors. We have and expect to continue to hire additional commercial, sales, scientific, technical and other personnel to support this process. If our marketing and educational efforts do not result in sufficient physician or patient demand, we may not be able to obtain adequate reimbursement for these tests. If we fail to successfully establish adoption of and additional reimbursement beyond Medicare for our colon cancer test, our reputation could be harmed and our business could suffer. If we fail to successfully establish adoption of and reimbursement for our prostate cancer test, our reputation could be harmed and our business could suffer.

We may experience limits on our revenues if patients decide not to use our tests.

Some patients may decide not to use our Onco*type* DX tests due to their price, all or part of which may be payable directly by the patient if the applicable payor denies reimbursement in full or in part. Even if medical practitioners recommend that their patients use our tests, patients may still decide not to use our tests, either because they do not want to be made aware of the likelihood of recurrence or they wish to pursue a particular course of therapy regardless of test results. Additionally, the current economic environment in the United States and abroad could continue to negatively impact patients, resulting in higher co-payments and insurance premiums or the loss of healthcare coverage, which may result in delayed medical checkups or an inability to pay for our tests. If only a small portion of the patient population decides to use our tests, we will experience limits on our revenues and our ability to achieve sustained profitability.

Our rights to use technologies licensed from third parties are not within our control, and we may not be able to sell our products if we lose our existing rights or cannot obtain new rights on reasonable terms.

We license from third parties technology necessary to develop our products. For example, we license technology from Roche Molecular Systems, Inc. that we use to analyze genes in our clinical reference laboratory to conduct our tests. In return for the use of a third party s technology, we may agree to pay the licensor royalties based on sales of our products. Royalties are a component of cost of product revenues and impact the margins on our tests. We may need to license other technologies to commercialize future products. We may also need to negotiate licenses to patents and patent applications after launching any of our commercial products. Our business may suffer if these licenses terminate, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid, if the patents or patent applications are unavailable for license or if we are unable to enter into necessary licenses on acceptable terms. Companies that attempt to replicate our tests could be set up in countries that do not recognize our intellectual property. Such companies could send test results into the United States and therefore reduce sales of our tests.

If we are unable to develop products to keep pace with rapid technological, medical and scientific change, our operating results and competitive position could be harmed.

In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. For example, technologies in addition to ours now permit measurement of gene expression in fixed paraffin-embedded tissue specimens. New chemotherapeutic or biologic strategies are being developed that may increase survival time and reduce toxic side effects. There have also been advances in methods used to analyze very large amounts of genomic information, specifically next generation sequencing, or NGS. These advances require us to continuously develop our technology, develop new products and enhance existing products to keep pace with evolving standards of care. Our tests could become obsolete unless we continually innovate and expand our products to demonstrate recurrence and treatment benefit in patients treated with new therapies. New treatment therapies typically have only a few years of clinical data associated with them, which limits our ability to

perform clinical studies and correlate sets of genes to a new treatment s effectiveness. If we are unable to demonstrate the applicability of our tests to new treatments, sales of our test could decline, which would harm our revenues.

If we are unable to maintain intellectual property protection, our competitive position could be harmed.

Our ability to compete and to achieve sustained profitability is impacted by our ability to protect our proprietary discoveries and technologies. We currently rely on a combination of issued patents, patent applications, copyrights, trademarks, and confidentiality, material data transfer, license and invention assignment agreements to protect our intellectual property rights. We also rely upon trade secret laws to protect unpatented know-how and continuing technological innovation. Our intellectual property strategy is intended to develop and maintain our competitive position. Patents may be granted to us jointly with other organizations, and while we may have a right of first refusal, we cannot guarantee that a joint owner will not license rights to another party, and we cannot guarantee that a joint owner will cooperate with us in the enforcement of patent rights.

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Our pending patent applications may not result in issued patents, and we cannot assure you that our issued patents or any patents that might ultimately be issued by the U.S. Patent and Trademark Office, or USPTO, will protect our technology. In addition, we do not file patent applications in every country nor is patent protection available in every country. We may face competition internationally in jurisdictions where we do not have intellectual property protection. Any patents that may be issued to us might be challenged by third parties as being invalid or unenforceable, or third parties may independently develop similar or competing technology that avoids our patents.

We cannot be certain that the steps we have taken will prevent the misappropriation and use of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

If patent regulations or standards are modified, such changes could have a negative impact on our business.

From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability and validity and any such changes could have a negative impact on our business. In addition, competitors may develop their own versions of our test in countries where we did not apply for patents or where our patents have not issued and compete with us in those countries, including encouraging the use of their test by physicians or patients in other countries.

There have been several cases involving gene patents and diagnostic claims that have been considered by the U.S. Supreme Court. In March 2012, the Supreme Court in *Mayo Collaborative v. Prometheus Laboratories,* or Prometheus, found a patented diagnostic method claim unpatentable because the relationship between a metabolite concentration and optimized dosage was a patent-ineligible law of nature. In June 2013, the Supreme Court ruled in *ACLU v. Myriad Genetics*, or Myriad, that an isolated genomic DNA sequence is not patent eligible while cDNA is eligible. Both the Prometheus and Myriad decisions affect the legal concept of subject matter eligibility by seemingly narrowing the scope of the statute defining patentable inventions.

In March 2014, the USPTO issued a memorandum to patent examiners providing guidelines for examining process claims for patent eligibility in view of the Supreme Court decision in Prometheus and Myriad. The guidance sets forth a procedure for examiners to review claims involving laws of nature, natural phenomena, or natural products. We cannot assure you that our patent portfolio will not be negatively impacted by the decisions described above, rulings in other cases or changes in guidance or procedures issued by the USPTO.

In 2012, Congress directed the USPTO to study effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist. It is unclear whether the results of this study will be acted upon by the USPTO or result in Congressional efforts to change the law or process in a manner that could negatively impact our patent portfolio or our future research and development efforts.

In addition, the Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in 2011, includes a number of significant changes to U.S. patent law. The USPTO has developed new regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the Act, and in particular the first to file provisions, became effective in March 2013. Substantive changes to patent law associated with the Act may affect our ability to obtain, enforce or defend our patents. Accordingly, it is not clear what, if any, impact the America Invents Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents, all of which could

have a material adverse effect on our business.

We may face intellectual property infringement claims that could be time-consuming and costly to defend, and could result in our loss of significant rights and the assessment of treble damages.

We have received notices of claims of infringement and misappropriation or misuse of other parties proprietary rights and may from time to time receive additional notices. Some of these claims may lead to litigation. We cannot assure you 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 the validity of our patents, will not be asserted or prosecuted against us.

We may also initiate claims to defend our intellectual property or to seek relief on allegations that we use, sell, or offer to sell technology that incorporates third party intellectual property. Intellectual property litigation, regardless of outcome, is expensive and time-consuming, could divert management s attention from our business and have a material negative effect on our business, operating results or financial condition. If there is a successful claim of infringement against us, we may be required to pay substantial damages (including treble damages if we were to be found to have willfully infringed a third party s patent) to the party claiming infringement, develop non-infringing technology, stop selling our tests or using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non- infringing technologies or license the proprietary rights on a timely basis could harm our business. In addition, revising our tests to include the non-infringing technologies would require us to re-validate our tests, which would be costly and time consuming. Also, we may be unaware of pending patent applications that relate to our tests. Parties making infringement claims on future issued patents may be able to obtain an injunction that could prevent us from selling our tests or using technology that contains the allegedly infringing intellectual property, which could harm our business.

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It is possible that a third party or patent office might take the position that one or more patents or patent applications constitute prior art in the field of genomic-based diagnostics. In such a case, we might be required to pay royalties, damages and costs to firms who own the rights to these patents, or we might be restricted from using any of the inventions claimed in those patents.

If we are unable to compete successfully, we may be unable to increase or sustain our revenues or achieve sustained profitability.

Our principal competition for our breast, colon and prostate cancer tests comes from existing diagnostic methods used by pathologists and oncologists. These methods have been used for many years and are therefore difficult to change or supplement. In addition, companies offering capital equipment and kits or reagents to local pathology laboratories represent another source of potential competition. These kits are used directly by the pathologist, which facilitates adoption more readily than tests like ours that are performed outside the pathology laboratory.

We also face competition from companies that offer products or have conducted research to profile genes, gene expression or protein expression in breast, colon or prostate cancer, including public companies such as GE Healthcare, a business unit of General Electric Company, Hologic, Inc., Myriad Genetics, Inc., NanoString Technologies, Inc., Novartis AG, Qiagen N.V. and Response Genetics, Inc., and many private companies. We also face competition from commercial laboratories with strong distribution networks for diagnostic tests, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated. We may also face competition from Illumina, Inc. and Thermo Fisher Scientific Inc,, both of which have announced their intention to enter the clinical diagnostics market. Other potential competitors include companies that develop diagnostic tests such as Roche Diagnostics, a division of Roche Holding, Ltd, Siemens AG and Veridex LLC, a Johnson & Johnson company, as well as other companies and academic and research institutions.

In our newly established prostate cancer market, we face comparatively greater competition than in our breast cancer market, including competition from products which were on the market prior to our product launch and which are supported by clinical studies and published data. This existing direct and indirect competition for tests and procedures may make it difficult to gain market share, impact our ability to obtain reimbursement or result in a substantial increase in resources necessary for us to successfully commercialize our Onco*type* DX prostate cancer test.

Others may invent and commercialize technology platforms such as next generation sequencing approaches that will compete with our test. Projects related to cancer genomics have received government funding, both in the United States and internationally. As more information regarding cancer genomics becomes available to the public, we anticipate that more products aimed at identifying targeted treatment options will be developed and that these products may compete with ours. In addition, competitors may develop their own versions of our tests in countries where we did not apply for patents, where our patents have not been issued or where our intellectual property rights are not recognized and compete with us in those countries, including encouraging the use of their test by physicians or patients in other countries.

We have changed the list price of our tests in the past and we expect to change prices for our tests in the future. Any increase or decrease in pricing could impact reimbursement of and demand for our tests. Many of our present and potential competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced tests that could be viewed by physicians and payors as functionally equivalent to our tests, or offer tests at prices designed to promote market penetration, which could force us to lower the list prices of our tests and impact our operating margins and our ability to achieve sustained profitability. Some competitors have developed tests cleared for marketing by the FDA. There may be a marketing differentiation or perception that an FDA-cleared test is more desirable than Onco*type* DX tests, and that may discourage adoption of and reimbursement for our tests. If we are unable to compete successfully against current or future competitors, we may be unable to increase market acceptance for and sales of our tests, which could prevent us from increasing or sustaining our revenues or achieving sustained

profitability and could cause the market price of our common stock to decline.

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 typically chemically preserved and embedded in paraffin wax and stored. Our clinical development relies on our ability to secure access to these archived tumor biopsy samples, as well as information pertaining to their associated clinical outcomes. Generally, the agreements under which we gain access to archival samples are nonexclusive. Other companies study archival samples and often compete with us for access. Additionally, the process of negotiating access to archived samples is lengthy since 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 archival 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.

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If we cannot maintain our current clinical collaborations and enter into new collaborations, our product development could be delayed.

We rely on and expect to continue to rely on clinical collaborators to perform a substantial portion of our clinical trial functions. If any of our collaborators were to breach or terminate its agreement with us or otherwise fail to conduct the contracted activities successfully and in a timely manner, the research, development or commercialization of the products contemplated by the collaboration could be delayed or terminated. If any of our collaboration agreements are terminated, or if we are unable to renew those agreements on acceptable terms, we would be required to seek alternatives. We may not be able to negotiate additional collaborations on acceptable terms, if at all, and these collaborations may not be successful.

In the past, we have entered into clinical trial collaborations with highly regarded organizations in the cancer field including, for example, the National Surgical Adjuvant Breast and Bowel Project, or NSABP. Our success in the future depends in part on our ability to enter into agreements with other leading cancer organizations. This can be difficult due to internal and external constraints placed on these organizations. Some organizations may limit the number of collaborations they have with any one company so as to not be perceived as biased or conflicted. Organizations may also have insufficient administrative and related infrastructure to enable collaborations with many companies at once, which can prolong the time it takes to develop, negotiate and implement collaboration. Additionally, organizations often insist on retaining the rights to publish the clinical data resulting from the collaboration. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for tests such as ours, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenues from any product that may result from a collaboration.

From time to time we expect to engage in discussions with potential clinical collaborators which may or may not lead to collaborations. However, we cannot guarantee that any discussions will result in clinical collaborations or that any clinical studies which may result will be enrolled or completed in a reasonable time frame or with successful outcomes. Once news of discussions regarding possible collaborations are known in the medical community, regardless of whether the news is accurate, failure to announce a collaboration agreement or the entity s announcement of a collaboration with an entity other than us could result in adverse speculation about us, our product or our technology, resulting in harm to our reputation and our business.

The loss of key members of our senior management team or our inability to attract and retain highly skilled scientists, clinicians and salespeople could adversely affect our business.

Our success depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions. The efforts of each of these persons together will be critical to us as we continue to develop our technologies and testing processes, continue our international expansion and transition to a company with multiple commercialized products. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

Our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians, including licensed laboratory technicians, chemists, biostatisticians and engineers. We may not be able to attract or retain qualified scientists and technicians in the future due to the competition for qualified personnel among life science businesses, particularly in the San Francisco Bay Area. In addition, it is expected that there will be a shortage of clinical laboratory scientists in coming years, which would make it more difficult to hire sufficient numbers of qualified personnel. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. In addition, our success depends on our ability to attract and retain salespeople with extensive experience in oncology and urology and close relationships with medical oncologists, urologists, surgeons,

pathologists and other hospital personnel. We may have difficulties locating, recruiting or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of our tests. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to support our research and development and sales programs. All of our employees are at-will, which means that either we or the employee may terminate their employment at any time.

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If our sole laboratory facility becomes inoperable, we will be unable to perform our tests and our business will be harmed.

We do not have redundant clinical reference laboratory facilities outside of Redwood City, California. Redwood City is situated near active earthquake fault lines. Our facility and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding and power outages, which may render it difficult or impossible for us to perform our tests for some period of time. The inability to perform our tests or the backlog of tests that could develop if our facility is inoperable 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.

In order to rely on a third party to perform our tests, we could only use another facility with established state licensure and CLIA accreditation under the scope of which Onco*type* DX tests could be performed following validation and other required procedures. We cannot assure you that we would be able to find another CLIA-certified facility willing to comply with the required procedures, that this laboratory would be willing to perform the tests for us on commercially reasonable terms, or that it would be able to meet our quality standards. In order to establish a redundant clinical reference laboratory facility, we would have to spend considerable time and money securing adequate space, constructing the facility, recruiting and training employees, and establishing the additional operational and administrative infrastructure necessary to support a second facility. We may not be able, or it may take considerable time, to replicate our testing processes or results in a new facility. Additionally, any new clinical reference laboratory facility opened by us would be subject to certification under CLIA and licensing by several states, including California and New York, which could take a significant amount of time and result in delays in our ability to begin operations.

International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Our business strategy incorporates international expansion, including increasing the size of and maintaining direct sales and physician outreach and education capabilities outside of the United States and expanding our relationships with international payors and distributors. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;

- competition from local and regional product offerings;

- failure by us or our distributors to obtain regulatory approvals for the use of our tests in various countries;

- difficulties in staffing and managing foreign operations;

- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;

- logistics and regulations associated with shipping tissue samples, including infrastructure conditions and transportation delays;

- limits in our ability to penetrate international markets if we are not able to process tests locally;

- lack of intellectual property protection in certain markets;

- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our tests and exposure to foreign currency exchange rate fluctuations;

- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and

- regulatory and compliance risks that relate to maintaining accurate information and control over the activities of our sales force and distributors that may fall within the purview of the FCPA, its books and records provisions or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenues and results of operations.

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Our dependence on distributors for sales of our Oncotype DX tests outside of the U.S. could limit or prevent us from selling our test in foreign markets and impact our revenue.

As of December 31, 2013, we have entered into exclusive distribution agreements for the sale of our breast, colon and prostate cancer tests with approximately 20 distributors covering more than 90 countries. We may enter into other similar arrangements to distribute our tests in other countries in the future. We intend to continue to grow our business internationally, and to do so we may need to attract additional distributors to expand the territories in which we sell our tests. Distributors may not commit the necessary resources to market and sell our tests to the level of our expectations. If current or future distributors do not perform adequately, or we are unable to enter into arrangements with distributors to market our tests in particular geographic areas, we may not realize long-term international revenue growth. In addition, our revenue from distributors could be negatively impacted as a result of changes in business cycles, business or economic conditions or other factors that could affect their ability to pay us for tests on a timely basis or at all. Regulatory requirements, costs of doing business outside of the United States and the reimbursement process in foreign markets may also impact our revenues from international sales or impact our ability to increase international sales in the future.

We may acquire other businesses, form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of complementary businesses and assets, as well as technology licensing arrangements. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our product offerings or distribution, or make investments in other companies. We have recently experienced and may in the future experience losses related to the recognition of our portion of the net losses of equity method investees, and we may in the future experience impairment losses related to our investments in companies if we determine that the value of an investment is impaired. Losses related to our investments in other companies could have a material negative effect on our results of operations. We have no experience with respect to acquiring other companies and limited experience with respect to the formation of strategic alliances and joint ventures. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an acquired company also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment.

To finance any acquisitions or investments, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. Periods of upheaval in the capital markets and world economy have in the past, and may in the future, cause volatility in the market price of our common stock. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Our marketable securities are subject to risks that could adversely affect our overall financial position.

We invest our cash in accordance with an established internal policy in instruments which historically have been highly liquid and carried relatively low risk. However, similar types of investments have in the past and may in the future experience losses in value or liquidity issues which differ from historical patterns. Should a portion of our marketable securities lose value or have their liquidity impaired, it could adversely affect our overall financial position by imperiling our ability to fund our operations and forcing us to seek additional financing sooner than we

would otherwise. Such financing, if available, may not be available on commercially attractive terms.

Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new tests and technologies and expand our operations.

We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure, commercial operations and research and development activities. Specifically, we may need to raise capital to, among other things:

- sustain commercialization of our Onco*type* DX tests and enhancements to those tests;
- fund commercialization of any future tests we may develop;
- increase our selling and marketing efforts to drive market adoption and address competitive developments;
- further expand our clinical laboratory operations;
- expand our technologies into other areas of cancer or other diseases;

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- expand our research and development activities;

- acquire, license or invest in technologies, including next generation sequencing and our proprietary liquid platform;

- acquire or invest in complementary businesses or assets; and

- finance capital expenditures and general and administrative expenses.

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

- the rate of progress in establishing and maintaining reimbursement arrangements with domestic and international third-party payors;

- the cost of expanding our commercial and laboratory operations, including our selling and marketing efforts;

- the rate of progress and cost of research and development activities associated with expansion of our Onco*type* DX breast, colon and prostate cancer tests;

- the rate of progress and cost of selling and marketing activities associated with establishing adoption of and reimbursement for our Onco*type* DX colon and prostate cancer and DCIS tests;

- costs related to future product launches;

- the rate of progress and cost of research and development activities associated with products in research and development focused on cancers other than breast, colon and prostate cancer;

- the rate of progress and cost of research and development activities associated with next generation sequencing;

- the costs of acquiring, licensing or investing in technologies, including next generation sequencing and our proprietary liquid platform;

- the cost of acquiring or investing in complementary businesses or assets;

- the cost of acquiring or achieving access to tissue samples and technologies;

- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

- the effect of competing technological and market developments;

- costs related to international expansion;

- costs and delays in product development as a result of any changes in regulatory oversight applicable to our products or operations;

- the impact of changes in Federal, state and international taxation; and

- the economic and other terms and timing of any collaborations, licensing or other arrangements into which we may enter or investments or acquisitions we may seek to effect.

If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. The credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the U.S. federal government. These events, along with the recent downgrade of debt issued by the United States and the European sovereign debt crisis, have generally made equity and debt financing more difficult to obtain. Accordingly, additional equity or debt financing might not be available on reasonable terms, if at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives. In addition, we may have to work with a partner on one or more of our product or market development programs, which could lower the economic value of those programs to us.

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We are dependent on our information technology and telecommunications systems, and any failure of these systems could harm our business.

We depend on information technology, or IT, and telecommunications systems for significant aspects of our operations. In addition, our third-party billing and collections provider is dependent upon telecommunications and data systems provided by outside vendors and information it receives from us on a regular basis. These IT and telecommunications systems support a variety of functions, including test processing, sample tracking, quality control, customer service and support, billing and reimbursement, research and development activities, and our general and administrative activities. Failures or significant downtime of our IT or telecommunications systems or those used by our third-party service providers could prevent us from processing tests, providing test results to physicians, billing payors, processing reimbursement appeals, handling patient or physician inquiries, conducting research and development activities, and managing the administrative aspects of our business. Any disruption or loss of IT or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business and our product revenues.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we and our third party billing and collections provider collect and store sensitive data, including legally protected health information, credit card information, personally identifiable information about our employees, intellectual property, and our proprietary business information and that of our customers, payors and collaboration partners. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based data center systems. These applications and data encompass a wide variety of business critical information including research and development information, commercial information and business and financial information. We face four primary risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure risk and inappropriate modification risk combined with the risk of our being able to identify and audit our controls over the first three risks.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third party billing and collections provider, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to process tests, provide test results, bill payors or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business.

In addition, the interpretation and application of consumer, health-related and data protection laws in the U.S., Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government imposed fines or orders requiring that we change our practices, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

We rely on a limited number of suppliers or, in some cases, a sole supplier, for some of our laboratory instruments and materials and may not be able to find replacement suppliers or immediately transition to alternative suppliers.

We rely on certain sole suppliers to supply and service some of the laboratory equipment on which we perform our tests. We believe that there are relatively few equipment manufacturers that are currently capable of supplying and servicing the equipment necessary for our tests. Although we have identified alternative suppliers, transition to a new supplier will be time consuming and expensive, and there can be no assurance that we will be able to secure alternative equipment and bring that equipment on line without experiencing interruptions in testing. If we should encounter delays or difficulties in securing the quality and quantity of equipment we require for our tests, we may need to reconfigure our test processes, which could result in an interruption in sales. If any of these events occur, our business and operating results could be harmed.

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We also rely on several sole suppliers for certain laboratory reagents and materials which we use to perform our tests. While we have developed alternate sourcing strategies for these materials, we cannot be certain that these strategies will be effective. If we should encounter delays or difficulties in securing these laboratory materials, if the materials do not meet our quality specifications, or if we cannot obtain acceptable substitute materials, an interruption in test processing could occur. Any such interruption may significantly affect future product revenues.

We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy.

Future growth will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth may place strain on our administrative and operational infrastructure, including customer service and our clinical reference laboratory. Our ability to manage our operations and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We plan to implement new enterprise software affecting a broad range of business processes and functional areas including order fulfillment, sample processing, customer service, supply chain management, and others. The time and resources required to implement these new systems is uncertain, and failure to complete this in a timely and efficient manner could adversely affect our operations. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy.

If we were sued for product liability or professional liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of our tests could lead to the filing of product liability claims if someone were to allege that our tests failed to perform as it was designed. We may also be subject to liability for errors in the test results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. For example, physicians sometimes order our Onco*type* DX breast cancer test for patients who do not have the same specific clinical attributes indicated on the report form as those for which the test provides clinical experience information from validation studies. It is our practice to offer medical consultation to physicians ordering our test for such patients, including patients with ER- breast cancers. A product liability or professional liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we maintain product and professional liability insurance, we cannot assure you that our insurance would fully protect us from the financial impact of defending against product liability or professional liability claims or any judgments, fines or settlement costs arising out of any such claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to our reputation, result in the recall of our products, or cause current clinical partners to terminate existing agreements and potential clinical partners to seek other partners, any of which could impact our results of operations.

If we use hazardous materials in a manner that causes injury, we could be liable for damages.

Our activities currently require the use of hazardous chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant and could negatively affect our operating results.

We must implement additional and expensive finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy public company reporting requirements, which will increase our costs and require additional management resources.

As a public reporting company, we are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the Securities and Exchange Commission. Compliance with Section 404 of the Sarbanes-Oxley Act and other requirements has increased our costs and required additional management resources. We will need to continue to implement additional finance, accounting, and business operating systems, procedures and controls as we grow our business and organization and to satisfy existing reporting requirements. If we fail to maintain or implement adequate controls, if we are unable to complete the required Section 404 assessment as to the adequacy of our internal control over financial reporting in future Form 10-K filings, or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting in future Form 10-K filings, our ability to obtain additional financing could be impaired. In addition, investors could lose confidence in the reliability of our internal control over financial reporting and in the accuracy of our periodic reports filed under the Exchange Act. A lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline.

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We are subject to increasingly complex taxation rules and practices, which may affect how we conduct our business and our results of operations.

As our business grows, we are required to comply with increasingly complex taxation rules and practices. We are subject to tax in multiple U.S. tax jurisdictions and in foreign tax jurisdictions as we expand internationally. The development of our tax strategies requires additional expertise and may impact how we conduct our business. Our future effective tax rates could be unfavorably affected by changes in, or interpretations of, tax rules and regulations in the jurisdictions in which we do business, by lapses of the availability of the U.S. research and development tax credit or by changes in the valuation of our deferred tax assets and liabilities. Furthermore, we provide for certain tax liabilities that involve significant judgment. We are subject to the examination of our tax returns by federal, state and foreign tax authorities, which could focus on our intercompany transfer pricing methodology as well as other matters. If our tax strategies are ineffective or we are not in compliance with domestic and international tax laws, our financial position, operating results and cash flows could be adversely affected.

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ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 6. EXHIBITS

Exhibit Number	Description
31.1	Rule 13a-14(a) Certification of Chief Executive Officer.
31.2	Rule 13a-14(a) Certification of Chief Financial Officer.
32.1#	Statement of Chief Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. §1350).
32.2#	Statement of Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. §1350).
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101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed filed for purposes of Section 18 of the Exchange Act.

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SIGNATURES

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

GENOMIC HEALTH, INC.

Date: May 7, 2014	By:	/s/ Kimberly J. Popovits Kimberly J. Popovits President and Chief Executive Officer (Principal Executive Officer)
Date: May 7, 2014	By:	/s/ Dean L. Schorno Dean L. Schorno Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

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GENOMIC HEALTH, INC.

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